

Health Policies

Updated November 13 2026

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Disclaimer Notice

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If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Alzheimer's disease (AD) is a fatal degenerative brain disease characterized by progressive loss of cognitive skills such as such as memory, language, navigation, problem-solving, and physical function. The hallmark of AD is the progressive accumulation of beta-amyloid protein plaques and neurofibrillary tangles of hyperphosphorylated tau protein in the brain; these are hypothesized to lead to damage and eventual death of neurons over decades.[1]

Lecanemab

Leqembi (lecanemab-irmb) is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against aggregated soluble and insoluble forms of amyloid beta. It was the second anti-amyloid agent approved under the accelerated pathway. Approval was based on data from the Phase 2 double-blind, placebo-controlled, parallel-group, dose-finding study (Study 201) of 856 patients. Patients receiving the treatment had significant dose- and time-dependent reduction of amyloid beta plaque, with patients receiving the approved dose of lecanemab, 10 mg/kg every two weeks, having a statistically significant reduction in brain amyloid plaque from baseline to Week 79 compared to the placebo arm, which had no reduction of amyloid beta plaque.

Data from the Phase 3 CLARITY AD trial were published in early January 2023. Clarity AD was an 18-month, multicenter, double blind, placebo-controlled, parallel-group trial involving persons with mild cognitive impairment due to Alzheimer's or mild Alzheimer's disease-related dementia ages 50-90. 1795 participants underwent randomization 1:1 to receive lecanemab 10 mg/kg every two weeks or placebo. The mean Clinical Dementia Rating–Sum of Boxes (CDR-SB) score at baseline was approximately 3.2 in both groups. The adjusted least-squares mean change from baseline at 18 months was 1.21 with lecanemab and 1.66 with placebo (difference, −0.45; 95% confidence interval [CI], −0.67 to −0.23; P<0.001). Lecanemab showed a 27% reduction in clinical decline compared to placebo at 18 months (a 0.45-point difference on the CDR-SB score. Lecanemab resulted in infusion-related reactions in 26.4% of the participants and amyloid-related imaging abnormalities (ARIA) with edema or effusions in 12.6%. 17.3% of participants in the lecanemab group experienced ARIA with microhemorrhages or hemosiderin deposits.

The Institute for Clinical and Economic Review (ICER) published its evidence report on lecanemab for Alzheimer's Disease April 2023. ICER's report concluded that significant uncertainties remain as to whether the average benefits of lecanemab will exceed its risks. A majority of the California Technology Assessment Forum was unconvinced that the current evidence adequately demonstrates lecanemab provides a net benefit to patients. They remained uncertain that amyloid removal is an appropriate surrogate outcome for clinical benefit and instead look to the clinical outcomes found in randomized trials. However, there is disagreement among experts about the clinical meaningfulness of the magnitude of change in CDR-SB in the lecanemab trial. ICER also remained concerned real world ARIA occurrences and consequences may be more severe if monitoring MRIs are not as frequent as in the clinical trial, the population treated differs from the trial population, and clinicians are less expert than those who participated in the randomized trial. **In aggregate, the net health benefits of lecanemab in patients with early AD may be small or even substantial, but there remains a possibility of net harm from ARIA**. ICER rated treatment with lecanemab in MCI due to AD or mild AD as "Promising but Inconclusive" (P/I). For adults with early Alzheimer's disease (i.e., Mild Cognitive Impairment due to Alzheimer's disease and mild Alzheimer's dementia), a **majority of panelists (12-3) found that current evidence is not adequate to demonstrate a net health benefit of lecanemab when compared to supportive care alone**.

ICER also noted concerns with different populations from the CLARITY-AD trial. The subgroup analysis of CLARITY-AD data suggests that there may be lower efficacy of lecanemab in ApoE ε4 homozygotes, as well as higher risk of ARIA. ARIA-E occurred more frequently in ApoE ε4 carriers compared to non-carriers in the lecanemab treated group (3.4% vs 1.4%), and also occurred more in ApoE ε4 homozygotes compared to heterozygotes (9.2% vs 1.7%). Like ARIA-E, ARIA-H occurred more frequently in ApoE ε4 carriers compared with non-carriers (19.7% versus 11.9% in the lecanemab treated group) and was more frequent in ApoE ε4 homozygotes compared to heterozygotes (39% versus 14%).

Leqembi was initially approved January 6, 2023, under the Accelerated Approval pathway. Following approval in January, there was petition from the Alzheimer's Association to provide wider coverage for Leqembi on Medicare. CMS rejected the petition, thus upholding coverage would only be for those in clinical trials under the national coverage determination. As of July 6, 2023, Medicare more broadly covers Leqembi under the NCD issued April 7, 2022, as Leqembi was granted traditional approval by the FDA. Per the CMS statement on July 6.

2023, to receive Medicare coverage, patients will need to: 1) be enrolled in Medicare, 2) be diagnosed with mild cognitive impairment or mild Alzheimer's disease dementia, with documented evidence of beta-amyloid plaque on the brain, and 3) have a physician who participates in a qualifying registry with an appropriate clinical team and follow-up care. The registry is available at: https://qualitynet.cms.gov/alzheimers-ced-registry.

Donanemab

Kisunla (donanemab-azbt) is a humanized immunoglobulin gamma 1 (IgG1) monoclonal antibody directed against insoluble Ntruncated pyroglutamate amyloid beta. The FDA had issued a CRL for the accelerated approval of donanemab in January 2023 due to the limited number of patients with at least 12 months of drug exposure data provided in the submission. However, Kisunla is now the third FDA-approved anti-amyloid therapy, approved on July 2, 2024. Approval of Kisunla was based on results from the Phase 3 TRAILBLAZER-ALZ-2 study and the TRAILBLAZER-ALZ program. In TRAILBLAZER-ALZ-2, Kisunla was evaluated in 1736 participants with early symptomatic AD (MCI or mild dementia due to AD) and the presence of confirmed AD neuropathology. Participants were randomized in a 1:1 ratio to receive donanemab (n = 860) or placebo (n = 876) intravenously every 4 weeks for 72 weeks. 1320 (76%) patients completed the trial. At 76 weeks, least-squares mean differences favored treatment by 3.25 points on the integrated Alzheimer's Disease Rating Scale (iADRS) in the low/medium tau group (35.1% slowing of disease progression) and 2.92 points in the overall population (22.3% slowing). 76.4% of patients in the donanemab group showed complete plaque clearance on PET at 76 weeks.

The incidence of serious adverse events in TRAILBLAZER-ALZ 2 was 17.4% in the donanemab group and 15.8% in the placebo group. Either ARIA-E or ARIA-H occurred in 314 participants (36.8%) receiving donanemab and 130 (14.9%) receiving placebo. ARIA-E occurred in 205 participants (24.0%) in the donanemab group and in 18 (2.1%) in the placebo group. The incidence of ARIA-H was higher in the donanemab group than the placebo group (268 participants [31.4%] vs 119 participants [13.6%]). The incidence of microhemorrhage and superficial siderosis was greater in the donanemab group than in the placebo group (microhemorrhage: 26.8% vs 12.5%; superficial siderosis: 15.7% vs 3.0%). Notably, in the TRAILBLAZER-ALZ 2 study, the incidence of serious ARIA was 1.6%, including two participants whose death was attributed to ARIA and a third participant who died after an incident of serious ARIA. Infusion-related reactions occurred in 8.7% of participants with most cases mild to moderate in severity.

Summary	
Effective Date of Policy:	3/10/2026
Indications	Treatment of Alzheimer's disease. Treatment with should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials
ICD10 Diagnosis Codes	G30 Alzheimer's Disease
HCPCS code	Leqembi: J0174 Kisunla: J0175
Availability	Leqembi: 500 mg/5 mL (100 mg/mL) single-dose vial, 200 mg/2 mL (100 mg/mL) single-dose vial, 360 mg/1.8 mL (200 mg/mL) single-dose prefilled autoinjector Kisunla: 350 mg/20 mL (17.5 mg/mL) single-dose vial
Duration	Initial: 6 months Continuation: 6 months

Medicare reviews are to follow the national coverage determination (NCD) issued by CMS effective 12/12/2022. The NCD can be found on the CMS website at:
https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=375&ncdver=1

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.
- CDPHP reserves the right to make decisions based on clinical judgment on a case-by-case basis.
- For Leqembi:
  - Member is having follow up MRI scans to rule out acute or sub-acute micro or macrohemorrhage prior to the 5th, 7th, and 14th infusions
  - After 18 months, can continue treatment once every 2 weeks IV or transition to an every 4 week intravenous or weekly subcutaneous maintenance dosage
- For Kisunla: Member is having follow up MRI scans to rule out acute or sub-acute micro or macrohemorrhage prior to the 2nd, 3rd, 4th, and 7th infusions

References

		Updated	Accessed
1	Lecanemab for Early Alzheimer's Disease: Final Evidence Report. Institute for Clinical and Economic Review. Available at: https://icer.org/wp-content/uploads/2023/04/ICER_Alzheimers-Disease_Final-Report_For-Publication_04172023.pdf	4/2023	8/2023
2	Leqembi [prescribing information]. Eisai Inc. Nutley, NJ.	7/2023	7/2023
3	van Dyck CH, Swanson CJ, Aisen P, et al. Lecanemab in Early Alzheimer's Disease. N Engl J Med. 2023;388(1):9-21. doi:10.1056/NEJMoa2212948	1/2023	7/2023
4	A Study to Confirm Safety and Efficacy of Lecanemab in Participants With Early Alzheimer's Disease (Clarity AD). ClinicalTrials.gov. Available at: https://clinicaltrials.gov/study/NCT03887455?cond=lecanemab&rank=3	6/2023	7/2023
5	Statement: Broader Medicare Coverage of Leqembi Available Following FDA Traditional Approval. Centers for Medicare & Medicaid Services. Available at: https://www.cms.gov/newsroom/press-releases/statement-broader-medicare-coverage-leqembi-available-following-fda-traditional-approval	7/2023	8/2023
6	Lecanemab for Early Alzheimer's Disease: Final Policy Recommendations. Institute for Clinical and Economic Review. Available at: https://icer.org/wp-content/uploads/2023/04/ICER_Alzheimers-Disease_Policy-Recommendations_04172023.pdf	4/2023	8/2023
7	Lecanemab for Early Alzheimer's Disease: Report-at-a-glance. Institute for Clinical and Economic Review. Available at: https://icer.org/wp-content/uploads/2023/04/ICER_Alzheimers-Disease_-RAAG_04172023.pdf	4/2023	8/2023
8	A Study of Donanemab (LY3002813) in Participants With Early Alzheimer's Disease (TRAILBLAZER-ALZ 2). ClinicalTrials.gov. Available at: https://clinicaltrials.gov/study/NCT04437511	6/2024	7/2024
9	Sims JR, Zimmer JA, Evans CD, et al. Donanemab in Early Symptomatic Alzheimer Disease: The TRAILBLAZER-ALZ 2 Randomized Clinical Trial. JAMA. 2023;330(6):512–527. doi:10.1001/jama.2023.13239	7/2023	7/2024
10	Ksiunla [prescribing information]. Eli Lilly and Company. Indianapolis, IN.	7/2024	7/2024

GOVERNMENT PROGRAMS

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application

CDPHP Pharmacy Services 3/10/2026

New: 9/2023

Revised	Reviewed
9/2024, 6/2025, 3/2026	2/2025

Revision Date	Changes Made
9/2024	Renamed from "Medicare Leqembi (lecanemab-irmb)" to "Medicare Advantage Anti-Amyloid Monoclonal Antibodies for Alzheimer's Disease" Added criteria for Kisunla (donanemab) Added MRI considerations for Kisunla
6/2025	Corrected CDR-SB to Global CDR score
3/2026	Updated policy to just include NCD link

This Pharmacy Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI), and Capital District Physicians' Health Care Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

CAPITAL DISTRICT PHYSICIANS' HEALTH PLAN, INC.
CDPHP UNIVERSAL BENEFITS,® INC.
(Collectively referred to within this policy as "CDPHP®")
Medicare Advantage
Pharmacy Policy

Policy/Procedure Name:	**Control Number:**
MEDICAL INJECTABLE DRUGS REQUIRING PRIOR AUTHORIZATION	**1350/20.000283**

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EFFECTIVE DATE OF POLICY: 1/1/2026

DESCRIPTION: CDPHP requires prior authorization for certain medical injectable drugs before they will be approved for coverage. This applies to drugs being administered in a physician's office or another medical setting when the claim is submitted on an HCFA 1500 for payment in Facets.

APPLICATION

- Coverage will be approved when specific approval criteria for the requested drug are met, according to CDPHP policies in effect.
- If there is not a CDPHP policy in effect that describes the criteria for prior-authorization approval, prior authorization will be reviewed using the Local Coverage Determination (LCD) for Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394). The LCD can be found on the CMS website at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33394&ver=54&=
- Testopel is billed with code S0189 and will require PA review. Testopel will be approved only for FDA-approved, Medicare-covered indications. It will not be covered for off-label use of erectile dysfunction, since this is not a Medicare-covered indication.

POLICY CONSIDERATION(S): The most up-to-date list of drugs requiring prior authorization, as well as the prior-authorization criteria, can be found on the CDPHP Medical Benefit Formulary and Medicare Advantage Prior Authorization Criteria documents for enrollees and practitioners on the CDPHP secure interfaces at https://www.cdphp.com.

MEDICARE ADVANTAGE: Subject to the terms and conditions noted in above application. Benefits for Medicare Part D prescription drugs are available only to enrollees who have elected a CDPHP Medicare Advantage plan. The CDPHP Medicare Advantage plan products do not cover any prescription drugs not covered by Medicare, with the exception of additional coverage purchased with a group-enhanced rider. In addition, for those individuals enrolled in the CDPHP Medicare Advantage product who have not elected a Part D option, CDPHP covers only those prescription drugs covered by Medicare Parts A and B, not those covered by Part D. Coverage is available for any eligible Part D drug prescribed for a medically accepted indication as cited in one or more of the following references: American Hospital Formulary Service Drug Information; United States Pharmacopeia Drug Information, or its successor; and DrugDex Information System. Coverage is available for any eligible Part D drug and biological used off-label in an anti-cancer chemotherapeutic regimen for a medically accepted indication as cited in one or more of the following references: American Hospital Formulary Service Drug Information; United States Pharmacopeia Drug Information, or its successor; DrugDex Information System; National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium; Clinical Pharmacology; and Wolters Kluwer Lexi-Drugs (Lexicomp). In addition, for Part D drugs used in anticancer chemotherapy regimens, coverage for additional off-label use may be available if scientific literature approved by the secretary of health and human services supports such use.

Policy History

Date	Note
7/2014	New policy
7/2017, 8/2021, 10/2022,8/2024	Reviewed, No updates
10/2015, 3/2016, 6/2016, 9/2016, 3/2017, 4/2018, 6/2018, 10/2018, 11/2018, 4/2019, 6/2019, 9/2019, 2/2020, 4/2020, 6/2020, 10/2020, 2/2021, 6/2022, 8/2023	Revised
12/2024	Revised with links to CMS Local Coverage Determination LCD33394
8/2025	Updated link to LCD 33394

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Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of a beneficiary's individual benefit plan.

If there is a discrepancy between this policy and a beneficiary's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Effective: 1/1/2026

Background

This document provides an overview of outpatient prescription drug coverage policies under Medicare. Beneficiaries who are inpatients of hospitals or skilled nursing facilities (SNF) during covered stays may receive drugs as part of their treatment. Typically, the payment for drugs is bundled into the Medicare Part A payments made to these types of facilities. Under the hospice benefit, beneficiaries receive drugs that are medically necessary for symptom control or for pain relief.

Part B Medications/Drugs

In general, references are seen to five major categories of Medicare Part B drug spending: 1. Drugs billed by physicians and typically provided in physicians' offices (such as chemotherapy drugs); 2. Drugs billed by pharmacy suppliers and administered through durable medical equipment (DME), such as respiratory drugs given through a nebulizer; 3. Drugs billed by pharmacy suppliers and self-administered by the patient (such as immunosuppressive drugs and some oral anti-cancer drugs); 4. Separately billable drugs provided in hospital outpatient departments; and 5. Separately billable End Stage Renal Disease (ESRD) drugs such as erythropoietin (EPO). Regional differences in Part B coverage policies for drugs can occur in the absence of a national coverage decision. A drug for which coverage is available under Part A or Part B, as it is being "prescribed and dispensed or administered" with respect to the individual, is excluded from the definition of a Part D drug and, therefore, cannot be included in Part D basic coverage.

Traditional Medicare (Part A/B) does not cover most outpatient prescription drugs. Medicare bundled payments made to hospitals and skilled nursing facilities generally cover all drugs provided during a stay. Medicare also makes payments to physicians for drug or biological products that are not usually self-administered (see definitions). This means that coverage is usually limited to drugs or biological products administered by infusion or injection. However, if the injection is generally self-administered (e.g., Imitrex), it is not covered.

For detailed coverage criteria for medications/drugs under Part B, refer to the Medicare Benefit Policy Manual, Chapter 15, Section 50- Drugs and Biologics.

Part B Covered Drugs in the Context of a Professional Service

Drugs furnished "incident to" a Physician's Service: These are injectable or intravenous drugs that are administered predominantly by a physician or under a physician's direct supervision as "incident to" a physician's professional service. The statute limits coverage to drugs that are not usually self-administered. In order to meet all the general requirements for coverage under the "incident to" provision, an FDA approved drug or biological product must:

- Be of a form that is not usually self-administered (as determined by the A/B MAC contractor-click here for exclusion list*);
- Must be furnished by a physician; and
- Must be administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision.

The charge, if any, for the drug or biological product must be included in the physician's bill and the cost of the drug or biological product must represent an expense to the physician. Drug and biological products furnished by other health professionals may also meet these requirements.

**Note as of 10/15/2021 Stelara has been added to the self-administered drug exclusion list (A53021). This means that the Part B MAC (NGS) has determined that more than 50% of all use is self-administered and claims will no longer be paid under Part B with a J code J3357. Claims will need to be submitted through the pharmacy Part D benefit.*

Relationship between Part B and Part D Coverage	Categories of Separately Billable Part B Drugs	Comments
The same drug dispensed by a **pharmacy** is covered under Part B if provided as part of a service in a provider setting, physician's office, or home.	1.Drugs furnished "incident to" a physician service 2. Separately billable ESRD drugs 3. Separately billable drugs in Hospital Outpatient Departments (HOPDs) 4. Separately billable drugs in Comprehensive Outpatient Rehabilitation Services (CORFs) 5. Drugs packaged under the Outpatient Prospective Payment System (OPPS) 6. Drugs furnished by ESRD facilities and included in Medicare's ESRD composite rate 7. Osteoporosis drugs provided by home health agencies under certain conditions 8. Drugs furnished by Critical Access Hospitals (CAHs) outpatient departments 9. Drugs furnished by Rural Health Clinics (RHCs) 10. Drugs furnished by Federally Qualified Health Centers (FQHCs) 11. Drugs furnished by Community Health Centers (CMHCs) 12. Drugs furnished by ambulances.	*Generally, if a beneficiary presents at a pharmacy with a script, it would be a Part D drug*. The availability of Part B coverage in a provider setting or physician's office should not result in a refusal of coverage under Part D for drugs dispensed by a pharmacy. This is the case because coverage is not available under Part B as the drug is being "prescribed and dispensed or administered" with respect to the individual. Thus, for example, while Part B covers certain injectables provided "incident to" a physician services, injectables dispensed by a pharmacy are not being "furnished" by a physician and would be Part D drugs. Part D sponsors should deny claims submitted by members for Part B-covered injectables if they are administered in a physician office from a physician's supply. Part D sponsors can subject injectables and infusables that would be covered under Part B as "incident to" a physician service, to a prior authorization program. To the extent that the sponsor determines based on medical literature that there exist serious safety concerns such that it would go against accepted medical practice for a particular injectable or infusible to be dispensed directly to an enrollee, the claim can be denied as not "reasonable." Safety-based reasonableness determinations will need to be made on a case-by-case basis, since circumstances will vary**. In general, however, there are very few instances when an injectable or infusible drug could not be reasonably dispensed directly to the patient.**

Part D Medications/Drugs

Definition of a Part D Covered Drug (see also Medicare Prescription Drug Benefit Manual, Chapter 6, Section 10- Definition of Part D Drugs).

A Part D covered drug is available only by prescription, approved by the FDA (or is a drug described under section 1927(k)(2)(A)(ii) or (iii) of the Act), used and sold in the United States, and used for a medically accepted indication (as defined in section 1927(k)(6) of the Act). In addition, for the applicable drugs of a manufacturer to be covered under Part D, the manufacturer must participate in the Manufacturer Discount Program (see Participating Manufacturers here).

A covered Part D drug includes prescription drugs, biological products, insulin as described in specified paragraphs of section 1927(k) of the Act, vaccines licensed under section 351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration. The definition also includes medical supplies directly associated with delivering insulin to the body, including syringes, needles, alcohol swabs, gauze, and insulin injection delivery devices not otherwise covered under Medicare Part B, such as insulin pens, pen supplies, and needle-free syringes, can satisfy the definition of a Part D drug. CMS defines those medical supplies to include syringes, needles, alcohol swabs, gauze, and those supplies directly associated with delivering insulin into the body.

Part D Excluded Drugs
The definition of a covered Part D drug specifically excludes drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under section 1927(d)(2) of the Act, with the exception of smoking cessation agents. The drugs or classes of drugs that may currently be otherwise restricted under Medicaid include:
• Agents when used for anorexia, weight loss, or weight gain (even if used for a non-cosmetic purpose (i.e., morbid obesity).
• Agents when used to promote fertility.
• Agents when used for cosmetic purposes or hair growth.
• Agents when used for the symptomatic relief of cough and colds.
• Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
• Nonprescription drugs.
• Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
• Agents when used for the treatment of sexual or erectile dysfunction (ED). ED drugs will meet the definition of a Part D drug when prescribed for medically-accepted indications approved by the FDA other than sexual or erectile dysfunction such as pulmonary hypertension. **However, ED drugs will not meet the definition of a Part D drug when used off label, even when the off-label use is listed in one of the compendia found in section** 1927(g)(1)(B)(i) of the Act**: American Hospital Formulary Service Drug Information, and DRUGDEX® Information System. ED drugs meet the definition of a Part D drug only when used for FDA-approved indications.**

Drugs Not Excluded from Part D Coverage
• Prescription drug products that otherwise satisfy the definition of a Part D drug are Part D drugs when used for AIDS wasting and cachexia due to a chronic disease, if these conditions are medically-accepted indications as defined by section 1927(k)(6) of the Act for the particular Part D drug. Specifically, CMS does not consider such prescription drug products being used to treat AIDS wasting and cachexia due to a chronic disease as either agents used for weight gain or agents used for cosmetic purposes.
• Part D drugs indicated for the treatment of psoriasis, acne, rosacea, or vitiligo are not considered cosmetic.
• Vitamin D analogs such as calcitriol, doxercalciferol, *and* paricalcitol when used for a medically-accepted indication as defined by section 1927(k)(6) of the Act, are not excluded because CMS interprets the exclusion of prescription vitamin D products as being limited to products consisting of ergocalciferol (vitamin D2) and/or cholecalciferol (vitamin D3).
• Prescription-only smoking cessation products.
• Prescription Niacin products (Niaspan, Niacor).
• Cough and cold medications are eligible to meet the definition of a Part D drug in clinically relevant situations other than those of symptomatic relief of cough and*/or* colds. For example, when *"*cough*"* medications are used *to treat a medical condition that causes a cough, such as the use of bronchodilators for the treatment of bronchospasm in asthma, CMS does not consider these "cough" medications as excluded drugs and, therefore, these medications may be covered under Part D. However, antitussives used to treat cough symptoms, and not the underlying medical condition causing the cough, are excluded from basic Part D coverage regardless of the medical condition causing the cough.*
• Benzodiazepines
• Barbiturates

Part B vs Part D Guidelines *see* Medicare Prescription Drug Benefit Manual Chapter 6, Appendix C- Part B vs. D Coverage Issues

Durable Medical Equipment (DME) Supply Drugs These are drugs that require administration by the use of a piece of covered DME (e.g., a nebulizer, external or implantable pump) - they are covered as a supply necessary for the DME to perform its function. The largest Medicare expenditures for drugs furnished as a DME supply are for inhalation drugs, which are administered **in the home** through the use of a nebulizer (e.g., albuterol sulfate, ipratropium bromide). These drugs are not covered under Part D for use with a nebulizer. However, if these drugs were delivered with a metered dose inhaler or other non-nebulized administration they would be Part D drugs. For the list of nebulizer drugs covered under Part B, refer to the Noridian DME MAC LCD for Nebulizers (L33370)

In the case of a beneficiary in a hospital, or a SNF bed, (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out or (3) whose stay is non-covered—inhalation DME supply drugs are not covered under Part B because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a ***hospital or SNF cannot be considered the beneficiary's "home" for this purpose***. In this case, coverage for the drugs would be available under Part D.

In addition to a hospital, a SNF or a distinct part SNF, the following facilities **cannot be considered a home** for purposes of receiving the Medicare DME benefit:

- a nursing home that is dually-certified as both a Medicare SNF and a Medicaid nursing facility (NF);
- a Medicaid-only NF that primarily furnishes skilled care;
- a non-participating nursing home (i.e., neither Medicare or Medicaid) that provides primarily skilled care; and
- an institution which has a distinct part SNF and which also primarily furnishes skilled care.

Infusion Pump Medications
Infusion pumps are medical devices used to deliver solutions containing parenteral drugs under pressure at a regulated flow rate. There is a National Coverage Determination (NCD) 280.14 on infusion pumps. Click here to review. The NCD specifies indications and limitations of coverage.

In general, the supplier would bill Part B if the drug was administered using an infusion pump and bill the Part D plan for infusion using other methods (e.g., IV push, IV minibag with pole). There is no Part B coverage in the home for infusion drugs administered **without** an infusion pump (e.g., IV push, IV minibag with pole). While professional services and supplies related to the administration of the infused drug are not payable under Part D, some coverage may be available under Part A or B home health benefits, under Medicaid, or from secondary commercial health benefits.

As a rule, drugs infused using an implantable pump would be covered under Part B. CDPHP will consider implantable infusion pumps and associated services medically reasonable and necessary for the conditions listed in the NCD above. Any drug(s) used to fill the implantable pump must be appropriate for the treatment of the individual patient. Drugs compounded for the special needs of a patient may be covered. Drugs filling the pump are often obtained singly or mixed with other drugs from compounding pharmacies. Unless the medications are administered in the exact concentrations available from national pharmaceutical companies, the medications will be considered as compounded. Compounded medications created by a pharmacist in accordance with the Federal Food, Drug and Cosmetic Act may be covered under Medicare. A compounded drug is defined as a combination of drugs mixed by a pharmacist. This definition does not include a simple reconstitution of a drug as directed by the package insert. Drugs currently approved for pain management through an implantable infusion pump include: bupivacaine, clonidine, droperidol, fentanyl, hydromorphone, ketamine, morphine, Prialt, sufentanil, and tetracaine.

Drugs infused in the home using an external pump are covered under Part B if they are included under the local coverage policy of the applicable Medicare DME MAC. *If the drug is being administered in the home with an infusion pump but the drug is **not covered** by the DME MAC policy then coverage should be considered under **Part D** based on whether the drug is on formulary.*

In the case of a beneficiary in a hospital or a SNF bed: (1) who does not have Part A coverage, (2) whose Part A coverage for the stay has run out, or (3) whose stay is non-covered—infusible DME supply drugs are not covered under Part B because the law limits coverage under Part B's DME benefit to those items that are furnished for use in a patient's home, and specifies that a hospital or SNF cannot be considered the beneficiary's "home" for this purpose. In this case, coverage for the drugs would be available under Part D.

In addition to a hospital, a SNF or a distinct part SNF, the following facilities **cannot be considered a home** for purposes of receiving the Medicare DME benefit:

- a nursing home that is dually-certified as both a Medicare SNF and a Medicaid nursing facility (NF);
- a Medicaid-only NF that primarily furnishes skilled care;
- a non-participating nursing home (i.e., neither Medicare or Medicaid) that provides primarily skilled care; and
- an institution which has a distinct part SNF and which also primarily furnishes skilled care.

Immunosuppressive Drugs Immunosuppressive therapy (such as cyclosporine) for a beneficiary who has received a **Medicare covered organ transplant** is covered under Part B; otherwise, the Part D plan is billed. Immunosuppressive drugs are substances that suppress or interfere with normal immune responses. They are used in controlling autoimmune diseases and in enhancing the chances for survival of foreign-tissue grafts and transplants. Examples of immunosuppressive drugs include:

- azathioprine
- cyclosporine
- gengraf
- mycophenolate
- neoral
- Nulojix Inj
- Prograf

- prednisone/prednisolone/methylprednisolone (when used in conjunction with immunosuppressive drugs as part of a therapeutic regimen)
- Rapamune Soln
- Sandimmune
- sirolimus
- tacrolimus
- Zortress

Part D sponsors are responsible to determine Part B vs. Part D coverage. Beginning in 2019, CMS will be launching a new web portal that will provide additional transplant information to plans. The portal is called Additional Beneficiary Information Initiatives (ABII) and will be part of a group of Acumen web portals. CMS will begin populating ABII with Medicare covered non-kidney transplant data derived from Medicare fee-for-service claims.

On April 1, 2019, the Centers for Medicare and Medicaid (CMS) issued a memo titled, "Using CMS Data when making B vs D Coverage Determinations for Immunosuppressants used to Prevent Transplant Rejections." In this memo, CMS clarifies that the kidney transplant data transmitted to plans via the Transaction Reply Report (TRR) has not been aligned with the member's Medicare Part A or Part B entitlement period. Members with End Stage Renal Disease (ESRD) and/or kidney transplants can have multiple, non-contiguous Medicare entitlement periods. Non-kidney transplant data provided via the Additional Beneficiary Information Initiative (ABII) database has already been checked against Medicare entitlement, so there is no issue using this data to make a Part B vs Part D determination.

Because kidney transplant data in the TRR may not reflect whether Medicare paid for the transplant, Part D sponsors may receive a TRR specifying a renal transplant date which does not fall within the Medicare entitlement periods presented within MARx. This has led to plan confusion as to whether the renal transplant was covered by Medicare or not. CMS clarified that it is critical that Part D sponsors always utilize ***both*** the transplant date and Medicare entitlement data provided via MARx when making these B vs D determinations. The Medicare entitlement data transmitted to plans via the TRR is only for the most recent entitlement period and may not reflect prior entitlements. Therefore, the plan must manually check MARx for previous Medicare entitlement periods.

CDPHP will utilize an Excel file which is updated to reflect members being passed on the TRR with transplant codes (i.e., 269) and ABII files. This file contains all member info including the Medicare eligibility dates from MARX. If the member was eligible for Medicare at the time they had their transplant, then the transplant was covered by Medicare and the drugs will process under Part B.

1. No Prior Part D Claims History for Immunosuppressants

a) The plan has received information from CMS (e.g., via MARx or ABII) indicating that Medicare covered the enrollee's transplant or, in the case of a Medicare Advantage enrollee, the MA Plan has medical claims history of a covered transplant regardless of previously received information from a prescriber on whether or not the transplant was covered by Medicare.

In this situation, plans are expected to rely on the CMS information (or in the case of an MA plan, its own medical claims history) and cannot cover Immunosuppressants under Part D even if information is also provided by the prescriber that indicates that the transplant was not Medicare covered.

b) The plan has **not** received information from CMS (via MARx or ABII) indicating that Medicare covered the transplant for the enrollee; in the case of a Medicare Advantage enrollee, the MA Plan does not have medical claims showing a history of a covered transplant; and the plan has not previously received information from a prescriber that the transplant was covered by Medicare.

In this situation, CMS expects plans to default to covering the Immunosuppressants under Part D and no longer expects plans to reach out to prescribers to inquire about Medicare coverage of the transplant. Such outreach is burdensome for plans and prescribers, and has been shown to be unreliable for accurately determining if Medicare covered a transplant. Nevertheless, the plan should approach this coverage decision using the best available information; if the plan has previously reached out to the prescriber and received information indicating that the that the transplant was covered by Medicare (in full or in part), the Part D plan may not cover Immunosuppressants under D.

2. Prior Part D Claims History <u>and</u> either MARx nor ABII currently indicates that Medicare covered the transplant:

A plan might have covered the drugs under Part D previously because either:

- MARx information was updated after the Part D sponsor relied on prior information from the prescriber that the transplant was NOT covered/ paid by Medicare; or

- The Part D sponsor had relied solely on information from the prescriber that the transplant was NOT covered/paid by Medicare without regard to MARx.

Under either scenario, the Part D sponsor must now rely on the MARx information **going forward** and notify the enrollee that the plan can no longer cover the immunosuppressant(s) under Part D because it is covered under Medicare Part B. No changes need to be made to prior Part D claims.

3. Prior Part D Claims History, no MARx indicator or MA plan medical claims history of a covered transplant BUT the Part D sponsor receives information from CMS that the transplant was covered by Medicare (e.g., Part D sponsor receives the information from CMS as part of a CMS Program Integrity audit or through ABII).

Under this scenario, the Part D sponsor must now rely on the CMS information **going forward** and provide notice to the enrollee that the plan will no longer cover the immunosuppressant(s) under Part D because it is covered under Medicare Part B. No changes need to be made to prior Part D claims.

Hemophilia Clotting Factors Hemophilia clotting factors are covered under Part B for patients competent to use such factors to control bleeding without medical supervision of factors and items related to the administration of such factors. These would not be covered under Part D.

Oral Anti-Cancer Drugs and Oral Anti-Emetics

Oral Chemotherapy (with potential for non-cancer indications)
If the medication is taken orally during chemotherapy and there is an infusible form of the drug that would be covered incident to a physician's visit the medication is covered under Part B; otherwise, it is covered under Part D (i.e., CYTOXAN or cyclophosphamide)

Oral Chemotherapy (with cancer indications only)
The following medications are **always** covered under the **Part B benefit** since they are always indicated for treatment of cancer (no non-cancer indications).

- capecitabine (XELODA)
- temazolamide (TEMODAR)

Oral Anti-Emetics If the oral anti-emetic is being used in relation to cancer treatment **and** as a full replacement for intravenous administration within 48 hours of cancer treatment, then they would be covered under Part B. If such drugs are dispensed for use **after** the 48-hour period **or** are prescribed for conditions other than the effects of cancer treatment, then they would be covered under Part D. The following are a list of examples (may not be all inclusive):

- dronabinol caps
- granisetron tabs
- ondansetron

The following drugs will follow the criteria set forth in the DME MAC Local Coverage Determination for Anti-Emetics. In addition to the LCD the related coverage article A52480 will detail the specific antiemetic drugs listed below**.**

- AKYNZEO caps (netupitant-palonosteron)
- EMEND (aprepitant)
- VARUBI tabs (rolapitant)

Criteria for Approval - AKYNZEO

1. The drug is being used as part of a cancer chemotherapy regimen
2. The oral anti-emetic formulation is being used as a full therapeutic replacement for an IV anti-emetic drug that would otherwise have been administered at the time of chemotherapy. *This criterion is not met when the chemotherapy drug is an oral drug or when the chemotherapy drug is administered intravenously in the home setting because the type and dosage of chemotherapy drugs administered in these situations do not require intravenous antiemetic drugs*
3. The oral drug must be given within 48 hours of chemotherapy
4. Akynzeo must be given as part of a regimen that includes an oral corticosteroid (i.e., dexamethasone)

5. The member must be receiving one or more of the following chemotherapeutic agents: Alemtuzumab, Azacitidine, Bendamustine, Carboplatin, Carmustine, Cisplatin, Clofarabine, Cyclophosphamide, Cytarabine, Dacarbazine, Daunorubicin, Doxorubicin, Epirubicin, Idarubicin, Ifosfamide, Irinotecan, Lomustine, Mechlorethamine, Oxaliplatin, Streptozocin

Criteria for Approval - EMEND, aprepitant and VARUBI (rolapitant)

1. The drug is being used as part of a cancer chemotherapy regimen
2. The oral antiemetic formulation is being used as a full therapeutic replacement for an IV antiemetic drug that would otherwise have been administered at the time of chemotherapy. *This criterion is not met when the chemotherapy drug is an oral drug or when the chemotherapy drug is administered intravenously in the home setting because the type and dosage of chemotherapy drugs administered in these situations do not require intravenous antiemetic drugs*
3. The oral drug must be given within 48 hours of chemotherapy
4. Varubi (rolapitant)/ Emend (aprepitant) must be given as part of a regimen that includes an oral corticosteroid (i.e., dexamethasone) and an oral 5-HT3 antagonist (i.e., ondansetron, granisetron)
5. The member must be receiving one or more of the following chemotherapeutic agents: Alemtuzumab, Azacitidine, Bendamustine, Carboplatin, Carmustine, Cisplatin, Clofarabine, Cyclophosphamide, Cytarabine, Dacarbazine, Daunorubicin, Doxorubicin, Epirubicin, Idarubicin, Ifosfamide, Irinotecan, Lomustine, Mechlorethamine, Oxaliplatin, Streptozocin

Immunizations Influenza and pneumococcal vaccines are always covered under Part B**.** Hepatitis B vaccine coverage depends on the risk of the individual. If the individual is at high or intermediate risk then Part B would cover. If the individual was at low risk then Part D would cover. In addition, there are some vaccines that may be covered under Part B if they are being administered because they are directly related to the treatment of an injury or direct exposure to a disease (i.e., Tetanus/diphtheria or Rabies). As of 1/1/2022 COVID-19 vaccine will be covered under Part B. For a list of complete vaccine coverage please go to cdphp.com and search for Medicare Vaccine Coverage guide.

Antigens These are prepared by a physician (usually an allergist) for a specific patient. The physician or physician's nurse generally administers them in the physician's office. In some cases, the physician prepares antigens and furnishes them to a patient who has been taught to self-administer them at home. There is no Part D coverage for antigens; they are always covered under Part B.

Parenteral Nutrition or Intradialytic parenteral nutrition (IDPN) If the therapy is being provided because of a non-functioning digestive tract then Part B would cover, otherwise these are Part D drugs.

Erythropoietin (EPO) EPO is covered for the treatment of anemia for patients with chronic renal failure who are on dialysis. When EPO is given in conjunction with dialysis (i.e., at the facility) it is considered covered under the per diem rate that CDPHP pays to the facility and it should be supplied by the facility. The member should not be filling under their Part D coverage at the pharmacy.

EPO is also covered for hip or knee surgery candidates at high risk for preoperative transfusions with significant anticipated blood loss and who meet all of the following criteria per the Medicare Benefit Policy Manual, Chapter 15, 50.5.2.2

- Members with anemia and a hemoglobin between 10 and 13 mg/dL
- Members who are not candidates for autologous blood transfusions
- Members who are expected to lose more than 2 units of blood
- Members who have had a work-up which indicates that their anemia appears to be that of chronic disease

Erythropoiesis Stimulating Agents (ESAs) **are covered** in cancer and related neoplastic conditions **only** in accordance with Medicare criteria. See the NCD for Erythropoiesis Stimulating Agents (ESAs) in Cancer and Related Neoplastic Conditions (110.21).

Nationally Covered Indications
ESA treatment for the anemia secondary to myelosuppressive anticancer chemotherapy in solid tumors, multiple myeloma, lymphoma, and lymphocytic leukemia is only reasonable and necessary under the following specified conditions:

- The hemoglobin level immediately prior to initiation or maintenance of ESA treatment is < 10 g/dL (or the hematocrit is < 30%).
- The starting dose for ESA treatment is the recommended FDA label starting dose, no more than 150 U/kg/3 times weekly for epoetin and 2.25 mcg/kg/1 time weekly for darbepoetin alpha. Equivalent doses may be given over other approved time periods.
- Maintenance of ESA therapy is the starting dose if the hemoglobin level remains below 10g/dL (or hematocrit is < 30%) 4 weeks after initiation of therapy and the rise in hemoglobin is ≥ 1g/dL (hematocrit ≥ 3%);

- For patients whose hemoglobin rises < 1g/dl (hematocrit rise < 3%) compared to pretreatment baseline over 4 weeks of treatment and whose hemoglobin level remains < 10g/dL after the 4 weeks of treatment (or the hematocrit is < 30%), the recommended FDA label starting dose may be increased once by 25%. Continued use of the drug is not reasonable and necessary if the hemoglobin rises < 1g/dl (hematocrit rise < 3%) compared to pretreatment baseline by 8 weeks of treatment.
- Continued administration of the drug is not reasonable and necessary if there is a rapid rise in hemoglobin > 1g/dl (hematocrit > 3%) over 2 weeks of treatment unless the hemoglobin remains below or subsequently falls to < 10g/dL (or the hematocrit is < 30%). Continuation and reinstitution of ESA therapy must include a dose reduction of 25% from the previously administered dose.
- ESA treatment duration for each course of chemotherapy includes the 8 weeks following the final dose of myelosuppressive chemotherapy in a chemotherapy regimen.

Nationally Non-Covered Indications
ESA treatment is not reasonable and necessary for beneficiaries with certain clinical conditions, either because of a deleterious effect of the ESA on their underlying disease or because the underlying disease increases their risk of adverse effects related to ESA use. These conditions include:

- Any anemia in cancer or cancer treatment patients due to folate deficiency, B-12 deficiency, iron deficiency, hemolysis, bleeding, or bone marrow fibrosis;
- The anemia associated with the treatment of acute and chronic myelogenous leukemias (CML, AML), or erythroid cancers;
- The anemia of cancer not related to cancer treatment;
- Any anemia associated only with radiotherapy;
- Prophylactic use to prevent chemotherapy-induced anemia;
- Prophylactic use to reduce tumor hypoxia;
- Patients with erythropoietin-type resistance due to neutralizing antibodies; and
- Anemia due to cancer treatment if patients have uncontrolled hypertension.

Members may have additional coverage of EPO under their Part D Prescription Drug benefit that is not addressed in this policy. See Part D policy 1350/20.000278 for drugs on the Part D formulary that require PA.

ESRD Drugs
The following drugs will be stopped for a determination at the pharmacy when there is an indicator in the member's eligibility that states **DIALYSIS = YES**.

A. If it is confirmed that the member is on dialysis **and** the drug is being given at the dialysis facility during dialysis then the drug should be covered as part of the per diem rate that CDPHP pays to the facility.
B. If the member is on dialysis and the drug is taken daily or being used outside the dialysis facility then the claim should process under the Part B benefit.
C. If the member is not on dialysis then the claim should process under Part D if it has FDA indications outside of dialysis.

- calcitriol caps/injection
- cinacalcet tabs
- heparin sodium injection 1000u/ml, 5000u/ml, 10000u/ml, 20000u/ml
- ibandronate 150mg tabs
- levocarnitine 1gm/10ml oral soln, 333mg tab
- lidocaine inj 0.5%, 1%, 1.5%, 2%
- lidocaine/prilocaine cream
- pamidronate inj
- paricalcitol caps

Sensipar/Parsabiv: January 2018 change - see below

Drugs used for the provision of renal dialysis services are defined in 42 CFR 413.234(a) *as a drug or biological with no injectable equivalent or other form of administration other than an oral form.* Prior to January 1, 2018 Sensipar J0604 (cinacalcet) met the definition under 42 CFR 413.234(a) and was paid under the Part D benefit. A new injectable drug, Parsabiv® (J0606, etelcalcetide), that falls within the bone and mineral metabolism functional category was approved for renal dialysis services by the United States Food and Drug Administration (FDA) in 2017. Therefore, as of January 1, 2018 Sensipar will no longer be payable under the Part D benefit if the member is on dialysis. Since Parsabiv is only indicated for use in patients on hemodialysis and given as an injection at the end of the dialysis treatment it is considered part of the per diem rate that CDPHP pays the dialysis facility.

Oral Phosphate Binders: January 2025

Under 42 C.F.R. § 413.174(f)(6), effective January 1, 2025, payment to an ESRD facility for renal dialysis service drugs and biologicals with only an oral form furnished to ESRD patients is incorporated within the prospective payment system rates established by CMS in § 413.230 and separate payment will no longer be provided.

Effective January 1, 2025, the following oral-only phosphate binders are approved for the TDAPA under the ESRD PPS:

- sevelamer carbonate, sevelamer hydrochloride,
- sucroferric oxyhydroxide (Velphoro)
- lanthanum carbonate
- ferric citrate (Auryxia)
- calcium acetate

Vafseo (vadadustat)

The Transitional Drug Add-On Payment Adjustment (TDAPA) is a payment adjustment under the ESRD PPS for certain new renal dialysis drugs and biological products. In October 2024, CMS approved a TDAPA application for Akebia's VAFSEO® (vadadustat) under the ESRD PPS.

Xpozah (tenapanor)

On October 17, 2023, a new oral phosphate lowering agent received FDA marketing approval. According to the FDA label information for this drug, XPHOZAHTM (tenapanor) is indicated to reduce serum phosphorus in adults with chronic kidney disease who are on dialysis. CMS has identified XPHOZAHTM to be a renal dialysis service because it is used to treat or manage a condition associated with ESRD. Specifically, it is used as an add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. CMS has also determined that XPHOZAHTM meets the current regulatory definition of an oral-only drug as defined at § 413.234(a), and therefore, in accordance with § 413.174(f)(6), is not paid for under the ESRD PPS until January 1, 2025. Consistent with policies adopted in the CY 2016 and CY 2023 ESRD PPS final rules (see 80 FR 69025 and 87 FR 67183), XPHOZAHTM will be included in the ESRD PPS effective January 1, 2025, using the drug designation process under § 413.234.

Intravenous and Subcutaneous Immune Globulin (IVIG and SCIg)

A. Intravenous Immune Globulin (IVIG) in the Home **See Medicare Benefit Policy Manual, Chapter 15, 50.6**

Intravenous immune globulin (IVIG) for the treatment of primary immune deficiency diseases is **covered** in the home under Part B if **all** of the following criteria are met:

- It is an approved pooled plasma derivative for the treatment of primary immune deficiency disease; and
- The patient has a diagnosis of primary immune deficiency disease (ICD-9 codes 279.04, 279.05, 279.06, 279.12, and 279.2 or ICD-10-CM codes D80.0, D80.5, D81.0, D81.1, D81.2, D81.6, D81.7, D81.89, D81.82, D81.9, D82.0, D83.0, D83.2, D83.8, or D83.9 if only an unspecified diagnosis is necessary); and
- The IVIG is administered in the home; and
- The treating physician has determined that administration of the IVIG in the patient's home is medically appropriate.

The supplier shall bill Part B is the diagnosis is Primary Immune Deficiency (see codes above). IVIG provided in the home for other diagnoses would be a Part D benefit and should be reviewed under Part D criteria policy 1350/20.000278.

B. Intravenous Immune Globulin (IVIG) in Office/Outpatient setting

Intravenous immune globulin (IVIG) will be covered as a Part B (medical) benefit if the product being given is for a medically accepted indication

C. Intravenous Immune Globulin (IVIG) for the Treatment of Autoimmune Mucocutaneous Blistering Diseases

IVIG **is covered** for the treatment of biopsy-proven: (1) Pemphigus Vulgaris, (2) Pemphigus Foliaceus, (3) Bullous Pemphigoid, (4) Mucous Membrane Pemphigoid (a.k.a., Cicatricial Pemphigoid), and (5) Epidermolysis Bullosa Acquisita.

For specific coverage guidelines refer to the National Coverage Determination (NCD) 250.3

D. Subcutaneous Immune Globulin (SCIg) Coverage **for the administration of SCIg using an external infusion pump is provided as stated in the** LCD External Infusion Pumps (L33794) **to be effective 7/18/2021. SQIg (codes below) is covered when criteria 1-3 AND criterion 4 OR 5 are met:**

1) The subcutaneous immune globulin preparation is a pooled plasma derivative which is FDA-approved; and
2) The SCIg is administered in the home; and,
3) The treating practitioner has determined that administration of the SCIg **in the patient's home** is necessary and appropriate; and,
4) The beneficiary has a primary immune deficiency disorder (Refer to the Group 3 ICD-10 code list in the LCD-related Policy Article for applicable diagnoses.); OR,
5) The beneficiary has a diagnosis of chronic inflammatory demyelinating polyneuropathy (CIDP) that has responded to IVIg treatment (Refer to the Group 6 ICD-10 code list in the LCD-related Policy Article for applicable diagnoses.).

SQIg Codes

CODE	DESCRIPTION
J1551	INJECTION, IMMUNE GLOBULIN (CUTAQUIG), 100MG
J1555	INJECTION, IMMUNE GLOBULIN (CUVITRU), 100 MG
J1558	INJECTION, IMMUNE GLOBULIN (XEMBIFY), 100 MG
J1559	INJECTION, IMMUNE GLOBULIN (HIZENTRA), 100 MG
J1561	INJECTION, IMMUNE GLOBULIN, (GAMUNEX-C/GAMMAKED), NON-LYOPHILIZED (E.G., LIQUID), 500 MG
J1562	INJECTION, IMMUNE GLOBULIN (VIVAGLOBIN), 100 MG
J1569	INJECTION, IMMUNE GLOBULIN, (GAMMAGARD LIQUID), NON-LYOPHILIZED, (E.G., LIQUID), 500 MG
J1575	INJECTION, IMMUNE GLOBULIN/HYALURONIDASE, (HYQVIA), 100 MG IMMUNEGLOBULIN
J7799	NOC DRUGS, OTHER THAN INHALATION DRUGS, ADMINISTERED THROUGH DME

Group 3 Codes:

Show entries: 100

Search: Search By: Code Description SEARCH GROUP CLEAR SEARC

ICD-10-CM CODE	DESCRIPTION
D80.0	Hereditary hypogammaglobulinemia
D80.2	Selective deficiency of immunoglobulin A [IgA]
D80.3	Selective deficiency of immunoglobulin G [IgG] subclasses
D80.4	Selective deficiency of immunoglobulin M [IgM]
D80.5	Immunodeficiency with increased immunoglobulin M [IgM]
D80.6	Antibody deficiency with near-normal immunoglobulins or with hyperimmunoglobulinemia
D80.7	Transient hypogammaglobulinemia of infancy
D81.0	Severe combined immunodeficiency [SCID] with reticular dysgenesis
D81.1	Severe combined immunodeficiency [SCID] with low T- and B-cell numbers
D81.2	Severe combined immunodeficiency [SCID] with low or normal B-cell numbers
D81.5	Purine nucleoside phosphorylase [PNP] deficiency
D81.6	Major histocompatibility complex class I deficiency
D81.7	Major histocompatibility complex class II deficiency
D81.89	Other combined immunodeficiencies
D81.9	Combined immunodeficiency, unspecified
D82.0	Wiskott-Aldrich syndrome
D82.1	Di George's syndrome
D82.4	Hyperimmunoglobulin E [IgE] syndrome
D83.0	Common variable immunodeficiency with predominant abnormalities of B-cell numbers and function
D83.1	Common variable immunodeficiency with predominant immunoregulatory T-cell disorders
D83.2	Common variable immunodeficiency with autoantibodies to B- or T-cells
D83.8	Other common variable immunodeficiencies
D83.9	Common variable immunodeficiency, unspecified
G11.3	Cerebellar ataxia with defective DNA repair

Group 6 Codes:

Show entries: 100

Search: Search By: Code Description SEARCH GROUP CLEAR SEARCH

ICD-10-CM CODE	DESCRIPTION
G61.81	Chronic inflammatory demyelinating polyneuritis

Injectable Drugs for the Treatment of Osteoporosis Chapter 7 of the Medicare Benefit Policy Manual Section 50.4.3

Sections 1861(m) and 1861(kk) of the Act provide for coverage of FDA approved injectable drugs for the treatment of osteoporosis. These drugs are expected to be provided by a home health agency (HHA) to **female beneficiaries** who are currently receiving services under an open home health plan of care, who meet existing coverage criteria for the home health benefit and who meet the criteria listed below. These drugs are covered on a cost basis when provided by an HHA under the circumstances listed below.

The home health visit (i.e., the skilled nurse's visit) to administer the drug is covered under all fee-for-service Medicare (Part A or Part B) home health coverage rules. Coverage of the drug is limited to female beneficiaries who meet each of the following criteria:

- The individual is eligible for Medicare Part B coverage of home health services (the nursing visit to perform the injection may be the individual's qualifying service);
- The individual sustained a bone fracture that a physician certifies was related to post-menopausal osteoporosis; and
- The individual's physician certifies that she is unable to learn the skills needed to self-administer the drug or is otherwise physically or mentally incapable of administering the drug, and that her family or caregivers are unable or unwilling to administer the drug.

This drug is considered part of the home health benefit under Part B. Therefore, Part B deductible and coinsurance apply regardless of whether home health visits for the administration of the drug are covered under Part A or Part B.

References

		Updated	Accessed
1	Medicare Prescription Drug Benefit Manual, Chapter 6		8/2018, 10/2022, 8/2023,8/2024, 9/2025
2	Medicare Prescription Drug Benefit Manual, Chapter 15		8/2018, 6/2021, 10/2022, 8/2023, 8/2024, 9/2025
3	Medicare Benefit Policy Manual, Chapter 7		8/2018
4	CMS Medicare Coverage Database- National Coverage Determinations https://www.cms.gov/medicare-coverage-database/search.aspx		8/2018, 8/2020, 10/2022, 8/2023, 8/2024, 9/2025
5	Local Coverage Determinations (LCDs) for National Government Services Inc. Part A and B MAC for NYS https://www.ngsmedicare.com/NGS_LandingPage/		8/2018, 8/2020, 6/2021, 10/2022, 8/2023, 9/2025
6	Local Coverage Determinations (LCDs) for Noridian Healthcare Solutions LLC NYS DME MAC https://med.noridianmedicare.com/web/jadme/policies/lcd/active		8/2018, 8/2020, 6/2021, 10/2022, 8/2023, 8/2024, 9/2025
7	Local Coverage Article A53021 Self-Administered Drug Exclusion List https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=53032&ver=118&keyword=self%20administered&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1		9/2021, 10/2022, 8/2023, 8/2024, 9/2025
8	CMS ESRD PPS Transitional Drug Add-On Payment Adjustment (TDAPA) https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-pps-transitional-drug-add-payment-adjustment		1/2025
9	CY 2025 ESRD PPS Final Rule https://www.cms.gov/newsroom/fact-sheets/calendar-year-2025-		1/2025

	end-stage-renal-disease-esrd-prospective-payment-system-pps-final-rule-cms-1805-f		

Definitions

Not Usually Self- Administered (as defined by Medicare):

a. Administered: The term "administered" refers only to the physical process by which the drug enters the patient's body. It does not refer to whether the process is supervised by a medical professional (for example, to observe proper technique or side-effects of the drug). Injectable drugs, including intravenously administered drugs, are typically eligible for inclusion under the "incident to" benefit. With limited exceptions, other routes of administration including, but not limited to, oral drugs, suppositories, topical medications are considered to be usually self-administered by the patient.

b. Usually: For the purposes of applying this exclusion, the term "usually" means more than 50 percent of the time for all Medicare beneficiaries who use the drug. Therefore, if a drug is self-administered by more than 50 percent of Medicare beneficiaries, the drug is excluded from coverage and the contractor may not make any Medicare payment for it.

c. By the patient: The term "by the patient" means Medicare beneficiaries as a collective whole. Includes only the patients themselves and no other individuals (that is, spouses, friends, or other care-givers are not considered the patient).

GOVERNMENT PROGRAMS

MEDICARE ADVANTAGE: Subject to the terms and conditions noted in above application. Benefits for Medicare Part D prescription drugs are only available to enrollees who have elected a CDPHP Medicare Advantage Part D plan. The CDPHP Medicare Choices Part D plan products do not cover any prescription drugs not covered by Medicare, with the exception of additional coverage purchased with a group-enhanced rider. In addition, for those individuals enrolled in the CDPHP Medicare Advantage product who have not elected a Part D option, CDPHP only covers those prescription drugs covered by Medicare Parts A and B, not those covered by Part D. Coverage is available for any eligible Part D drug prescribed for a medically accepted indication as cited in one or more of the following references: American Hospital Formulary Service Drug Information, and DrugDex Information System. Coverage is available for any eligible Part D drug and biological used off label in an anti-cancer chemotherapeutic regimen for a medically accepted indication as cited in one or more of the following references: American Hospital Formulary Service Drug Information, DrugDex Information System, National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Clinical Pharmacology and Wolters Kluwer Lexi-Drugs (Lexicomp). In addition, for Part D drugs utilized in anticancer chemotherapy regimens, coverage for additional off-label use may be available if scientific literature approved by the Secretary of Health and Human Services (Secretary) supports such use.

CDPHP Pharmacy Services

Policy History

Date	Note
1/2009	New policy
8/09, 7/12, 8/15, 8/16, 8/17	Reviewed, No updates
8/10, 7/11, 10/11, 7/13, 7/14, 11/2018, 8/2019, 8/2020, 6/2021, 9/2021	Revised
5/2022	Added codes for IVIG
10/2022	Updated all links
12/2022	Added new code for coverage of IVIG in the home effective 10/1/2022
8/2023	Updated all hyperlinks. Removed reference to Local Coverage Article for IVIG given in office setting A53446 as it is retired.
8/2024	Updated all hyperlinks
9/2025	Updated all hyperlinks

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Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Some medications that are administered as part of the Part B benefit may have limitations of coverage. When these medications are limited, they typically have additional requirements that need to be met in order to ensure medical necessity and appropriate use. An example of a requirement can be step therapy. Step therapy is when a member is required to try a preferred medication before a non-preferred medication is approved.

All Part B Step Therapy is reviewed by the CDPHP Pharmacy and Therapeutics Committee. The committee will base clinical decisions on the strength of scientific evidence and standards of practice, including assessment of peer reviewed medical literature, pharmacoeconomic studies, outcomes research data, and other information as is deemed appropriate.

Step therapy requirements will apply to new starts of non-preferred medications and as part of the Part B benefit only.

Preferred medications include:

Class	Non-preferred	Preferred
Osteoporosis	Prolia (denosumab) Bosaya (denosumab-kyqq) Conexxence (denosumab-bnht) Jubbonti (denosumab-bbdz) Osvyrti (denosumab-desu) Ospomyv (denosumab-dssb) Stoboclo (denosumab-bmwo)	Bildyos (denosumab-nxxp) Enoby (denosumab-qbde)
Rituxan Biosimilars	Rituxan (rituximab) Rituxan Hycela (rituximab and hyaluronidase) Riabni (rituximab-arrx)	Ruxience (rituximab-pvvr) Truxima (rituximab-abbs)
Herceptin Biosimilars	Herceptin (trastuzumab) Herceptin Hylecta (trastuzumab and hyaluronidase) Ogivri (trastuzumab-dkst) Herzuma (trastuzumab-pkrb) Ontruzant (trastuzumab-dttb) Hercessi (trastuzumab-strf)	Trazimera (trastuzumab-qyyp) Kanjinti (trastuzumab-anns)
Avastin Biosimilars	Avastin (bevacizumab) Vegzelma (bevacizumab-adcd) Alymsys (bevacizumab-maly) Jobevne (bevacizumab-nwgd)	Mvasi (bevacizumab-awwb) Zirabev (bevacizumab-bvzr)
Multiple Sclerosis	Lemtrada (alemtuzumab)	Tysabri (natalizumab)
Blood Disorders/Biosimilars	Fylnetra (pegfilgrastim-pbbk) Stimufend (pegfilgrastim-fpgk) Udenyca (pegfilgrastim-cbqv) Ziextenzo (pegfilgrastim-bmez) Rolvedon (eflapegrastim-xnst) Ryzneuta (efbemalenograstim alfa-vuxw)	Neulasta (pegfilgrastim) Nyvepria (pegfilgrastim-apgf) Fulphila (pegfilgrastim-jmdb)
	Granix (tbo-filgrastim) Neupogen (filgrastim) Releuko (filgrastim-ayow)	Zarxio (filgrastim-sndz) Nivestym (filgrastim-aafi)

	Nypozi (filgrastim-txid)	
Eosinophilic Asthma	Cinqair (reslizumab)	Nucala (mepolizumab) Fasenra (benralizumab)
Osteoarthritis – Hyaluronic Acid	Durolane Euflexxa Gelsyn-3 Genvisc 850 Hymovis Supartz FX Synvisc-One Triluron Trivisc Hyalgan Visco-3 SynoJoint	Gel-One Monovisc Orthovisc

Summary	
Effective Date of Policy:	8/1/2026

Required Criteria for Approval	
All of the following conditions for the requested indication must be met in order to approve therapy	
Drug Class	**Clinical Criteria**
Osteoporosis	Preferred: **Bildyos (Q5162), Enoby (Q5167)** *Bildyos and Enoby for use in an FDA-approved indication does not require prior authorization.* Non-preferred: Prolia (J0897), Conexxence (Q5158), Jubbonti (Q5136), Ospomyv (Q5159), Stoboclo (Q5157), Bosaya (Q5161), Osvyrti (Q5166) *Non-preferred agents (Prolia or any biosimilar) use for any indication will require prior authorization.* Criteria for non-preferred agent: Prolia, Jubbonti, Stoboclo, Conexxence, Ospomyv, Osvyrti, or Bosaya may be used in the following scenarios: • For existing utilizers: This is a continuation of therapy • For New Starts: Requests for non-preferred denosumab products will require a previous trial and failure (defined as a decrease in BMD or a fracture while on osteoporosis therapy) of **BOTH** Bildyos and Enoby unless there is medical reason why Bildyos and Enoby cannot be used due to formulation differences in the inactive ingredient(s) (e.g., differences in stabilizing agent, buffering agent, and/or surfactant) which, according to the prescriber, would result in a significant allergy or serious adverse reaction (documentation required) Prolia and all biosimilars will be covered for FDA and compendia approved uses according to the LCD33394 and local coverage article A52399
Rituxan Biosimilars	Preferred: **Ruxience (Q5119), Truxima (Q5115)** *Preferred biosimilar products of Rituxan for use in an FDA-approved indication do not require prior authorization.* Non-preferred: Rituxan (J9312), Rituxan Hycela (J9311), Riabni (Q5123) *Non-preferred agents use for any indication will require prior authorization* Criteria for non-preferred agent (Rituxan, Rituxan Hycela, Riabni): Rituxan or Rituxan Hycela may be used in the following scenarios: • Member has failed treatment with **two** preferred rituximab biosimilar agents due to documented intolerable/significant adverse reactions **OR** • This is a continuation of therapy for Rituxan, Rituxan Hycela or non-preferred biosimilar Clinical criteria for use of a preferred rituximab biosimilar: • Medication is being requested for an FDA-approved indication or consensus guideline recommendation (i.e., NCCN guideline recommendation)

Herceptin Biosimilars	Preferred: **Trazimera (Q5116), Kanjinti (Q5117)** *Preferred biosimilar products of Herceptin for use in an FDA-approved indication do not require prior authorization.* Non-preferred: Herceptin (J9355), Herceptin Hylecta (J9356), Ogivri (Q5114), Herzuma (Q5113), Ontruzant (Q5112), Hercessi (Q5146) *Non-preferred agents use for any indication will require prior authorization* Criteria for non-preferred agent (Herceptin, Herceptin Hylecta, Ogivri, Herzuma, Ontruzant): Herceptin or Herceptin Hylecta may be used in the following scenarios: • Member has failed treatment with **two** preferred Herceptin biosimilar agents due to documented intolerable/significant adverse reactions **OR** • This is a continuation of therapy for Herceptin, Herceptin Hylecta or non-preferred biosimilar Clinical criteria for use of a preferred Herceptin biosimilar: • Medication is being requested for an FDA-approved indication or consensus guideline recommendation (i.e., NCCN guideline recommendation)
Avastin Biosimilars	Preferred: **Mvasi (Q5107), Zirabev (Q5118)** *Preferred biosimilar products of Avastin for use in an FDA-approved indication do not require prior authorization.* Non-preferred: Avastin (J9035), Alymsys (Q5126), Vegzelma (Q5129), Jobevne (Q5160) *Non-preferred agents use for any indication will require prior authorization EXCEPT:* **Ophthalmic use of Avastin does not require the use of a biosimilar.** Criteria for non-preferred agents (Avastin, Alymsys, Vegzelma, Jobevne): Avastin may be used in the following scenarios: • Member has failed treatment with **two** preferred Avastin biosimilar agents due to documented intolerable/significant adverse reactions **OR** • This is a continuation of therapy for Avastin or non-preferred biosimilar Clinical criteria for use of a preferred Avastin biosimilar: • Medication is being requested for an FDA-approved indication or consensus guideline recommendation (i.e., NCCN guideline recommendation) as noted in the local coverage article A52370
Multiple Sclerosis	Preferred: **Tysabri (J2323)** *Tysabri for use in an FDA-approved indication does not require prior authorization.* Non-preferred: Lemtrada (J0202) *Lemtrada for any use will require prior authorization.* Criteria for non-preferred agent (Lemtrada): • History of use of Tysabri with minimal clinical response to therapy **OR** • Member demonstrates intolerance to Tysabri **OR** • Member has contraindication to Tysabri **OR** • This is a continuation of therapy of Lemtrada Clinical criteria for non-preferred agent (Lemtrada): Lemtrada may be used in the following scenarios: • Diagnosis of a relapsing form of Multiple Sclerosis **AND** • Inadequate response to two or more drugs indicated for the treatment of Multiple Sclerosis

Blood Disorders/ Biosimilars – short acting	Preferred: **Zarxio Q5101, Nivestym Q5110** *Preferred agent use for an FDA-approved indication does not require prior authorization* Non-preferred: Neupogen J1442, Granix J1447, Releuko Q5125, Nypozi J3590 *Non-preferred agent use for any indication will require prior authorization.* Criteria for non-preferred agent: • Member has failed treatment with **two** preferred products due to documented intolerable/significant adverse reactions
Blood Disorders/ Biosimilars – longer acting	Preferred: **Neulasta J2506, Fulphila Q5108, Nyvepria Q5122** *Preferred agent use for an FDA-approved indication does not require prior authorization* Non-preferred: Udenyca Q5111, Ziextenzo Q5120, Stimufend Q5127, Fylnetra Q5130, Rolvedon J1449, Ryzneuta J9361 *Non-preferred agent use for any indication will require prior authorization.* Criteria for non-preferred agent: • Member has failed treatment with **two** preferred products due to documented intolerable/significant adverse reactions
Eosinophilic Asthma	Preferred: **Nucala (J2182), Fasenra (J0517)** *Preferred agent use for an FDA-approved indication does not require prior authorization* Non-preferred: Cinqair (J2786) *Non-preferred agent use for any indication will require prior authorization.* Criteria for non-preferred agent: • Member has failed treatment with **both** Nucala and Fasenra due to documented intolerable/significant adverse reactions OR • This is a continuation of therapy for Cinqair
Osteoarthritis	Preferred: **Gel-One (J7326), Monovisc (J7327) and Orthovisc (J7324)** *Preferred agent use for an FDA-approved indication does not require prior* Non-preferred: Durolane: (J7318); Genvisc 850: (J7320); Supartz FX: (J7321); Hymovis: (J7322); Euflexxa: (J7323); Synvisc-One: (J7325); Gelsyn-3: (J7328); Trivisc: (J7329); Triluron: (J7332), Hyalgan (J7321), Visco-3 (J7321), SynoJoint (J7331) *Non-preferred agent use for any indication will require prior authorization.* Criteria for non-preferred agent: • Member has failed treatment with **two** preferred hyaluronic acid products due to documented intolerable/significant adverse reactions

Continuation Criteria

- Requests will be reviewed per criteria every 12 months.

Considerations

- This policy does not apply to medications being obtained through the Part D pharmacy benefit
- Prior authorization is obtained through the CDPHP pharmacy department.
- Step therapy Criteria **only applies to new-starts** of non-preferred medications.

References

		Updated	Accessed
1	LeBoff, M., Greenspan, S., Insogna, K. *et al.* The clinician's guide to prevention and treatment of osteoporosis. *Osteoporos Int* **33**, 2049–2102 (2022).	10/22	11/24

2	Management of osteoporosis in postmenopausal women: the 2021 position statement of The North American Menopause Society. Menopause. 2021 Sep 1;28(9):973-997.	9/21	11/24
3	Humphrey, M.B., Russell, L., Danila, M.I., et al. (2023), 2022 American College of Rheumatology Guideline for the Prevention and Treatment of Glucocorticoid-Induced Osteoporosis. Arthritis Rheumatol, 75: 2088- 2102	9/23	11/24
4	Shane E, Burr D, Ebeling PR, et al. Atypical subtrochanteric and diaphyseal femoral fractures: Report of a task force of the American Society for Bone and Mineral Research. J Bone Miner Res 2010; 25:2267–2294.		
5	Guideline for the Diagnosis and Management of Osteoporosis in postmenopausal women and men from the age of 50 years in the UK. National Osteoporosis Guideline Group, United Kingdom. July 2010.		
6	Prolia Prescribing Information. Amgen, Inc. Thousand Oaks, CA.	3/24	11/24
7	Micromedex® 2.0, (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: http://www.micromedexsolutions.com/		3/21
8	CMS approved Prior Authorization Criteria 2021		3/21
9	RITUXAN (rituximab) prescribing information, Genentech, Inc., South San Francisco, CA 94080.	12/21	11/24
10	RITUXAN HYCELA (rituximab and hyaluronidase human) prescribing information, Genentech, Inc., South San Francisco, CA 94080.	6/21	11/24
11	National Government Services Inc (NGS) Local Coverage Determination (LCD) Drugs and Biologicals for Label and Off-Label use (L33394)	8/24	9/2025
12	Herceptin prescribing information, Genentech, Inc., South San Francisco, CA 94080.	6/24	11/24
13	Herceptin Hylecta prescribing information, Genentech, Inc., South San Francisco, CA 94080. Revised February 2019	6/24	11/24
14	U.S. Food and Drug Administration. Overview of the Regulatory Guidance for the Development and Approval of Biosimilar Products in the US. Available at: https://www.fda.gov/files/drugs/published/FDA%E2%80%99s-Overview-of-the-Regulatory- Guidancefor-the-Development-and-Approval-of-Biosimilar-Products-in-the-US.pdf		3/21
15	Avastin prescribing information, Genentech, Inc., South San Francisco, CA 94080.	9/22	11/24
16	National Government Services Inc. (NGS) Local Coverage Determination (LCD) Drugs and Biologicals for Label and Off-Label use (L33394) and related local coverage article A52370 bevacizumab and biosimilars	10/24	11/24
17	Tysabri prescribing information, Biogen Idec Inc., Cambridge, MA 02142.	10/23	11/24
18	Bhadra AK, Altman R, Dasa V, et al. Appropriate Use Criteria for Hyaluronic Acid in the Treatment of Knee Osteoarthritis in the United States. Cartilage. 2017 Jul;8(3):234-254. doi: 10.1177/1947603516662503. Epub 2016 Aug 10.	8/16	11/24
19.	Neupogen [package insert]. Thousand Oaks, CA; Amgen Inc.; April 2023.	4/23	11/24
20.	Neulasta [package insert]. Thousand Oaks, CA; Amgen Inc.; February 2021	2/21	11/24
21.	Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hematopoietic Growth Factors V1.2025. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed October 30, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org		11/24
22.	Global Initiative for Asthma (GINA) Report: Global Strategy for Asthma Management and Prevention. 2024 Update. Available from: http://www.ginasthma.org	5/24	11/24

GOVERNMENT PROGRAMS

MEDICARE ADVANTAGE:

Subject to the terms and conditions noted in above application. Benefits for Medicare Part D prescription drugs are only available to enrollees who have elected a CDPHP Medicare Advantage Part D plan. The CDPHP Medicare Advantage Part D plan products do not cover any prescription drugs not covered by Medicare, with the exception of additional coverage purchased with a group-enhanced rider. In addition, for those individuals enrolled in the CDPHP Medicare Advantage product who have not elected a Part D option, CDPHP only covers those prescription drugs covered by Medicare Parts A and B, not those covered by Part D. Coverage is available for any eligible Part D drug prescribed for a medically accepted indication as cited in one or more of the following references: American Hospital Formulary Service Drug Information, and DrugDex Information System. Coverage is available for any eligible Part D drug and biological used off-label in an anti-cancer chemotherapeutic regimen for a medically accepted indication as cited in one or more of the following references: American Hospital Formulary Service Drug Information, DrugDex Information System, National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Clinical Pharmacology and Wolters Kluwer Lexi-Drugs (Lexicomp). In addition, for Part D drugs utilized in anti- cancer chemotherapy regimens, coverage for additional off-label use may be available if scientific literature approved by the Secretary of Health and Human Services (Secretary) supports such use.

CDPHP Pharmacy Services 8/1/2026

New: 1/2022

Effective Date	Changes Made
1/1/2022	New
8/2022	Reviewed, no changes needed
10/2022	Added Alymsys
3/2023	Added Vegzelma, updated link for A52370, removed hyperlink for A52452, retired
5/2023	Added statement that P and T Committee reviews all Part B Step Therapy
8/2023,8/2024	Reviewed, no changes needed
12/2024	Riabni moved from Preferred to Non-preferred Ogivri, Herzuma, Ontruzant moved from Preferred to Non-preferred Vegzelma and Alymsys moved from Preferred to Non-preferred Blood Disorders/Biosimilars Long and Short Acting added as new category Eosinophilic Asthma added as a new category Osteoarthritis-Hyaluronic Acid added as a new Category
9/2025	Added all denosumab biosimilars for Prolia as non-preferred agents Removed all additional plan criteria for Prolia and biosimilars and added links to LCD and local coverage article for guidance beyond step therapy
8/2026	Updated denosumab biosimilars and preferred agents

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MEDICAL POLICY

Medical Policy Title	**Abdominoplasty, Panniculectomy, and Lipedema Reduction Surgery**
Policy Number	**7.01.53**
Current Effective Date	**November 1, 2026**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Abdominoplasty

I. An abdominoplasty (tummy tuck) including umbilical transposition and fascial plication for repair diastasis recti, or belt lipectomy (lower body lift) is considered cosmetic and, therefore, is **not medically necessary** for all indications.

Panniculectomy

II. A panniculectomy is considered **medically appropriate** when **ALL** of the following criteria are met:

   A. The panniculus is Grade 2 or higher (covering the genitals and upper thigh crease), documented by photographs;

   B. A clinically significant skin integrity-related functional impairment resulting from a documented recurrent or persistent medical condition directly related to excess tissue and skin folds of the pannus (e.g., intertrigo, dermatitis, cellulitis, panniculitis, ulceration, or necrosis) which is **both**:

      1. Documented by color photographs;

      2. Refractory to at least three (3) months of prescribed standard medical management with documented adherence to **both** of the following:

         a. Hygiene practices and applicable wound care; **and**

         b. Systemic antibiotics, antifungal agents, or corticosteroids;

   C. There is a documented expectation that surgery will improve or resolve the significant skin integrity-related functional impairment;

   D. If the member has had significant weight loss, medical records must document **either** of the following:

      1. For weight loss as a result of bariatric surgery, **all** of the following must be met:

a. A minimum of 18 months has elapsed from the date of the bariatric surgery;

b. Stable weight has been maintained for at least six (6) months prior to the consultation for panniculectomy; **and**

c. Post-operative weight loss is documented by **one (1)** of the following:

i. Body mass index (BMI) is less than or equal to 30 kg/m^2;

ii. Percentage of excess weight loss (%EWL) greater than or equal to 40%, calculated from the documented pre-intervention weight; **or**

iii. At least a 100-pound weight loss; **or**

2. For weight loss not related to bariatric surgery, **both** of the following must be met:

a. BMI is less than or equal to 30 kg/m^2; **and**

b. Stable weight has been maintained for at least six (6) months prior to the consultation for panniculectomy.

III. A panniculectomy is considered **not medically necessary** for all other indications, including but not limited to:

A. Improving appearance or self-esteem;

B. Correction for poorly fitting clothes or problems with hygiene;

C. Treatment of superficial inflammation or infection when controlled only with topical medications;

D. Treatment of neck or back pain;

E. When performed as an adjunct to other medically necessary abdominal or gynecological surgery (e.g., ventral hernia repair, bariatric surgery, hysterectomy, pelvic procedures), unless panniculectomy criteria are met separately.

<u>Lipedema Reduction Surgery</u>

IV. Lipectomy or liposuction for the treatment of lipedema is considered **medically appropriate** when **ALL** of the following criteria are met:

A. Documented diagnosis of lipedema established by clinical history and physical examination, supported by **all** of the following:

1. Palpable nodules in the adipose tissue;

2. Bilateral, symmetric excess adipose tissue deposition in the extremities;

3. Absence of pitting edema;

4. Easy bruising;

5. Pressure induced pain or tenderness to palpation at affected areas **and**

6. Negative Stemmer sign;

B. Lipedema results in **either** of the following:

1. A clinically significant physical functional deficit (e.g., difficulty ambulating or performing activities of daily living); **or**
2. A documented medical complication (e.g., recurrent cellulitis);

C. Signs and symptoms have not responded to at least six (6) consecutive months of optimal conservative medical management (e.g., weight loss, exercise compression garment/devices, and manual lymphatic drainage);

D. The post-operative treatment plan includes use of compression garments as instructed and continuation of conservative treatment, to maintain benefits, including weight management.

V. Lipectomy or liposuction is considered cosmetic and **not medically necessary** when performed solely for the removal of excess adipose tissue in the absence of a documented functional deficit. However, lipectomy may be an integral part of other covered services.

RELATED POLICIES

Corporate Medical Policy

Cosmetic & Reconstructive Surgery, 1370/20.000071

POLICY GUIDELINE(S)

I. Preoperative photographs are an absolute requirement for determination of medical appropriateness.

II. Documentation of functional impairment(s) (e.g., inability to perform activities of daily living), all prescribed standard medical management, and weight trends can be documented by any of the member's treating providers, including but not limited to the performing surgeon, primary care physician, and/or specialist (e.g., wound care, dermatology).

III. The criteria for panniculectomy apply regardless of the cause of the excess fatty tissue or redundant skin. These criteria apply to removal of fatty tissue or redundant (excessive) skin caused by obesity and apply to weight loss due to any reason, including bariatric surgery.

IV. A panniculectomy is ideally performed after the patient maintains a stable weight for two (2) to six (6) months. For post-bariatric surgery patients, this often occurs 12-18 months after surgery or at the 25 kg/m^2 to 30 kg/m^2 weight range (ASPS 2017).

V. The American Society of Plastic Surgeons' (2017) grading system for the severity of abdominal deformities is as follows:

Grade 1: Panniculus covers hairline and mons pubis but not the genitals

Grade 2: Panniculus covers genitals and upper thigh crease

Grade 3: Panniculus covers upper thigh

Grade 4: Panniculus covers mid-thigh

Grade 5: Panniculus covers knees and below

DESCRIPTION

The American Society of Plastic Surgeons (2017) defines the following:

Abdominoplasty ("tummy tuck") is a procedure typically performed for cosmetic purposes, involving the removal of excess skin and fat from the pubis to the umbilicus or above, and may include fascial plication of rectus muscle diastasis and neoumbilicoplasty.

Circumferential lipectomy (also known as belt lipectomy or lower body lift) combines the elements of an abdominoplasty or panniculectomy with removal of excess skin and fat from the lateral thighs and buttocks. The procedure removes a "belt" of tissue from around the circumference of the lower trunk, eliminating lower back rolls and providing elevation of the outer thighs, buttocks, and mons pubis. It may include suction-assisted lipectomy where necessary.

Panniculectomy involves the removal of a hanging pannus of excess skin and fat in a transverse or vertical wedge but does not include muscle plication, neoumbilicoplasty, or flap elevation. Unlike abdominoplasty, panniculectomy does not involve abdominal muscle tightening. Deformities associated with massive weight loss vary depending on body type, fat deposition pattern, and the amount of weight gained or lost. These deformities can lead to inability to exercise, impaired ambulation, chronic back, neck, and shoulder pain, difficulty with hygiene, and symptoms such as uncontrolled intertrigo, infections, and skin necrosis.

Lipedema

Lipedema is a chronic, progressive disorder characterized by abnormal distribution of subcutaneous adipose tissue, accompanied by pain or discomfort in affected areas. It predominantly affects women, often with a family history, and is frequently misdiagnosed as obesity or lymphedema. Lipedema typically presents with bilateral, disproportionate fat accumulation in the extremities (including the hips, buttocks, legs, and thighs), characteristically sparing the hands and feet. The arms may also be affected without edema of the hands. The presence of a nodular or fibrotic texture is palpable in affected areas.

Symptoms include heaviness, pain with pressure, easy bruising, loss of strength, and reduced daily activity levels that significantly affect health and quality of life. The excessive fat deposits are typically unresponsive to diet, exercise, or bariatric surgery. Lipedema typically presents with a negative Stemmer sign (ability to pinch the dorsal skin of the second toe), which helps distinguish it from lymphedema. However, a positive Stemmer sign does not rule out lipedema and likely indicates concomitant lymphedema (termed "lipo-lymphedema").

Untreated lipedema may result in secondary problems, including osteoarthritis and reduced mobility. Over time, the weight of excessive fat can impair the ability to walk. Initially, the lymphatic system can manage the increased interstitial fluid, but in later stages, secondary lymphedema (lipo-lymphedema) can occur if the fatty deposits compromise lymphatic function.

There is no cure for lipedema. The goal of therapy is to reduce symptoms, disability, and functional limitations and to prevent disease progression. Conservative treatment includes manual lymphatic

drainage, compression garments, intermittent pneumatic compression, skin care, and exercise. Individuals with lipedema may have obesity as a comorbidity, and dietary guidance is frequently prescribed. Conservative care may alleviate symptoms, but benefits are often short-lived and may require repeat treatment. For individuals who do not respond to conservative treatment, liposuction may be recommended.

SUPPORTIVE LITERATURE

Badran et al (2023) performed a dose-response meta-analysis of 22 studies (n=493) evaluating metabolic changes after surgical fat removal (SFR). Peak metabolic benefits at day 50 included reductions in body mass index (2 units), fat mass (3 kilograms), waist circumference (5 centimeters), serum leptin (15 µg/L), tumor necrosis factor-alpha (TNF-a; 0.75 pg/mL), total cholesterol (0.25 mmol/L), and blood pressure (3.5 mmHg systolic/diastolic), but most returned to baseline by day 180. Only insulin sensitivity showed sustained improvement beyond 6 months, with maximum reductions in fasting insulin (17 pmol/L) and Homeostatic Model Assessment for Insulin Resistance (HOMA-IR; 1 point) at day 180. No significant changes were observed in lean body mass, serum adiponectin, resistin, interleukin-6, C-reactive protein, triglycerides, low-density lipoproteins, free fatty acids, or fasting blood glucose. Key limitations include the small number of eligible studies with small sample sizes and heterogeneity introduced by pooling different SFR types (abdominoplasty vs. liposuction), which have dissimilar physiological effects on metabolic parameters. The authors recommended well-designed prospective studies to evaluate metabolic changes and safety beyond 6 months.

Liposuction for Lipedema

In 2021, a Delphi-based consensus on the standard of care for lipedema in the United States was created by a panel of 21 lipedema experts (Herbst 2021). According to the panel, lipedema reduction surgery is currently the only available technique for removing abnormal lipedema tissue (e.g., adipocytes, nodules, fibrotic extracellular matrix, and other non-adipocyte components). It is also the only treatment that slows progression of lipedema and ideally would be performed before complications and disabilities from lipedema develop. The panel found that lipedema reduction surgery significantly improves symptoms, mobility, stance, gait, valgus rotation/deformity of the knee and ankle, quality of life, and redistributes and restores the plantar arch. It also improves lymphatic symptoms, reducing the need for compression and manual therapy and improves lymphatic function as shown by radionucleotide lymphangioscintigraphy.

- Grade A consensus recommendations include that lipedema should be regarded as an LCT disease versus a disease of just adipocytes (fat); lipedema has a distinct distribution of pathologic tissue that differs from non-lipedema obesity.
- Grade B consensus recommendations include that lipedema LCT can affect the abdomen; lipedema tissue is resistant to reduction by diet, exercise, or bariatric surgery; rice-grain, pearl-sized or larger nodules in LCT should be part of the diagnostic criteria for lipedema; lipedema tissue is frequently painful especially when touched.
- Grade C consensus recommendations include that standard conservative therapy for lipedema

includes nutritional guidance, manual therapy, compression garments, pneumatic compression device (external pump), and home exercise.

Mortada et al (2024) performed a systematic review and meta-analysis of 20 prospective cohort studies (n=1,785 patients) assessing liposuction for lipedema. The majority of patients were stage 2 or 3, with tumescent liposuction being the most common technique (81%). Meta-analysis of nine studies revealed significant improvements in quality of life, pain, pressure sensitivity, bruising, cosmetic impairment, heaviness, walking difficulty, and itching (all $p<.0001$). Severe complications were rare, with no instances of shock, recurrence, or mortality. Mean follow-up was 15 months (range 1–96 months). Limitations included the absence of controlled trials, potential publication bias from prospective cohort designs, and limited generalizability, as 70% of studies originated from Germany. The authors concluded that liposuction, especially the tumescent technique, is effective in treating lipedema, enhancing outcomes across different modalities.

Fijany et al (2024) performed a meta-analysis of 10 studies encompassing 2,542 procedures on 906 patients, evaluating traditional tumescent liposuction (TTL), power-assisted liposuction (PAL), and water-assisted liposuction (WAL). All techniques showed significant improvements in pain, bruising, edema, tension, pressure sensitivity, and cosmetic and general impairment (all $p<0.00001$). Overall complication rates were low: TTL 1.5%, PAL 4.0%, WAL 0%, and combined PAL/WAL at 2.3%. Limitations included high heterogeneity for some outcomes and only one study using WAL exclusively, restricting definitive conclusions about technique superiority. The authors concluded that while all techniques are effective, further comparative studies are needed to establish optimal surgical approaches.

Kruppa et al (2026) published a Delphi consensus study in which experts from 19 countries reached consensus on 59 statements regarding the definition and management of lipedema. The panel defined lipedema as a chronic disease characterized by disproportionate, symmetrical expansion of subcutaneous adipose tissue in the extremities, accompanied by pain and sensitivity, with diagnosis relying on clinical history, physical examination, and exclusion of differential diagnoses, as no imaging or laboratory tests are officially approved for diagnostic verification. Conservative management (compression therapy, exercise, nutritional optimization, and Complex Decongestive Therapy) aims at symptom alleviation but does not achieve long-lasting benefits and cannot prevent disease progression. The panel reached consensus that lipedema reduction surgery is the only technique for removing pathological tissue and slowing progression, should be performed by providers with extensive lipedema knowledge as part of an integrated approach, and that lymph vessel-sparing surgery should be considered when there is potential for positive symptom impact. When lipedema coincides with obesity, treatment for obesity should be prioritized before surgery. The panel noted limited evidence overall, highlighting the need for further research and standardized reporting.

Vazirnia et al (2026) conducted a systematic review of 61 studies, composed of observational cohorts and case series with few randomized trials, evaluating lipedema diagnosis, clinical manifestations, and therapeutics, grading evidence using a modified Oxford scale. Conservative therapies including ketogenic diets, compression therapy, and aquatic exercise were associated with reduced pain and swelling (Grade 2A–2B evidence). Tumescent liposuction received a Grade 1 recommendation based on the strongest available evidence for sustained improvement in symptoms, mobility, and quality of

life. The authors noted that lipedema is a distinct, progressive condition requiring early recognition and intervention. Conservative therapies may provide partial relief, but tumescent liposuction remains the most effective treatment. Standardized diagnostic criteria, validated patient-reported outcomes, and clearer guidelines are needed to harmonize care and improve long-term outcomes.

PROFESSIONAL GUIDELINE(S)

Abdominoplasty

In 2018, the American Society of Plastic Surgeons (ASPS) reaffirmed the recommended insurance coverage criteria for third-party payers related to abdominoplasty. When abdominoplasty is performed solely to enhance appearance in the absence of any signs or symptoms of functional abnormalities, the procedure should be considered cosmetic in nature and not a compensable procedure.

Panniculectomy

In 2017, the ASPS issued a practice parameter for the surgical treatment of skin redundancy for obese and massive weight loss patients, outlining preoperative assessment and screening, management (e.g., timing, operative treatment), and postoperative care. A panniculectomy could be considered as a functional correction in patients who are of appropriate height and weight, and have a history of problems including panniculitis or chronic back pain that have persisted despite an adequate trial of non-surgical management, or have a functional impairment in activities of daily living/work, etc. Body contouring surgery is ideally performed after the patient maintains a stable weight for two (2) to six (6) months. For post-bariatric surgery patients, this often occurs 12 to 18 months after surgery or at the 25 kg/mg^2 to 30 kg/mg^2 weight range (ASPS 2017).

In 2019, the ASPS re-approved the recommended insurance coverage criteria for third-party payers related to panniculectomy. Panniculectomy should be considered a reconstructive procedure when performed to correct or relieve structural defects of the abdominal wall, improve skin health within the fold beneath the pannus, and/or help improve chronic low back pain due to functional incompetence of the anterior abdominal wall.

Liposuction for Lipedema

In 2022, the National Institute for Health and Care Excellence issued clinical guidance on liposuction for lipedema, recommending that liposuction for lipedema should be used only in the context of research because the evidence on safety and efficacy is inadequate.

REGULATORY STATUS

Not Applicable

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).

- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15832	; thigh
15833	; leg
15834	; hip
15835	; buttocks
15836	; arm
15837	; forearm or hand
15838	; submental fat pad
15839	; other area
15847 (NMN)	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (e.g., abdominoplasty) (includes umbilical transposition and fascial plication) (List separately in addition to code for primary procedure)
15876	Suction assisted lipectomy; head and neck
15877 (*NMN)	Suction assisted lipectomy; trunk (*NMN when billed for abdominoplasty or belt lipectomy.)
15878	; upper extremity
15879	; lower extremity

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

American Society of Plastic Surgeons [Internet]. ASPS recommended insurance coverage criteria for third-party payers. Abdominoplasty. 2006 Jul; Reaffirmed 2018 Sept 26. [accessed 2026 Apr 20]. Available from: https://www.plasticsurgery.org/documents/Health-Policy/Reimbursement/insurance-2018-abdominoplasty.pdf

American Society of Plastic Surgeons [Internet]. ASPS recommended insurance coverage criteria for third-party payers. Panniculectomy. 2006 Jul; Re-approved 2019 Mar [accessed 2026 Apr 20]. Available from: https://www.plasticsurgery.org/documents/Health-Policy/Reimbursement/insurance-2019-panniculectomy.pdf

American Society of Plastic Surgeons [Internet]. Practice parameter for surgical treatment of skin redundancy for obese and massive weight loss patients. 2017 June [accessed 2026 Apr 20]. Available from: https://www.plasticsurgery.org/documents/Health-Policy/Guidelines/guideline-2017-skin-redundancy.pdf

Badran S, et al. Metabolic changes after surgical fat removal: A dose-response meta-analysis. J Plast Reconstr Aesthet Surg. 2023 Jan;76:238-250. Epub 2022 Nov 2.

Baumgartner A, et al. Long-term benefit of liposuction in patients with lipoedema: a follow-up study after an average of 4 and 8 years. Br J Dermatol. 2016 May;174(5):1061-7.

Brodell RT, et al. Intertrigo [Internet]. In: UpToDate, Fowler J, Ofori AO (Eds), Wolters Kluwer. Last updated 2025 Jan [accessed 2026 Apr 20]. Available from: https://www.uptodate.com/contents/intertrigo

Fijany AJ, et al. Comparing the safety and effectiveness of different liposuction techniques for lipedema. J Plast Reconstr Aesthet Surg. 2024 Oct;97:256-267.

Gomez-Samano MA, et al. Effect of liposuction on body weight and serum concentrations of leptin, lipids, glucose, and insulin: a meta-analysis. Plast Reconstr Surg. 2023 Mar 1;151(3):402e-411e.

Herbst KL, et al. Standard of care for lipedema in the United States. Phlebology. 2021 Dec;36(10):779-796.

Kruppa P, et al. Lipedema world alliance delphi consensus-based position paper on the definition and management of lipedema: results from the 2023 Lipedema World Congress in Potsdam. Nat Commun. 2026 Jan 10;17(1):427.

Mortada H, et al. Safety and effectiveness of liposuction modalities in managing lipedema: systematic review and meta-analysis. Arch Plast Surg. 2024 Aug 6;51(5):510-526.

National Institute for Health and Care Excellence (NICE) [Internet]. Liposuction for chronic lipoedema. HealthTech guidance. HTG618. 2022 May [accessed 2026 Apr 20]. Available from: https://www.nice.org.uk/guidance/htg618

Sachs D, et al. Panniculectomy. StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; last updated: 2023 Jul [accessed 2026 Apr 20]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK499822/

Shestak KC, et al. Evidenced-based approach to abdominoplasty update. Aesthet Surg J 2019 May 16;39(6):628-642.

Troppmann C, et al. Impact of panniculectomy on transplant candidacy of obese patients with chronic kidney disease declined for kidney transplantation because of a high-risk abdominal panniculus: A pilot study. Surgery. 2016 Jun;159(6):1612-1622.

Vazirnia A, et al. Lipedema diagnosis, clinical manifestations, and therapeutics: a systematic review. Int J Dermatol. 2026 Jan 7.

Witte T, et al. Water-jet-assisted liposuction for the treatment of lipedema: standardized treatment protocol and results of 63 patients. J Plast Reconstr Aesthet Surg. 2020 Mar 14;S1748-6815(20)30119-4.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Abdominoplasty and panniculectomy are not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 06/07

Revised: 05/08, 11/14, 07/15, 01/16, 03/18, 03/19, 7/21, 11/22, 3/23, 3/24, 3/25, 7/26 **Reviewed**: 05/09, 05/10, 05/11, 05/12, 05/13, 05/14, 05/16, 03/17, 3/20, 3/21, 3/22, 3/26	
Date	**Summary of Changes**
11/1/2026	• Transitioned Abdominoplasty, Panniculectomy & Abdominal Lipectomy policy 1370/20.000443 to Lifetime Healthcare Companies policy template and criteria.
4/1/2024 *No change to effective date of policy	• Clarified verbiage on type of panniculus that meets medical criteria. • Updated requirements for submitting medical photographs.
4/1/2024	• No criteria changes. • Updated policy name to Abdominoplasty, Panniculectomy and Abdominal Lipectomy. • Removed codes 15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839, 15876, 15877, 15878, 15879 as these are addressed in the Cosmetic and Reconstructive Surgery policy.
4/1/2023	• Added clarification for lipectomy billed with a panniculectomy under Policy Considerations and abdominoplasty under Exclusions.
12/1/22 *No change to effective date of policy	• Added language to require original photographs
8/1/21	• Under the Position Statement, removed the separate criteria of the need to have a documented cellulitis and updated bullet 2 criteria to include cellulitis as a type of skin condition.

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InterQual Transparency Tool

MEDICAL POLICY

Medical Policy Title	**Allergy Testing**
Policy Number	**2.01.10**
Current Effective Date	**January 1, 2026**
Next Review Date	**July 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. The following **allergy** tests are considered **medically appropriate** in the diagnosis of the allergic patient:

A. Percutaneous test(s) (scratch, puncture, prick) with allergenic extracts;

B. Combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal) with venoms, drugs or biologics;

C. Intracutaneous (intradermal) test(s) with allergenic extracts, including airborne allergens;

D. Patch or application tests(s);

E. Photo patch test(s);

F. Photo test(s);

G. Inhalation bronchial challenge testing (not including necessary pulmonary function tests), with histamine, methacholine, or similar compounds;

* If dust, ragweed, or other common allergens are the suspected cause of the problem, this test is **not medically appropriate**, as skin tests can be used in these situations.

H. Ingestion challenge test;

I. Gammaglobulin (immunoglobulin), IgE;

J. Allergen-specific IgE **only** when testing for allergens (e.g., inhalant, food, insect, drug) under the following circumstances:

1. When direct skin testing is impossible due to extensive dermatitis or marked dermatographism;
2. For patients unable to discontinue use of interfering medications (e.g., antidepressants, antihistamines, or beta-blocking agents);
3. For patients who have had a near fatal reaction to an allergen;
4. In children younger than four (4) years of age;

5. In patients who will not or cannot cooperate with percutaneous testing due to mental or physical disease (e.g., Down syndrome, intellectual disability, dementia);
6. To follow patients with food allergies and/or insect sting allergies previously documented by history and in-vivo or in-vitro testing;
7. For patients with suspected latex allergy;
8. For patients with suspected insect sting allergy with prior negative skin testing; **or**
9. For patients with suspected penicillin allergy.

II. The following allergy tests are considered **investigational**:

A. Allergen-specific IgG (when above criteria are not met);
B. Leukocyte histamine release test (LHR);
C. Ophthalmic mucous membrane tests;
D. Direct nasal mucous membrane test;
E. Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA);
F. Cytotoxicity, Provocative testing (e.g., Rinkel test), Rebuck skin window test.

III. Allergy and laboratory testing for a treatment program (e.g., Southern California Food Allergy Tolerance Induction Program) is considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

Pharmacy Policies:

Biologicals and Prescription Drugs Covered as a Medical Benefit, 1350/20.000052

Palforzia (peanut allergen powder), 1350/20.000384

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Allergic or hypersensitivity disorders may be manifested by generalized systemic reactions and/or localized reactions in any organ system of the body. The reactions may be acute, subacute, or chronic, and immediate or delayed, and they may be caused by numerous offending agents (e.g., pollen, molds, dust, mites, animal dander, stinging insect venoms, foods, and drugs).

The optimum management of the allergic patient should include a careful history and physical examination and may include confirming the cause of allergic reaction by information from various testing methods. Once the offending allergenic agent(s) is (are) identified, treatment is provided by avoidance, medication, and/or immunotherapy.

Percutaneous Tests

The number of tests required may vary widely from patient to patient, depending upon the patient's history, and may require up to 80 tests. Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous is usually used when percutaneous testing is not considered to be sensitive enough to be the cause of an allergic reaction. The number of tests required may vary widely from patient to patient, depending upon the patient's history, and may require up to 40 tests.

Intracutaneous Tests

This may be used to represent serial endpoint testing (SET), which is a form of intradermal skin testing that uses increasing doses of antigen to determine the concentration at which the reaction changes from negative to positive (the "endpoint"). The test has been used for diagnosing allergic disorders and to guide the initiation of immunotherapy by using the endpoint dilution as the starting antigen dose. A physician or other qualified health care provider uses intracutaneous tests, sequential and incremental, with allergenic extracts for airborne allergens, immediate type reaction, to determine a patient's specific allergies. The number of tests must be specified (each sequential test = 1 unit). This includes test interpretation and provider report.

Patch or Application Tests

Also known as delayed hypersensitivity testing, this testing modality identifies allergens causing contact dermatitis. The suspected allergens are applied to the patient's back under dressings and allowed to remain in contact with the skin for 48 to 72 hours. The area is then examined for evidence of delayed hypersensitivity reactions.

Photo Patch Tests

This test reflects contact photosensitization. The suspected sensitizer is applied to a patch of skin for 48 hours. If no reaction occurs, the area is exposed to a dose of ultraviolet light sufficient to produce inflammatory redness of the skin. If the test is positive, a more severe reaction develops at the patch site than on the surrounding skin.

Inhalation Bronchial Challenge Test

Histamine or methacholine is used to perform this test, when it is necessary to determine whether the patient has hyper-responsive airways. Volatile chemicals are used to perform the test, when the allergy is encountered in an occupational setting.

Ingestion Challenge Test

With these tests, the patient ingests a food, drug or other substance to which sensitivity is suspected. This may be done in an open or blinded manner. Testing may be done at home, but in some instances of extreme suspected hypersensitivity, it may be performed in the office setting.

IgE Test

Total serum IgE concentration testing is not indicated in most allergic patients but may be indicated for patients suspected of having allergic bronchopulmonary aspergillosis, immune deficiency disease characterized by increased IgE levels (e.g., Wiskott-Aldrich syndrome, hyper-IgE staphylococcal abscess syndrome), IgE myeloma, pemphigoid, or a poorly controlled moderate-to-severe asthmatic patient being considered for possible anti- IgE treatment.

Leukocyte Histamine Release Test

The leukocyte histamine release test is a measurement of the amount of histamine released in-vitro. Varying concentrations of an allergen extract are added to the patient's peripheral blood leukocytes. Histamine is normally released as a consequence of the interaction of allergen with cell-bound IgE antibodies. If an individual is atopic to a specific antigen, the leukocytes will not release the histamine in-vitro. Only a limited number of allergens can be tested from a single aliquot of blood and quality control studies have shown considerable variability in the measurement of histamine results.

SUPPORTIVE LITERATURE

Ferastraoaru et al (2017) reported, in an independent analysis of 75 patients with over 1600 tests between January 2014 and May 2015, for comparison of skin-prick (SPT), intradermal (IDST), and serum-specific immunoglobulin E (ssIgE) testing, that IDST detected more additional environmental sensitizations, compared with ssIgE testing. The authors concluded that IDST may be useful when the SPT and/or ssIgE testing results are negative, but the exposure history indicates relevant allergic sensitization. Serology added only a little more information when both SPT and IDST results were negative, but may be useful in combination with SPT, if IDST cannot be performed.

Leukocyte histamine release testing (LHRT) is a technique to evaluate the in vitro release of histamine from leukocytes in response to an allergen. It provides an in vitro correlate to an in vivo allergic response. Published literature reflects that commercially available LHRT studies suffer from not having been performed in a blinded manner or do not indicate whether or not there were blinded interpretations of the tests. Some studies included patients with known allergies, which did not represent the same population with equivocal allergy histories that would undergo testing. Studies of LHRT are potentially prone to spectrum, referral, and ascertainment bias, and are not sufficient to permit conclusions on the diagnostic accuracy of the tests. It has been suggested that LHRT may be a valuable test in those patients with discordant results of skin prick testing and RAST testing, but studies focusing on this subgroup of patients have not been identified.

Poto et al (2023) stated that mast cells are multi-functional immune cells with complex roles in tissue homeostasis and disease. Cardiac mast cells (HCMCs) are strategically located within the human myocardium and express the high-affinity receptor (FcεRI) for IgE and can be activated by anti-IgE and anti-FcεRI. Autoantibodies to IgE and/or FcεRI have been found in the serum of patients with a variety of immune disorders. The authors compared the effects of different preparations of IgG anti-IgE obtained from patients with atopic dermatitis (AD) with rabbit IgG anti-IgE on the release of preformed (histamine and tryptase) and lipid mediators [prostaglandin D2 (PGD2) and cysteinyl leukotriene C4 (LTC4)] from HCMCs. Functional human IgG anti-IgE from one out of six AD donors

and rabbit IgG anti-IgE induced the release of pre-formed (histamine, tryptase) and de-novo synthesized mediators (PGD2 and LTC4) from HCMCs. Human IgG anti-IgE was more potent than rabbit IgG anti-IgE in inducing pro-inflammatory mediators from HCMCs. Human monoclonal IgE was a competitive antagonist of both human and rabbit IgG anti-IgE. The authors concluded that although functional anti-IgE autoantibodies rarely occur in patients with AD, when present, they could powerfully activate the release of pro-inflammatory and vasoactive mediators from HCMCs.

A number of procedures have been shown to be invalid for any clinical purpose. Studies of cytotoxic tests and provocation-neutralization tests have demonstrated that results are not reproducible. Electrodermal diagnosis and applied kinesiology have not been evaluated for efficacy. The "reaginic" pulse test and chemical analysis of body tissues have not been substantiated as valid allergy tests.

There is a lack of published research on the diagnostic accuracy of peanut allergen-specific quantitative assessment of multiple epitopes using ELISA (e.g., VeriMAP Peanut Diagnostic and VeriMAP Peanut Sensitivity, AllerGenis). The evidence is insufficient to determine the effects of the technology on health outcomes.

Suprun et al (2019) presents the quantification and validation of a Bead-Based Epitope Assay (BBEA) that through multiplexing of epitopes and multiple sample processing enables completion of large experiments in a short period of time, using minimal quantities of patients' blood. Peptides that are uniquely coupled to beads are incubated with serum or plasma samples, and after a secondary fluorophore-labeled antibody is added, the level of fluorescence is quantified with a Luminex reader. The signal is then normalized and converted to epitope-specific antibody binding values. The authors show that the effect of technical artifacts, i.e., well position or reading order, is minimal and batch effects can be easily estimated and eliminated from the data. The authors analyzed the relationship between IgE and IgG4 binding to 50 peanut epitopes in a cohort of 160 children. The authors state they showed that epitope-specific IgE alone was sufficient to distinguish between peanut allergic and non-allergic children; with IgG4 and IgG4-IgE ratio providing no additional information. Larger studies of epitope-specific antibody responses might be helpful in determining the role of IgG4 and different levels of peanut reactivity. To further advance the molecular allergy diagnostics and potentially bring it to the clinic, the authors have developed a Bead-Based Epitope Assay (BBEA) that allows high-throughput screening of samples and epitopes with significantly smaller volumes of serum or plasma compared to current molecular assays. BBEA provides greater sensitivity and reproducibility than microarrays and better resolution than component resolved diagnostics, making it a promising tool for the development of diagnostic and prognostic biomarkers. The authors concluded that epitope-specific antibody binding quantified with BBEA is highly reliable, reproducible and has greater sensitivity of epitope detection compared to peptide microarrays. IgE directed at allergenic epitopes is a sensitive biomarker of food allergy and can be used to predict allergy severity and phenotypes; and quantification of the relationship between epitope-specific IgE and IgG4 can further improve our understanding of the immune mechanisms behind allergic sensitization.

There is lack of published research showing the efficacy of Tolerance Induction Programs (e.g., Southern California Food Allergy Institute's Tolerance Induction Program) to treat food allergies. These treatment programs and the extensive testing required to participate in the treatment is considered investigational.

PROFESSIONAL GUIDELINE(S)

According to a March 2008 American Academy of Allergy, Asthma, and Immunology (AAAAI) practice parameter addressing Allergy Diagnostic Testing, IgE antibody assay technology has improved, with new high-binding capacity, solid-phase matrices, non-isotopic labels for detection antibodies, and standards calibrated to the World Health Organization IgE reference preparation. These enhancements have led to an evolution in assay methods from the first-generation qualitative assays (e.g., RAST, MAST, EAST), through the second generation semi-quantitative IgE assays (e.g., AutoCAP, Alastat, HYTech, Matrix, MagicLite), to the present state-of-the-art quantitative third generation autoanalyzers. Two third-generation immunoassays are the Immunocaptured System (Phadia) and the Immulite 2000 (Diagnostic Products Corp.), the chemistry of which is similar to the original RAST, but which employ non-isotopic labels and have more rapid throughput with improved precision, accuracy, and analytical sensitivity. Their automated chemistries report out allergen specific IgE antibody quantitatively. In a 2022 publication on Practice Parameters for Drug Allergy, a joint task force of the AAAAI, the American College of Allergy, Asthma and Immunology (ACAAI), and the Joint Council of Allergy, Asthma & Immunology included in its executive summary a statement validating the use of intracutaneous (intradermal) tests, which are generally used for specific allergens (e.g., Hymenoptera venoms and penicillin), but may also be applied if prick/puncture test results are negative, and there is a strong historical likelihood of clinical allergy to specific allergens.

REGULATORY STATUS

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service. Laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA).

Laboratories that offer laboratory-developed tests must be licensed by CLIA for high-complexity testing. More information is available at: Clinical Laboratory Improvement Amendments (CLIA) | FDA [accessed 2026 Jun 06].

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
95004	Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests

Code	Description
95017	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with venoms, immediate type reaction, including test interpretation and report, specify number of tests
95018	Allergy testing, any combination of percutaneous (scratch, puncture, prick) and intracutaneous (intradermal), sequential and incremental, with drugs or biologicals, immediate type reaction, including test interpretation and report, specify number of tests
95024	Intracutaneous (intradermal) tests with allergenic extracts, immediate type reaction, including test interpretation and report, specify number of tests
95027	Intracutaneous (intradermal) tests, sequential and incremental, with allergenic extracts for airborne allergens, immediate type reaction, including test interpretation and report, specify number of tests
95028	Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction, including reading, specify number of tests
95044	Patch or application test(s) (specify number of tests)
95052	Photo patch test(s) (specify number of tests)
95056	Photo tests
95060 (E/I)	Ophthalmic mucous membrane tests
95065 (E/I)	Direct nasal mucous membrane test
95070	Inhalation bronchial challenge testing (not including necessary pulmonary function tests), with histamine, methacholine, or similar compounds
95076	Ingestion challenge test (sequential and incremental ingestion of test items, e.g., food, drug, or other substance); initial 120 minutes of testing
95079	Ingestion challenge test (sequential and incremental ingestion of test items, e.g., food, drug, or other substance); each additional 60 minutes of testing (List separately, in addition to code for primary procedure.)
82785	Gammaglobulin (immunoglobulin), IgE
86001 (E/I)	Allergen-specific IgG; quantitative or semiquantitative, each allergen
86003	Allergen-specific IgE; quantitative or semiquantitative, crude allergen extract, each
86005	Allergen-specific IgE; qualitative, multi-allergen screen (e.g., disk, sponge, card)
86008	Allergen-specific IgE; quantitative or semiquantitative, recombinant or purified component, each

Code	Description
86343 (E/I)	Leukocyte histamine release test (LHR)
0165U (E/I)	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, individual epitope results and probability of peanut allergy
0178U (E/I)	Peanut allergen-specific quantitative assessment of multiple epitopes using enzyme-linked immunosorbent assay (ELISA), blood, report of minimum eliciting exposure for a clinical reaction

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
B44.0-B44.9	Aspergillosis (code range)
B48.4	Penicillosis
D80.3	Selective deficiency of immunoglobulin G (IgG) subclasses
D82.0	Wiskott-Aldrich syndrome
H10.411-H10.419	Chronic giant papillary conjunctivitis (code range)
H10.45	Other chronic allergic conjunctivitis
J30.0	Vasomotor rhinitis
J30.1-J30.9	Allergic rhinitis (code range)
J45.20-J45.998	Asthma (code range)
L23.0-L23.9	Allergic contact dermatitis (code range)
L24.0-L24.9	Irritant contact dermatitis (code range)
L25.0-L25.9	Unspecified contact dermatitis (code range)
L27.0-L27.9	Dermatitis due to substances taken internally (code range)

Code	Description
L30.0	Nummular dermatitis
L30.2	Cutaneous autosensitization
L30.8	Other specified dermatitis
L30.9	Dermatitis, unspecified
L50.0	Allergic urticaria
L50.3	Dermatographic urticaria
T36.0X5A-T36.0X5S	Adverse effect of penicillins (code range)
T36.1X5A-T36.1X5S	Adverse effect of cephalosporins and other beta-lactam antibiotics (code range)
T39.015A-T39.015S	Adverse effect of aspirin (code range)
T39.095A-T39.095S	Adverse effect of salicylates (code range)
T63.001A-T63.94XS	Toxic effect of contact with venomous animals and plants (code range)
T65.811A-T65.814S	Toxic effect of latex (code range)
T78.00XA-T78.09XS	Anaphylactic reaction due to food (code range)
T78.2xxA	Anaphylactic shock, unspecified, initial encounter
T78.3xxA	Angioneurotic edema, initial encounter
T78.40XA	Allergy, unspecified, initial encounter
T78.41xA	Arthus phenomenon, initial encounter
T78.49xA	Other allergy, initial encounter
T88.2xxA	Shock due to anesthesia, initial encounter
T88.52XA	Failed moderate sedation during procedure, initial encounter
T88.59xA	Other complications of anesthesia, initial encounter

Code	Description
T88.6XXA	Anaphylactic reaction due to adverse effect of correct drug or medicament properly administered, initial encounter
Z91.010-Z91.09	Allergy status other than drugs & biologicals (code range)

REFERENCES

American Academy of Otolaryngic Allergy [Internet]. Clinical Care Statements 2020. [accessed 26 Jun 06]. Available from: https://www.aaos.org/quality/quality-programs/clinical-practice-guidelines/

Bernstein I, et al. American Academy of Allergy, Asthma, and Immunology; American College of Allergy, Asthma, and Immunology. Allergy diagnostic testing: an updated practice parameter. Ann Allergy Asthma Immunol. 2008 Mar;100(3 Suppl 3):S1-148.

Brettig T, et al. The accuracy of diagnostic testing in determining tree nut allergy: A systematic Review. J Allergy Clin Immunol Pract. 2021; 9(5): 2028-49.

Ferastraoaru D, et al. Diagnosing environmental allergies: comparison of skin-prick, intradermal, and serum specific immunoglobulin E testing. Allergy Rhinol (Providence). 2017 Jun 1;8(2):53-62.

Hurst D, et al. Intradermal testing doubles identification of allergy among 110 immunotherapy-responsive patients with eustachian tube dysfunction. Diagnostics. 2021; 11(763): 1-12.

Khan D, et al. American Academy of Allergy, Asthma, and Immunology Drug allergy: A 2022 practice parameter update. J Allergy Clin Immunol. 2022 Dec;150(6):1333-1393.

Kulalert P, et al. Minimum number, and types of allergens for a skin prick test panel in Thai children with allergic respiratory diseases. Allergy Asthma Clin Immunol. 2022 Aug;18(1):77.

Peltier J, et al. Comparison of intradermal dilutional testing, skin prick testing, and modified quantitative testing for common allergens. Otolaryngol Head Neck Surg. 2007 Aug;137(2):246-9.

Poto R, et al. Autoantibodies to IgE can induce the release of proinflammatory and vasoactive mediators from human cardiac mast cells. Clin Exp Med. 2023 Aug;23(4):1265.1276.

Seshul M, et al. Use of intradermal dilutional testing and skin prick testing: clinical relevance and cost efficiency laryngoscope. 2006 Sep;116(9):1530-8.

Suprun M, et al. Novel bead-based epitope assay is a sensitive and reliable tool for profiling epitope-specific antibody repertoire in food allergy. Sci Rep. 2019 Dec 5;9(1):18425.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Food Allergy Testing and Treatment (110.11) [accessed 2026 Jun 06]

NCD - Cytotoxic Food Tests (110.13) [accessed 2026 Jun 06]

NCD - Challenge Ingestion Food Testing (110.12) [accessed 2026 Jun 06]

LCD - RAST Type Tests (L33591) [accessed 2026 Jun 06]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New:11/89

Revised: 07/91, 02/93, 12/94, 10/96, 11/97, 02/98, 03/99, 01/00, 11/00, 10/02, 10/03, 09/04, 11/04, 07/05, 10/06, 05/07, 05/08, 07/08, 07/09, 07/10, 07/11, 07/12, 03/13, 07/13, 01/14, 07/14, 03/15, 07/16, 01/18, 09/18, 7/19, 07/20, 07/21, 9/22, 7/24, 7/25, 9/25, 11/25

Reviewed: 01/92, 08/93, 10/95, 02/00, 06/06, 07/15, 07/17, 07/18, 7/22, 7/23, 9/26

Date	Summary of Changes
9/1/2025	• Removed statement from Policy Considerations regarding 95165 as it is now addressed in payment policy 1550/20.000227, Antigen Preparation for Allergy Immunotherapy.
8/1/2025	• Moved code 86005 from exclusions to In Vitro Allergy Testing section and added additional criteria for in vitro testing.
8/1/2024	• Added a link for NYS DOH August 2016 Medicaid update for immunotherapy to the Select Plan/HARP section.
1/1/2023	• Added statement under Allergy Immunotherapy (code 95165) will be allowed up to a maximum of 150 doses per rolling 12 months. • Under Exclusions added home immunotherapy.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

11/1/2021	• Removed termed code 95071 from Procedure Codes section. • Added criteria for Skin Endpoint Titration (SET) (95027) and updated when SET would deny in the exclusions section. • Under Policy Considerations added: Periodic skin tests for enrollees should not be repeated unless there is a new condition or for symptomatic/therapeutic reasons. • Under Allergy Immunotherapy removed: Periodic skin tests for enrollees receiving immunotherapy may not be repeated more frequently than every two years, except for a new condition. • Under Exclusions removed: Bronchial thermoplasty for treatment of asthma (31660, 31661) as this procedure is also listed on the Non-Covered Technologies policy as experimental/investigational.
11/1/2020	• Removed termed code 95075 from Procedure Codes section.

MEDICAL POLICY

Medical Policy Title	**Allogeneic Hematopoietic Stem Cell Transplantation (Allo-HSCT)**
Policy Number	**7.02.02**
Current Effective Date	**July 1, 2026**
Next Review Date	**February 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Allogeneic hematopoietic stem cell transplantation (allo-HSCT) is considered **medically appropriate** when **ALL** of the following are met:

A. Candidates have met the transplanting institution's selection criteria;

B. The multidisciplinary team has evaluated the individual and recommends treatment (see Policy Guidelines for required documentation);

AND

C. The individual is being treated for **ONE (1)** of the following indication-specific criteria, if applicable:

1. Acute Lymphoblastic Leukemia (ALL);
2. Acute Myeloid Leukemia (AML);
3. Chronic Myeloid Leukemia (CML);
4. Chronic Lymphocytic Leukemia (CLL)
5. Non-Hodgkin Lymphoma (B and T-cell Lymphomas);
6. Myelodysplastic Diseases when the following criteria are met:
   a. Disease status is considered intermediate or high risk;
7. Multiple Myeloma;
8. Sickle Cell Anemia, when the following criteria are met:
   a. Children or young adults who have a matched related donor* who are at risk for complications of sickle cell disease who meet **ONE (1)** of the following criteria:
      i. Has experienced an overt stroke, or has an abnormal transcranial doppler ultrasound;

ii. Has frequent pain, and does not respond or have an inadequate response to standard of care treatments (e.g., hydroxyurea, new targeted therapies, chronic transfusion therapies); **or**

iii. Has had recurrent episodes of acute chest syndrome despite standard of care treatment;

*Children or young adults who do not have a matched related donor may be eligible for an unrelated donor transplant in the context of a clinical trial, if there is an indication for HSCT as above.

9. Transfusion-dependent Thalassemia;
10. Bone Marrow Failure Syndromes; including but not limited to:
    a. Acquired Severe Aplastic Anemia;
    b. Fanconi Anemia;
    c. Dyskeratosis Congenita;
    d. Shwachman-Diamond Syndrome;
    e. Diamond-Blackfan Syndrome;
    f. Congenital Amegakaryocytic Thrombocytopenia;
11. Severe/Combined Immunodeficiency and Immune Dysregulation, including but not limited to:
    a. T Cell Immunodeficiency;
    b. Wiskott-Aldrich Syndrome;
    c. Immune dysregulation, Polyendocrinopathy, Enteropathy, X-linked syndrome **(**IPEX) Syndrome;
12. Hemophagocytic Disorders (e.g., Hemophagocytic Lymphohistiocytosis [HLH]);
13. Phagocytic/Innate Immune Cell Disorders, including but not limited to:
    a. Severe Congenital Neutropenia (including Kostmann Syndrome);
    b. Chronic Granulomatous Disease;
    c. Chediak-Higashi Syndrome;
    d. Leukocyte Adhesion Deficiencies;
14. Common Variable Immunodeficiency;
15. Lysosomal/Peroxismal Storage and Leukodystrophy Disorders, including but not limited to:
    a. Mucopolysaccharoidosis I (MPSI, Hurler);

b. Maroteaux-Lamy Syndrome (MPS VI);
c. Gaucher Disease;
d. Globoid Cell Leukodystrophy (Krabbe Disease);
e. Metachromatic Leukodystrophy;
f. Cerebral X-Linked Adrenoleukodystrophy; **or**

16. Skeletal/Metabolic Bone Disorders, including but not limited to:
    a. Osteopetrosis;
    b. Infantile Malignant Osteopetrosis (Albers-Schöberg disease or marble bone disease).

II. Allo-HSCT is considered **investigational** for **ALL** other indications.

RELATED POLICIES

Corporate Medical Policy

7.02.03 Autologous Hematopoietic Stem Cell Transplantation (Auto-HSCT)

7.02.11 Chimeric Antigen Receptor T-cell (CAR-T) Therapy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Recipient Selection Guidelines: Each individual considered for allo- HCT must be evaluated by the transplant center for potential difficulties that would complicate and diminish the success of transplantation. Consideration will be given to the patient's risk of death without transplantation, along with the presence and severity of potential contraindications.

I. Required documentation from the multidisciplinary team that includes the individual's eligibility and risk for autologous stem cell transplant should include:
   A. Clinical Evaluation:
      1. Confirmation of diagnosis;
      2. Identification of comorbidities;
      3. Current assessment of co-morbidities;
      4. Management of co-morbidities;
      5. Consult notes (if applicable);
   B. Psycho-Social Evaluation:
      1. Identification of stressors (e.g., family support, noncompliance issues, motivational issues, alcohol, or smoking/substance abuse);
   C. Performance Status:

1. Karnofsky performance score;
2. Eastern Cooperative Oncology Group (ECOG) performance status,
3. Palliative Performance Scale (PPS) score; or
4. Lansky Play-Performance Scale (for age 1 to 16 years);

D. Oral Health Evaluation;

E. Lab Tests:

1. Complete blood count (CBC), metabolic profile;
2. Serologies: Cytomegalovirus (CMV), Hepatitis B and C;
3. Human Immunodeficiency Virus (HIV) testing;

F. Cardiac Assessment:

1. 12 lead electrocardiogram (EKG);
2. Echochardiogram or multigated acquisition (MUGA) Scan;

G. Pulmonary Assessment:

1. Chest x-ray;
2. Pulmonary function tests (PFTs) for high-risk of respiratory failure (e.g., chronic obstructive pulmonary disease (COPD), emphysema, a-1-antitrypsin deficiency, hepatopulmonary syndrome, or significant smoking history);

H. Age-Appropriate Screening Tests:

Please refer to the U.S Preventive Services Task Force (USPSTF) website for list of age-appropriate screening guidelines: https://www.uspreventiveservicestaskforce.org/uspstf/ [accessed 2026 Jan 19.]

DESCRIPTION

Stem cells differ from other blood cells in that they are capable of both unlimited self-renewal and differentiation to form white blood cells, red blood cells, or platelets. Stem cells can be collected from two sources: direct aspiration of bone marrow or through a pheresis procedure to harvest peripheral blood stem cells (PBSC). Prior to harvesting the stems cells, pretreatment with drugs called "growth factors" or "colony stimulating factors" are given to the donor to enhance stem cell production. The harvested stem cells are then cryopreserved until transplanted.

Hematopoietic stem cell transplantation refers to a procedure that infuses hematopoietic stem cells to restore bone marrow function in cancer patients who receive bone marrow-toxic doses of drugs with or without whole-body radiotherapy.

In allogeneic hematopoietic stem cell (allo-HSCT) transplantation, cells are obtained from a matched related or unrelated donor. The more closely matched the donor to the recipient's tissue type, the

more favorable the outcome for the transplant. Allo-HSCT entails the transfer of an entire hematopoietic system, including a foreign adaptive immune system to a new host. Allo-HSCT is associated with potential complications and benefits. One complication that may develop is graft-vs-host disease (GVHD). In GVHD, the donor cells may attack the recipient tissue which could eventually lead to death. A potential benefit, the graft-vs-tumor effect, arises when the donor cells attack the recipient's tumor tissue. This effect may account for lower relapse rates.

Reduced-intensity conditioning (RIC) refers to chemotherapy regimens that seek to reduce adverse effects secondary to bone marrow toxicity while retaining the beneficial graft-versus-tumor effect of allo-HSCT. These regimens do not eradicate the patient's hematopoietic ability, and allow for relatively prompt hematopoietic recovery (e.g., 28 days or less) even without a transplant. Patients who undergo RIC with allo-HSCT initially demonstrate donor cell engraftment and bone marrow mixed chimerism. Most will subsequently convert to full donor chimerism, which may be supplemented with donor lymphocyte infusions to eradicate residual malignant cells. A number of different cytotoxic regimens, with or without radiotherapy, may be used for RIC allotransplantation.

Myeloablative conditioning (MAC) is the most intense form of conditioning for allo-HSCT and has the greatest risk for regimen-related toxicity. The classic MAC regimen combines myeloablative doses of busulfan with cyclophosphamide and ATG. Commonly referred to as Bu-Cy-ATG, this regimen has been used successfully to treat a broad range of immunodeficiency disorders. MAC agents are expected to produce profound pancytopenia and myeloablation within 1–3 weeks from administration. Pancytopenia is long-lasting, usually irreversible and in most instances fatal, unless hematopoiesis is restored by hemopoietic stem cell infusion.

Acute lymphoblastic leukemia (ALL) is a heterogeneous disease with different genetic variations resulting in distinct biologic subtypes. Patients are stratified to risk-adapted therapy according to certain clinical and genetic risk factors that predict an outcome. Therapy may include HSCT.

Acute myeloid leukemia (AML) refers to leukemias that arise from a myeloid precursor in the bone marrow. AML has a high incidence of relapse, which has prompted research into various post-remission strategies using either allogeneic or autologous HSCT.

Primary refractory acute myeloid leukemia (AML) is defined as leukemia that does not achieve a complete remission after conventionally dosed (non-marrow ablative) chemotherapy.

Chronic Myeloid Leukemia (CML) is a hematopoietic stem cell disorder characterized by the presence of a chromosomal abnormality called the Philadelphia chromosome and predominantly affects older adult males over the age 60. The natural history of the disease consists of an initial (indolent) chronic phase, lasting a median of 3 years, and typically transforms into an accelerated phase, followed by a blast crisis which is usually the terminal event. Most patients present in chronic phase, often with nonspecific symptoms secondary to anemia and splenomegaly. A diagnosis is based on the presence of the Philadelphia chromosome abnormality by routine cytogenetics, or by detection of abnormal BCR-ABL products by fluorescence in situ hybridization or molecular studies, in the setting of persistent unexplained leukocytosis. Conventional dose chemotherapy regimens used for chronic phase disease can induce multiple remissions and delay the onset of blast crisis to a median of 4 to 6 years. However, successive remissions are invariably shorter and more difficult to achieve than their

predecessors. HSCT has shown to be the only curative option.

Chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL) are neoplasms of hematopoietic origin characterized by the accumulation of lymphocytes with a mature, generally well-differentiated morphology. In CLL, these cells accumulate in the blood, bone marrow, lymph nodes, and spleen; in SLL they are generally confined to lymph nodes. Chronic lymphocytic leukemia and SLL share many common features and are often referred to as blood and tissue counterparts of each other, respectively. Both tend to present as asymptomatic enlargement of the lymph nodes, tend to be indolent, but can undergo transformation to a more aggressive form of the disease (e.g., Richter transformation). The median age at diagnosis of CLL is approximately 72 years, but it may present in younger individuals, often as a poor-risk disease with significantly reduced life expectancy. The Revised European-American/World Health Organization Classification of Lymphoid Neoplasms considers B-cell CLL and SLL a single disease entity.

Non-Hodgkin's Lymphoma (NHL) is the most common hematological malignancy worldwide (Thandra et al 2021). NHL refers to a diverse class of B-cell and T-cell proliferations. NHL differs from Hodgkin's lymphoma by the clinical characteristics, the absence of Reed-Sternberg cells, and Cd15 and Cd30 staining on histology (Thandra et al 2021). There are over 40 major subtypes, the most common types include follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL). Each type is associated with unique driver genetic mutations (e.g., 14:18 translocation in FL, 11:14 translocation in Mantle Cell, 8:14 in Burkitts lymphoma) and unique risk factors (Epstein–Barr Virus (EBV) for Burkitt's lymphoma, human T-cell lymphoma virus (HTLV-1) for T-cell lymphoma).

NHLs are often divided into two groups, indolent and aggressive depending on the types of affected cells and the rate of growth of the cells. Indolent Non-Hodgkin Lymphomas (NHLs) tend to grow and spread slowly with few symptoms. They are low-grade cancers which are often very responsive to treatments like chemotherapy, radiation, and immunotherapy. However, treatment is often deferred until the patient becomes symptomatic. The goal of treatment is often management as indolent lymphomas are rarely cured unless it is diagnosed when still localized. Thus, treatment options are more varied with no standardization. NHLs are fast growing and are described as intermediate or high grade. They can be treated with chemotherapy, radiotherapy, monoclonal antibody therapy, or a combination. The decision on the exact course of treatment is usually dependent on a number of factors such as, the stage of the disease, the number of nodes involved, the presence of lymphoma in other organs, and age.

Tandem transplants usually are defined as the planned administration of two successive cycles of high dose myeloablative chemotherapy, each followed by infusion of autologous hematopoietic stem cells, whether or not there is evidence of persistent disease following the first treatment cycle. Sometimes, the second cycle may use nonmyeloablative immunosuppressive conditioning followed by infusion of allogeneic stem cells.

The term salvage therapy describes therapy given to patients with refractory or relapsed disease. For patients with peripheral T-cell lymphoma, salvage therapy includes patients who do not achieve a complete response (e.g., achieve only a partial response, have no response, or have progressive disease) with first-line induction chemotherapy (refractory disease) or who relapse after achieving a

complete response with first-line induction chemotherapy.

Sickle cell disease (SCD) is the most common inherited hemoglobinopathy in the United States. In SCD, the shape of the red blood cells is affected and have a sickle or crescent moon appearance. This abnormal shape can cause blood flow disruption or a total blockage. SCD is characterized by continuous intravascular hemolysis and microvascular occlusion resulting in recurrent vaso-occlusive painful events and severe organ complications (Aydin et al 2021). SCD symptoms can begin to show when a child is about 5 to 6 months of age and can result in significant morbidities and early mortality.

Acute chest syndrome (ACS) is a complication of SCD, and it can cause chest pain, cough, fever, low oxygen levels, and cause injury to the lungs. ACS syndrome is the leading cause of hospitalization and death in people with sickle cell disease. Hematopoietic stem cell transplantation (HSCT) is currently the only established curative intervention for SCD that can restore normal hematopoiesis.

High-risk T-cell and natural killer cell neoplasms are a clinically heterogeneous group of rare disorders, most of which have an aggressive clinical course and poor prognosis. The exception includes the following subtypes, which typically have a relatively indolent and protracted course (T-cell large granulocyte leukemia, chronic lymphoproliferative disorder of natural killer cells, early-stage mycosis fungoides, primary cutaneous anaplastic large-cell lymphoma, and anaplastic lymphoma kinase-anaplastic large-cell lymphomas).

Myelodysplastic syndromes (MDS) and myeloproliferative neoplasms refer to a heterogeneous group of clonal hematopoietic disorders with the potential to transform into acute myelocytic leukemia. Allo-HSCT has been proposed as a curative treatment option for patients with these disorders (Saber and Horowitz 2016).

Myeloid neoplasms are categorized according to criteria developed by the World Health Organization (WHO). Neoplasms are risk-stratified using the International Prognostic Scoring System (IPSS).

Disability Scores

I. The Karnofsky performance status score describes a patient's functional status as a comprehensive 11-point scale correlating to percentage values ranging from 100% (no evidence of disease, no symptoms) to 0% (death). Adapted from Peus et al 2013:

A: Able to carry on normal activity and to work. No special care is needed.	100	Normal, no complaints, no evidence of disease.
	90	Able to carry on normal activity, minor signs or symptoms of disease.
	80	Normal activity with effort, some signs, or symptoms of disease.
B: Unable to work. Able to live at home, care for most personal needs.	70	Cares for self, unable to carry on normal activity or to do active work.

A varying degree of assistance is needed.	60	Requires occasional assistance but is able to care for most of personal needs.
	50	Requires considerable assistance and frequent medical care.
C: Unable to care for self. Requires equivalent of institutional or hospital care. Disease may be progressing rapidly.	40	Disabled, requires special care and assistance. [In bed more than 50% of the time]
	30	Severely disabled, hospitalization is indicated although death not imminent. [Almost completely bedfast]
	20	Very ill, hospitalization and active supportive treatment necessary. [Totally bedfast and requiring extensive nursing care by professionals and/or family]
	10	Moribund, fatal processes progressing rapidly. [Comatose or barely arousable]
	0	Dead.

II. Palliative Performance Scale (PPS) score; adapted from Fast Facts and Concepts (Wilner and Arnold 2006):

Percentage	Ambulation	Activity Level/Evidence of Disease	Self-Care	Intake	III. Level of Consciousness
100	Full	Normal No Disease	Full	Normal	Full
90	Full	Normal Some Disease	Full	Normal	Full
80	Full	Normal with Effort Some Disease	Full	Normal or reduced	Full
70	Reduced	Can't do normal job or work.	Full	As above	Full

		Some Disease			
60	Reduced	Can't do hobbies or housework. Significant Disease	Occasional Assistance Needed	As above	Full or confusion
50	Mainly sit/lie	Can't do any work. Extensive Disease	Considerable Assistance Needed	As above	Full or Confusion
40	Mainly in bed	As above	Mainly Assistance	As above	Full or Drowsy or Confusion
30	Bed Bound	As above	Total Care	Reduced	As above
20	Bed Bound	As above	As above	Minimal	As above
10	Bed Bound	As above	As above	Mouth care only	Drowsy or coma
0	Death	-	-	-	-

III. Eastern Cooperative Oncology Group (ECOG) performance status; adapted from ECOG-ACRIN Cancer Research group:

Grade	ECOG PERFORMANCE STATUS
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
5	Dead

IV. Lansky Play-Performance Scale (for age 1 to 16 years)

The Lansky play-performance scale is used for children aged 1-16 with any type of malignancy. It is

typically rated by parents based on their child's activity over the past week. Adapted from: Performance status | HemOnc.org - A Hematology Oncology Wiki [accessed 2025 Nov 24]:

Rating	Description
100	Fully active, normal
90	Minor restrictions with strenuous physical activity
80	Active, but gets tired quickly
70	Both greater restriction of, and less time spent in, active play
60	Up and around, but minimal active play; keeps busy with quieter activities
50	Lying around much of the day, but gets dressed; no active play; participates in all quiet play activities
40	Mostly in bed; participates in quiet activities
30	Stuck in bed; needs help even for quiet play
20	Often sleeping; play is entirely limited to very passive activities
10	Does not play or get out of bed
0	Unresponsive

SUPPORTIVE LITERATURE

Masetti et al (2022) conducted a meta-analysis of allo-HSCT for pediatric patients with AML in first complete response. Both prospective and retrospective studies comparing allo-HSCT to chemotherapy in higher-risk patients were considered. A total of 9 studies (5 prospective, 4 retrospective) were included. None of the prospective studies were randomized. The meta-analysis showed that overall survival (OS) was improved with allo-HSCT compared with chemotherapy. Similarly, disease-free survival (DFS) was improved compared to chemotherapy. Risk of relapse was higher among patients who received chemotherapy.

Huang and colleagues (2025) performed a cross-study analysis of two-phase III Children's Oncology Group clinical trials to evaluate whether hematopoietic stem cell transplantation (HSCT) improves outcomes for pediatric patients with high-risk acute myeloid leukemia (AML). They compared patients who received HSCT in first complete remission (CR1) with those treated with chemotherapy alone in CR1. The analysis included 463 patients with high-risk cytogenetic or molecular features and 72 patients with standard-risk features who had positive measurable residual disease (MRD) after the first induction cycle. Among these groups, 33.9% of high-risk patients and 45.8% of standard-risk

patients underwent HSCT in CR1. Across both risk groups, HSCT was associated with lower relapse rates and improved disease-free survival (DFS). In the high-risk cohort, 5-year DFS was 26% for patients treated with chemotherapy alone, compared with 49.8% for those who received both chemotherapy and HSCT. Similarly, in the standard-risk cohort, 5-year DFS was 16.9% with chemotherapy alone versus 50.9% for those who underwent HSCT. Overall, the authors concluded that HSCT in CR1 is associated with significantly improved outcomes for pediatric patients with high-risk AML.

Barge et al (2025) aimed to examine the use of Allo-HSCT in the modern era of chronic lymphocytic leukemia (CLL) treatment by collecting data from the Australian and New Zealand Transplant and Cellular Therapy Registry for all patients who underwent HSCT for CLL between January 2009 and December 2018. Outcomes were compared between two periods of time, 2009-2013 (n=94) vs. 2014-2018 (n=50) and included patients who were treated with pathway inhibitors prior to transplant, which was more likely for those patients treated in the later cohort. Authors reviewed median time to engraftment, incidence of graft vs host disease, cytomegalovirus reactivation, survival, and cause of death. The median time to neutrophil engraftment for the 2009-2013 cohort was 16 days, and 17 days for the 2014-2018, while median platelet engraftment occurred at 19 and 16 days for the 2009-2013 and 2014-2018 cohorts, respectively. The cumulative incidence of graft versus host disease at 100 days was less for the later cohort at 33% vs. 52% for 2009-2013 with similar differences seen at 5 years. At the follow up time frame of 7.6 years for 2009-2013 cohort and 5.0 years for the 2014-2018 cohorts, there were no differences in OS, progression free survival (PFS), reported cause of death or relapse, but there was a significant improvement in non-relapse mortality from 42% to 23% in the later cohort. Authors concluded that allo-HSCT remains a viable treatment option for select patients with CLL.

Allo-HSCT is an established curative treatment option for patients with sickle cell disease (SCD). The pediatric population has primarily been the focus of published data. Studies have shown that allo-HSCT, if performed before the age of 10 are associated with reduced mortality and lower health care costs (Iqbal et al 2021). There are few studies that evaluate the efficacy of allo-HSCT for adults.

Recently an international effort on behalf of the pediatric diseases working party of European Society for blood and bone marrow transplantation and sickle cell disease transplantation international consortium conducted a systematic review and meta-analysis on the efficacy of allo-HSCT for the treatment of sickle cell disease. There were 33 studies representing 2853 patients who met inclusion criteria. Data was collected on patients undergoing allo-HSCT between 1986 and 2017 who had recurrent vaso-occlusive crisis, acute chest syndrome, and stroke. The majority of patients had multiple indications, but the most common indication was for vaso occlusive crisis. A matched related sibling was the most common donor source, and bone marrow was the most common hematopoietic cell source. All groups (both adults and pediatric) had an OS rate of 96%, DFS 90%, acute graft versus host disease (aGVHD) of 20%, chronic graft versus host disease (cGVHD) of 10%, nonrelapse mortality of 4% and graft failure of 5% (Iqbal et al 2021).

Du et al (2023) performed a systematic review and meta-analysis on transplant for refractory or relapsed peripheral T cell-lymphoma (R/R-PTCL) and reported outcomes of allo-HSCT and autologous HSCT for R/R-PTCL. Individuals in the two groups had similar survival rates, as opposed to individuals

with R/R-PTCL who underwent autologous HSCT had fewer adverse events than those who underwent allogeneic HSCT. Per researchers this could possibly be due to GVHD counterbalances the accompanying graft versus lymphoma effect after allogeneic HSCT. In considering the pretransplant status, most patients in the allogeneic HSCT group were insensitive to chemotherapy, and allogeneic HSCT served as a salvage therapy, which provided an additional survival advantage for patients with R/R-PTCL. The findings of this study suggest that, overall, HSCT is an effective therapy for R/R-PTCL. Individuals with R/R-PTCL with lower-risk stratification might prefer autologous HSCT, although allo-HSCT can still serve as a salvage therapy in those with a higher-risk disease stage.

PROFESSIONAL GUIDELINE(S)

In 2020, the American Society of Transplantation and Cellular Therapy (ASTCT) convened a guideline committee to make recommendations for the use of hematopoietic cell transplantation and immune effector cell therapy. Indications were categorized as (1) Standard of care, where indication is well defined and supported by evidence; (2) Standard of care, clinical evidence available, where large clinical trials and observational studies are not available but have shown to be effective therapy; (3) Standard of care, rare indication, for rare diseases where demonstrated effectiveness exists but large clinical trials and observational studies are not feasible; (4) Developmental, for diseases where preclinical or early-phase clinical studies show promising results, and (5) not generally recommended, where available evidence does not support the routine use of hematopoietic stem cell transplantation. For updated guidelines, visit: https://www.guidelinecentral.com/guideline/26026/#section-336178 [accessed 2026 Jan 19].

Following the ASTCT guideline recommendations, several indication specific guidelines have been published, including:

- Newly Diagnosed Adult Acute AML (Dholaria et al 2021);
- Pediatric Acute AML and Myelodysplastic Syndromes (Tarlock et al 2022);
- Follicular Lymphoma (a collaborative effort on behalf of ASTCT and the European Society for Blood and Marrow Transplantation (Iqbal et al 2024);
- Severe Aplastic Anemia (Iftikhar et al 2024);
- Mycosis Fungoides and Sézary Syndrome (a joint recommendation with the United States Cutaneous Lymphoma Consortium [USCLC]) (Goyal et al 2024);
- Diffuse Large B Cell Lymphoma (Epperla et al 2023);
- Classical Hodgkin Lymphoma (Pre-proof, Ahmed et al 2025);
- Evaluation of Children with Malignancies for Blood and Marrow Transplantation (Fraint et al 2023);

In 2020, the European Society for Medical Oncology (ESMO) published clinical practice guidelines for the diagnosis, treatment, and follow up of chronic lymphocytic leukemia (CLL) (Eichhorst et al) that are endorsed by the European Hematology Association (EHA) through the Scientific Working Group on CLL/European research initiative on CLL (ERIC). The panel recommended that patients who are

refractory to chemoimmunotherapy with TP53 mutation or del(17p), but fully responsive to novel inhibitor therapy; patients refractory to chemoimmunotherapy and to novel inhibitor therapy, even those with a higher risk of non-relapse mortality (evidence level III,B), as well as patients with Richter's transformation in remission after therapy and clonally related to CLL.

In 2021, Kanter and colleagues published clinical guidelines for sickle cell disease (SCD): stem cell transplantation on behalf of the American Society of Hematology (ASH). The review of the evidence conducted by the panel yielded no randomized controlled trials, with all recommendations being made based upon very low certainty in the evidence and resulting in a recommendation for the development of a robust SCD registry to serve as a comparator for future HSCT studies. The conditional recommendations were as follows:

- "The ASH guideline panel suggests HLA-matched related HSCT rather than standard of care (hydroxyurea (H/U)/transfusion) in patients with SCD who have experienced an overt stroke or have an abnormal transcranial Doppler ultrasound;
- For patients with frequent pain, the ASH guideline panel suggests using related matched allogeneic transplantation rather than standard of care;
- For patients with recurrent episodes of acute chest syndrome (ACS), the ASH guideline panel suggests using related allogeneic transplantation over standard of care;
- For patients with SCD with an indication for HSCT who lack an MSD, the ASH guideline panel suggests using transplants from alternative donors in the context of a clinical trial;
- For allogeneic HSCT, the ASH guideline panel suggests using either total-body irradiation (TBI) #400 cGy or chemotherapy-based conditioning regimens.
- For children with SCD who have an indication for allogeneic HSCT and an MSD, the ASH guideline panel suggests using myeloablative conditioning over RIC that contains melphalan/fludarabine regimens;
- For adults with SCD who have an indication for allogeneic HSCT and an MSD, the ASH guideline panel suggests nonmyeloablative conditioning over RIC that contains melphalan/fludarabine regimens;
- In patients with an indication eligible for HSCT, the ASH guideline panel suggests using allogeneic transplantation at an earlier age rather than an older age;
- The ASH guideline panel suggests the use of HLA-identical sibling cord blood when available (and associated with an adequate cord blood cell dose and good viability) over bone marrow (BM)"

In 2023, Fraint and colleagues published a report from the ASTCT Committee on practice guidelines for the evaluation of children with malignancies for blood and marrow transplantation. ASTCT states, "Children with malignancy who require HCT for cure have a unique set of psychosocial needs, physical comorbidities, and disease risk features that differentiate them from adults. Given the inability for some of the important pre-HCT risk indices developed for adults to be applied to children, a specialized approach is needed, ideally with harmonization among centers." Although rigorous data

on physiologic differences and randomized trials on management are lacking for children, the recommendations provided are meant to serve as a guide for pre-HCT preparations.

In 2025, Damaj et al published recommendations from the European Society for Blood and Marrow Transplantation (EBMT) Practice Harmonisation and Guidelines Committee for allogeneic hematopoietic cell transplantation in peripheral T-cell lymphoma. Recommendations included:

- "Allogeneic HCT is the treatment of choice in patients with insufficient response or refractory to first-line therapy; and with relapsed disease after first complete response regardless of prior treatment, including autologous HCT;
- Eligibility for allogeneic HCT should be established early, donor search should be initiated as soon as no response to first-line treatment becomes obvious; proceed to allogeneic HCT, regardless of result of salvage therapy, as long as transplant eligibility is retained;
- There is no strict age limit for allogeneic HCT; age should be evaluated in context of other risk factors, candidates with a HCT comorbidity Index (HCT-CI) score of 2 or less with good performance status are most suitable for allogeneic HCT; however these factors must be considered together with age, comorbidities, and disease status to determine the overall risks of allogeneic HCT;
- Although patients in complete remission have the best outcomes after allogeneic HCT, patients in partial remission should also proceed directly to allogeneic HCT; Patients with stable or progressive disease can expect a probability of long-term survival and thus should be considered for allogeneic HCT, if eligible, on an individual basis;
- The preferred donor hierarchy is in the order: matched sibling donor, matched unrelated donor, haploidentical donor, mismatched unrelated donor; both peripheral blood stem cells and bone marrow are acceptable graft sources.

The National Comprehensive Cancer Network (NCCN) V.1.2026 Guidelines for B-Cell Lymphomas recommend consolidation with allo-HCT in patients with relapsed/refractory mantle cell lymphoma that is in remission following second-line therapy with fixed-duration regiments, additionally for those patients with MCL that is refractory to or progressing on second-line subsequent therapy and for disease relapse or progressive disease following CAR T-cell therapy.

NCCN V.5.2026 Guidelines for Multiple Myeloma identifies the potential use of allo-HCT given the lack of significant cure rate for single or tandem autologous HCT, for those individuals with multiple myeloma as initial therapy or as therapy for relapsed or refractory disease.

NCCN V.1.2026 Guidelines for Pediatric Acute Lymphoblastic Leukemia recommends the use of allo-HCT in those with persistent disease, or disease with high-risk features (KMT2A rearrangements) based on limited data available, stating it is "reasonable to consider HCT in first remission for certain patients."

NCCN V.2.2025 Guidelines for Acute Lymphoblastic Leukemia acknowledge that allo-HCT is more likely to be a utilized treatment in adult patients with evidence of high-risk features (Ph-like disease, or persistent measurable residual disease) and in post consolidative therapy in adolescents and

young adults, and therefore recommend that, "HLA typing and bone marrow transplant referral should be considered for all patients with newly diagnosed disease and patients with relapsed disease who have not yet undergone transplant to facilitate timely donor identification, and ultimately allogeneic transplant if warranted.

NCCN V.2.2026 Guidelines for Acute Myeloid Leukemia (AML), allo-HCT can be considered an option for individuals with intermediate-risk and poor-risk AML in those who have already achieved remission and have a donor available.

NCCN V.1.2026 Guidelines for T-Cell Lymphomas recommend that allo-HCT can be a treatment option for patients who achieve a complete or partial response after initial therapy and also acknowledge that given the poor prognosis associated with T-cell prolymphocytic leukemia, patients should be enrolled in a clinical trial.

NCCN V.3.2025 Guidelines for Waldenstrom Macroblobulinemia/Lymphoplasmacytic Lymphoma recommend that myeloablative or non-myeloablative allo-HSCT be considered only within the context of a clinical trial.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates vaccines, blood, and blood products (including hematopoietic stem cells), and biologics via the Center for Biologics Evaluation and Research (CBER) which ensures the safety, efficacy, and quality of these products. Refer to the FDA vaccines/blood/biologics website. Available from: https://www.fda.gov/vaccines-blood-biologics [accessed 2026 Jan 21]

The FDA maintains information for consumers and health professionals on vaccine, blood and biologics warnings and other safety information. Available from: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/recalls-biologics [accessed 2026 Jan 21]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
38205	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; allogeneic
38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, T-cell depletion

Code	Description
38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal
38213	Transplant preparation of hematopoietic progenitor cells; platelet depletion
38230	Bone marrow harvesting for transplantation, allogeneic
38240	Hematopoietic progenitor cell (HPC); allogeneic transplantation per donor
38242	Allogeneic lymphocyte infusions
38243	Hematopoietic progenitor cell (HPC); HPC boost

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HCPCS Codes

Code	Description
S2142	Cord blood-derived stem-cell transplantation, allogeneic
S2150	Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including: pheresis and cell preparation/storage; marrow ablative therapy; drugs, supplies, hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre- and posttransplant care in the global definition

ICD10 Codes

Code	Description
C26.0-C26.9	Malignant neoplasm of other and ill-defined digestive organs (code range)
C33	Malignant neoplasm of trachea
C34.00-C34.92	Malignant neoplasm of bronchus and lung (code range)
C38.1-C38.8	Malignant neoplasm of mediastinum and pleura (code range)
C47.0-C47.9	Malignant neoplasm of peripheral nerves and autonomic nervous system (code range)
C48.0	Malignant neoplasm of retroperitoneum
C49.0-C49.9	Malignant neoplasm of other connective and soft tissue (code range)
C50.011-C50.919	Malignant neoplasm of breast (code range)

Code	Description
C62.00-C62.92	Malignant neoplasm of testis (code range)
C71.0-C71.9	Malignant neoplasm of brain (code range)
C81.00-C81.99	Hodgkin lymphoma (code range)
C82.00-C82.59	Follicular lymphoma (code range)
C82.60-C82.99	Cutaneous follicle center lymphoma
C83.00-C83.99	Non-follicular lymphoma (code range)
C84.60-C84.79	Anaplastic large cell lymphoma, ALK-positive or ALK-negative (code range)
C86.5	Angioimmunoblastic T-cell lymphoma
C86.6	Primary cutaneous CD30-positive T-cell proliferations
C88.2-C88.9	Malignant immunoproliferative diseases and certain other B-cell lymphomas (code range)
C90.00-C90.32	Multiple myeloma and malignant plasma cell neoplasms (code range)
C91.10-C91.12	Chronic lymphocytic leukemia of B-cell type (code range)
C94.40-C94.42	Acute panmyelosis with myelofibrosis (code range)
C94.6	Myelodysplastic disease, not classified
D46.0-D46.9	Myelodysplastic syndromes (code range)
D46.A-D46.Z	Refractory cytopenia with multilineage dysplasia (code range)
D47.1	Chronic myeloproliferative disease
D47.3	Essential (hemorrhagic) thrombocythemia
D47.9	Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified

Code	Description
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
D56.0-D56.9	Thalassemia (code range)
D57.00-D57.819	Sickle-cell disorders (code range)
D60.0-D61.9	Acquired pure red cell aplasia [erythroblastopenia] (code range)
D81.0-D82.0	Combined immunodeficiencies (code range)
E75.21-E75.3	Other sphingolipidosis (code range)
E76.01-E76.03	Disorders of glycosaminoglycan metabolism (code range)
E77.0-E77.9	Disorders of glycoprotein metabolism (code range)
G35	Multiple sclerosis
M32.0-M32.9	Systemic lupus erythematosus (SLE) (code range)
M34.0-M34.9	Systemic sclerosis [scleroderma] (code range)

REFERENCES

Ahmed S, et al. ASTCT clinical practice recommendations for transplantation in classical Hodgkin lymphoma. Transplant and Cell Ther. 2025 Dec 9;doi: https://doi.org/10.1016/j.jct.2025.12.944.

American Society for Transplantation and Cellular Therapy (ASTCT) [Internet]. Indications for autologous and allogeneic hematopoietic cell transplantation. 2015 Aug 07. [Last updated 2025 Dec 10; accessed 2026 Jan 21]. Available from: https://www.guidelinecentral.com/guideline/26026/#section-336178

Anagnostopoulos A, et al. Stem cell transplantation (SCT) for Waldenstrom's macroglobulinemia (wm). Bone Marrow Transplant. 2002;29:943-947.

Aydin M, et al. Haploidentical allogeneic stem cell transplantation in sickle cell disease: a systematic review and meta-analysis. Transplant Cell Ther. 2021 Dec;27(12):1004.e1-1004.e8.

Barge L, et al. Outcomes of allogeneic haemopoietic transplant for chronic lymphocytic leukaemia in the modern era. Int Med Journal. 2025 March 02;55:1105-1113.

Bashir Q, et al. Predictors of prolonged survival after allogeneic hematopoietic stem cell transplantation for multiple myeloma. Am J Hematol. 2012 Mar;87(3):272-6.

Bensinger W, et al. Allo-SCT for multiple myeloma: a review of outcomes at a single transplant center. Bone Marrow Transplant. 2012; 47(10):1312–1317.

Bernt KM, et al. Current concepts in pediatric Philadelphia chromosome-positive acute lymphoblastic leukemia. Front Oncol. 2014 Mar 25;4:54.

Bewersdorf JP, et al. Outcomes of allogeneic hematopoietic cell transplantation in patients with myelofibrosis- a systematic review and meta-analysis. Transplant Cell Ther.

Bishop MR et al. Second-line Tisagenlecleucle to standard care in aggressive B Cell Lymphoma. The England Journal of Medicine. 2022 Feb;386 (7):629-639.

Bornhauser M, et al. Allogeneic hematopoietic cell transplantation vs standard consolidation chemotherapy in patients with intermediate-risk acute myeloid leukemia a randomized clinical trial. JAMA Oncology. 2023 Feb 09;9(4):519-526.

Chakraborty R, et al. Impact of autologous transplantation on survival in patients with newly diagnosed multiple myeloma who have high-risk cytogenetics: A meta-analysis of randomized controlled trials. Cancer. 2022 Jun;128(12)2288-2297.

Cortelazzo S, et al. Mantle cell lymphoma. Crit Rev Oncol Hematol. 2012 Apr;82(1):78-101.

Cortes J, et al. Chronic myeloid leukaemia. The Lancet. 2021 Nov 20-26;398(10314):1914-1926.

Crocchiolo R, et al. Tandem autologous-allo-SCT is feasible in patients with high-risk relapsed non-Hodgkin's lymphoma. Bone Marrow Transplant. 2013;48(2):249-52.

Crump M, et al. Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR-1 study. Blood. 2017 Oct 19;130(16):1800-1808.

Damaj G, et al. Allogeneic haemoatopoietic cell transplantation in peripheral T-cell lymphoma: recommendations from the EBMT Practice Harmonisation and Guidelines Committee. Lancet Haematol. 2025 Jul;12(7):e542-e554.

Dholaria B, et al. Hematopoietic cell transplantation in the treatment of newly diagnosed adult acute myeloid leukemia: an evidence-based review from the American Society of Transplantation and Cellular Therapy. Transplant and Cell Ther. 2021;27(2021):6-20.

Dietrich SA, et al. Patterns and outcome of relapse after autologous stem cell transplantation for mantle cell lymphoma. Cancer. 2011 May 1;117(9):1901-10.

Dodero A, et al. Allogeneic transplantation following a reduced-intensity conditioning regimen in relapsed/refractory peripheral T-cell lymphomas: long-term remissions and response to donor lymphocyte infusions support the role of a graft-versus-lymphoma effect. Leukemia. 2012 Mar;26(3):520-6.

Du J, et al. Comparison of Allogeneic Stem Cell Transplant and Autologous Stem Cell Transplant in Refractory or Relapsed Peripheral T-Cell Lymphoma: A Systematic Review and Meta-analysis. JAMA Netw Open. 2021 May 3;4(5):e219807.

ECOG-ACRIN Cancer Research Group [Internet]. ECOG performance status scale. 2025 [accessed

2025 Nov 21]. Available from: https://ecog-acrin.org/resources/ecog-performance-status/

Epperla N, et al. ASTCT clinical practice recommendations for transplantation and cellular therapies in diffuse large B Cell lymphoma. Transplant and Cell Ther. 2023;29(2023):548-555.

Fraint E, et al. Evaluation of children with malignancies for blood and marrow transplantation: a report from the ASTCT Committee on Practice Guidelines. 2023 Feb 03;29(2023):293-301.

Garnier A, et al. Allogeneic hematopoietic stem cell transplantation allows long-term complete remission and curability in high-risk Waldenström's macroglobinemia. Results of a retrospective analysis of the Société Française de Greffe de Moelle et de Thérapie Cellulaire. Hematologica. 2010 Jun;95(6):950-5.

Gertz MA, et al. Stem cell transplant for Waldenström macroglobulinemia: an underutilized technique. Bone Marrow Transplant. 2012 Sep;47(9):1147-53.

Goyal A, et al. ASTCT and USCLC Clinical practice recommendations for allogeneic stem cell transplant in Mycosis Fungoides and Sézary Syndrome. Transplant and Cell Ther. 2024;30(2024):1047-1060.

Gribben JG. How and when I do allogeneic transplant in CLL. Blood. 2018 Jul 5;132(1):31-39.

Gupta V, et al. Allogeneic, but not autologous, hematopoietic cell transplantation improves survival only among younger adults with acute lymphoblastic leukemia in the first remission: an individual patient data meta-analysis. Blood. 2013;121(2):339-50.

Hamadani M, et al. How we approach patient evaluation for hematopoietic stem cell transplantation. Bone Marrow Transplant. 2010;45(8):1259-68.

Huang BJ, et al. Hematopoietic stem cell transplantation outcomes for high-risk AML: a report from the children's oncology group. J Clin Oncol. 2025 Apr 28;43(17):1961-1971.

Iftikhar R, et al. Allogeneic hematopoietic cell transplantation for the treatment of severe aplastic anemia: evidence-based guidelines from the American Society for Transplantation and Cellular Therapy. Transplant Cell Ther. 2024 Sep 20:S2666-6367(24)00682-1.

Iqbal M, et al. Systematic review/meta-analysis on efficacy of allogeneic hematopoietic cell transplantation in sickle cell disease: An international effort on behalf of the pediatric diseases working party of the European Society for Blood and Marrow Transplantation and the Sickle Cell Transplantation International Consortium. Transplant Cell Ther. 2021 Feb;27(2):167.e1-167.e12.

Iqbal M, et al. Clinical practice recommendations for hematopoietic cell transplantation and cellular therapies in follicular lymphoma: a collaborative effort on behalf of the American Society for Transplantation and Cellular Therapy and the European Society for Blood and Marrow Transplantation. Transplant Cell Ther. 2024;30(2024):832-843.

Kanate AS, et al. Indications for hematopoietic cell transplantation and immune effector cell therapy: guidelines from the American Society for Transplantation and Cellular Therapy. Biology of Blood and Marrow Transplantation. 2020 Jul;26(7):1247-1256.

Kanter J, et al. American Society of Hematology 2021 guidelines for sickle cell disease: stem cell transplantation. Blood Adv. 2021 Sep 28;5(18):3668-3689.

Koehne G, et al. Allogeneic hematopoietic stem cell transplantation for multiple myeloma: curative but not the standard of care. Curr Opin Oncol. 2012 Nov;24(6):720-6.

Kyriakou C, et al. Allogeneic stem-cell transplantation in patients with Waldenström Macroglobulinemia: report from the Lymphoma Working Party of the European Group for Blood and Marrow Transplantation. J Clin Oncol. 2010;28(33):4926-34.

Masetti R, et al. Allogeneic hematopoietic stem cell transplantation for pediatric acute myeloid leukemia in first complete remission: a meta-analysis. Ann Hematol. 2022 Nov;101(11):2497-2506.

National Cancer Institute [Internet]. NCI dictionary of cancer terms: Allogeneic stem cell transplant. 2025 [accessed 2026 Jan 21]. Available from: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/allogeneic-stem-cell-transplant

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology: Acute Lymphoblastic Leukemia. V.2.2025. 2025 Jun 27 [accessed 2026 Jan 15] Available from: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology: Acute Myeloid Leukemia. V.3.2026. [accessed 2026 Jan 15] Available from: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology: B-cell lymphoma. V.1.2026. 2025 Dec 22 [accessed 2026 Jan 15]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology: Hodgkin lymphoma. V.1.2026. October 22, 2025. [accessed 2026 Jan 15]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/hodgkins.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology: Multiple Myeloma. V.5.2026. 2026 Jan 9 [accessed 2026 Jan 15]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology: Pediatric Acute Lymphoblastic Leukemia. V1.2026 2025 Aug 11. [accessed 2026 Jan 15]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/ped_all.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology: Waldenström's Macroglobinemia /Lymphoplasmocytic Lymphoma. V.1.2026. 2025 Jun24. [accessed 2026 Jan 15]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/waldenstroms.pdf

Niederwieser C, Kröger N. Transplantation in CML in the TKI era: who, when, and how? Hematology Am Soc Hematol Educ Program. 2022 Dec 9;2022(1):114-122.

Peus D, et al. Appraisal of the Karnofsky Performance Status and proposal of a simple algorithmic

system for its evaluation. BMC. 2013 Jul 19;72(2013):1-7.

Rotin LE, et al. A systematic review comparing allogeneic hematopoietic stem cell transplant to gene therapy in sickle cell disease. Hematology. 2023 Dec;28(1):2163357.

Saber W and Horowitz MM, Transplantation for myelodysplastic syndromes: who, when, and which conditioning regimens. American Society of Hematology. 2016 Dec 2;2016(1):478-484.

Sung AD, et al. Home-based hematopoietic cell transplantation in the United States. Transplant Cell Ther. 2022 Apr;28(4):207.el-207.e8.

Tarlock K, et al. Hematopoietic cell transplantation in the treatment of pediatric acute myelogenous leukemia and myelodysplastic syndromes: guidelines from the American Society of Transplantation and Cellular Therapy. Trans Cell Ther. 2022;28(2022):530-545.

Thandra KC, et al. Epidemiology of Non-Hodgkin's Lymphoma. Med Sci (Basel). 2021 Jan 30;9(1):5.

Thomson RJ, et al. Tyrosine Kinase Inhibitors. [Updated 2023 Jul 18]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Jan, accessed 2026 Jan 08. Available from: https://www.ncbi.nlm.nih.gov/books/NBK563322/

Wilhelmsson M, et al. Long-term outcomes in survivors of childhood AML treated with allogeneic HSCT: a NOPHO-AML study. Bone Marrow Transplant.2019;54:726-736.

Wilner LS and Arnold RM. The palliative performance scale #125. J Palliat Med. 2006 Aug;9(4):994.

SEARCH TERMS

Peripheral blood stem cell transplant, umbilical cord blood transplant, allo transplant, allograft.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Stem Cell Transplantation (NCD 110.23) [accessed 2026 Jan 21]

Allogeneic Hematopoietic Stem Cell Transplant for MDS (Coverage with Evidence Development) [accessed 2026 Jan 21]

Allogeneic Hematopoietic Stem Cell Transplant for Multiple Myeloma (Coverage with Evidence Development) [accessed 2026 Jan 21]

Allogeneic Hematopoietic Stem Cell Transplant for Myelofibrosis (Coverage with Evidence Development) [accessed 2026 Jan 21]

Allogeneic Hematopoietic Stem Cell Transplant for Sickle Cell Disease (Coverage with Evidence Development) [accessed 2026 Jan 21]

Allogeneic Hematopoietic Stem Cell Transplantation (HSCT) for Myelosdysplastic Syndromes (MDS) (NCA CAG-00415R) [accessed 2026 Jan 21]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do

not apply.

- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 3/26 **Revised:** **Reviewed:**	
Date	**Summary of Changes**
7/1/2026	• New

Policy/Procedure Name: Alpha$_1$-Proteinase Inhibitors (Human) **Control Number: 1350/20.000310**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Alpha$_1$-antitrypsin (AAT), or alpha 1 proteinase inhibitor, is a protein that is made by the liver whose main function in the body is to protect tissues from being damaged due to proteolytic enzymes, especially neutrophil elastase (NE). Alpha$_1$-antitrypsin deficiency is a hereditary, autosomal recessive disorder that can increase the risk of lifelong complication in patients with the genetic disorder. The *SERPINA1* gene encodes for the AAT protein and it has several alleles that account for the different levels of function the resulting protein will possess. The most common, normal allele of the proteinase inhibitor (PI) is the *PI*M* variant. The *PI*Z* variant is the most common pathogenic allele that is a stronger indicator that a patient may have an increased risk of a clinical deficiency. The two other more common variants include the *PI*S* allele that results in a functionally deficient protein and the *PI*null* allele that results in either no mRNA or no protein. Patients with AAT deficiency are at an increased risk of developing liver and lung disease due to an inability to prevent inflammation to these tissues. The most common patient presentation includes emphysema.

There are four medications that are currently Food and Drug Administration (FDA)-approved for the treatment of AAT deficiency: Prolastin-C®, Aralast NP®, Zemaira®, and Glassia®. All of the medications are made with purified human alpha$_1$-proteinase inhibitors. These medications help to inhibit NE, therefore increasing protection against damage in the lung tissues.

Summary

Effective Date of Policy	5-1-2018
Indications	Emphysema due to alpha$_1$-antitrypsin (AAT) deficiency
ICD10 Diagnosis Codes	E88.01 – Alpha$_1$-antitrypsin deficiency
Availability	Prolastin-C 1,000mg, 20mL solution for inj Aralast NP 1,000mg, 50mL solution for inj, 500mg powder for injection, 25mL solution for inj Zemaira 1,000mg, 4000mg and 5000mg powder for injection, 20mL, 76mL, 95mL solution for inj Glassia 1,000mg, 50mL solution for inj
HCPCS codes	Prolastin C: J0256; Glassia: J0257; Aralast: J0256; Zemaira: J0256
Limitations	Alpha$_1$-Proteinase Inhibitors cannot be approved for those with a non-approved mutations
Duration	Initial approval: six months Continuation approval: six months

Required Criteria for Initial Approval		
All of the following conditions for the requested indication must be met in order to approve Alpha$_1$-Proteinase Inhibitors (Human):		
Indication	**Inclusion**	**Exclusion**
Alpha$_1$-Antitrypsin Deficiency (FDA approval) ICD 10: E88.01	1. The enrollee has a diagnosis of alpha$_1$-antitrypsin (AAT) deficiency **AND** 2. The enrollee is 18 years of age or older **AND** 3. Medication must be prescribed by a pulmonologist with expertise in treatment of AAT deficiency **AND** 4. There is a confirmed mutation of PI*SZ, PI*ZZ, PI*Z-null, or PI*null-null **AND** 5. Member has a serum AAT level <57mg/dL by nephelometry **AND** 6. Member has clinical evidence of emphysema **AND** 7. Patient must be a current non-smoker, which may include documentation of a negative cotinine urine test at the discretion of the provider	Medications will NOT be approved: • For members who are active smokers • In heterozygote mutations that include a normal (*PI*M*) allele or a homozygous mutation of *PI*SS* • Any contraindications to treatment are present
Approved Dosing	• All medications are to be dosed at 60mg/kg IV infusion once weekly	
Continuation Criteria		
Continue current approval for Alpha$_1$-Proteinase Inhibitors (Human) if following criteria is met:		
	1. The enrollee still meets the inclusion criteria listed above **AND** 2. Member is tolerating therapy without signs of unacceptable drug toxicity during previous treatment with these medications	

Considerations

- Requests for off-label indications or dosing of Alpha$_1$-Proteinase Inhibitors (Human) will be reviewed on a case-by-case basis using the criteria established in pharmacy policy: *Off-Label Uses of FDA Approved Drugs, control #1350/20.000048.*
- CDPHP reserves the right to make decisions based on clinical judgment on a case-by-case basis.
- For Medicare members utilizing these therapies within the prescription benefit, refer to policy 1350/20.000278.

References

		Accessed
1	Prolastin-C® [package insert]. Research Triangle Park, NC; Grifols Therapeutics Inc. 2020 May.	9/2023
2	Zemaira® [package insert]. Kankakee, IL; CSL Behring L.L.C.2022 Sep.	8/2024
3	Glassia® [package insert]. Lexington, MA; Kamada Ltd. 2022 Sep.	9/2023
4	Aralast NP® [package insert]. Lexington, MA; Takeda Pharmaceuticals U.S.A., Inc. 2023 Mar.	9/2023
5	Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2023.	9/2023
6	Am J Respir Crit Care Med Vol 168. pp 818–900, 2003. DOI: 10.1164/rccm.168.7.818	9/2023
7	Sandhaus RA, Turino G, Brantly ML, et al. The diagnosis and management of alpha-1 antitrypsin deficiency in the adult. *Chronic Obstr Pulm Dis*. 2016; 3(3): 668-682.	9/2023
8	MICROMEDEX Healthcare Series Online: alpha-1 proteinase inhibitor. Thomson Micromedex, 2009.	9/2023

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE CHOICES: Subject to all terms and conditions noted in above application.

SELECT PLAN/HARP: Medical Benefit - Subject to all terms and conditions noted in above application.

Pharmacy Benefit - Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program

CDPHP Pharmacy Services 12/3/2025

Revision Date	Notes
12/2017	New Policy
12/2018, 12/2019, 12/2020, 12/2021, 12/2022, 12/2023, 12/2024, 12/2025	Reviewed

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MEDICAL POLICY

Medical Policy Title	**Ambulance: Air**
Policy Number	**11.01.06**
Current Effective Date	**September 1, 2026**
Next Review Date	**March 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Air ambulance transportation services may be determined to be **medically appropriate** only to the nearest facility that can provide the appropriate care when **ALL** of the following criteria are met:

   A. The individual's medical condition, required immediate and rapid ambulance transportation that was necessary to minimize risk of death or deterioration of the individual's condition and that could not have been provided by land ambulance and **either** of the following indications;

      1. The point of pick-up is inaccessible by land vehicle;
      2. Great distances or other obstacles (e.g., traffic, weather conditions) would impact getting the individual to the nearest hospital with appropriate facilities, if the individual were to be transported via land/ground ambulance.

Hospital-to-Hospital Air Transport

II. Hospital-to-hospital air ambulance transportation is considered **medically appropriate** when **BOTH** of the following are met:

   A. Transferring an individual to a higher level of care hospital to provide medical services that are unavailable at the transferring facility;

   B. Ground ambulance would endanger the individual's health.

III. Hospital-to-hospital air ambulance transportation services are considered **not medically appropriate** for **EITHER** of the following indications:

   A. Transportation to a non-acute care facility;

   B. Non-emergent transportation of a stabilized individual.

RELATED POLICIES

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Corporate Medical Policy

10.01.07 Land/Ground Ambulance Services

Clinical Review Preauthorization List

POLICY GUIDELINE(S)

I. Air ambulance transportation services are contract specific. Please refer to the member's subscriber contract for limitations and/or exclusions. Some contracts may:

   A. Exclude air ambulance transportation services or limit transportation distances; or

   B. Require air ambulance claims to be accompanied by a Pre-Hospital Care Report.

II. Benefits are not available for elective or convenience air ambulance transportation.

III. Air ambulance services may be **eligible for coverage** based on the time of death pronouncement of the individual in the following scenarios:

   A. After takeoff to the point-of-pickup (POP) and before the individual is loaded on board the air ambulance; or

   B. After the individual is loaded on board the air ambulance and before or upon arrival at the receiving facility.

IV. Air ambulance service is **ineligible for coverage** if the individual is pronounced dead before the ambulance is dispatched.

V. Prior authorization for interfacility transfer is contract-dependent, authorization must be obtained prior to transfer of the individual.

VI. If the member's subscriber contract requires prior authorization for inpatient admissions, prior authorization is required to accept a transfer of a registered inpatient from another facility through the emergency department.

VII. Examples of emergency situations that can be considered for air ambulance transfer:

   A. In obstetric individuals, air transport's advantage of minimized out-of-hospital time must be balanced against the risks inherent to land transport delivery. If transport is necessary for a patient whose delivery is thought to be imminent, then a ground vehicle is most often the preferred mode of transport. Air transport may be considered in the rare circumstances when ground transport is logistically not feasible and/or there are circumstances, including but not limited to, the following:

      1. Active premature labor with contractions resulting in progressive effacement and dilation of the cervix when estimated gestational age is less than 34 weeks or estimated fetal weight is less than 2,000 grams;

      2. Severe pre-eclampsia or eclampsia;

      3. Third-trimester hemorrhage;

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4. Fetal hydrops; or
5. Acute abdominal emergencies (e.g., likely to require surgery) when estimated gestational age is less than 34 weeks or estimated fetal weight is less than 2,000 grams;

B. Transplant candidates with end-stage organ disease when they have all of the following indications:

1. The candidate is on the waiting list for organ transplantation;
2. The organ to be transplanted has been procured;
3. The transplant is imminent; and
4. Organ preservation times are critical (e.g., heart or lung).

VIII. Examples of individuals for whom hospital-to-hospital air transport (e.g., emergency room to tertiary care facility) may be considered for the following indications, including, but are not limited to:

A. Individuals with dissecting aortic aneurysms, who are receiving intravenous pressor drug titration or invasive monitoring;

B. Individuals with unstable vital signs, who require enroute pharmacologic interventions that would not be available or medically advisable by ground transport; or

C. Transplantation individuals who are unable to tolerate prolonged out-of-hospital times or who have acute organ rejection.

DESCRIPTION

Ambulance services involve the assessment and administration of care to the ill or injured individual by specially trained personnel and the transportation of the individual in specially designed and equipped vehicles within an appropriate, safe, and monitored environment. Ambulance services are frequently the initial step in the chain of the delivery of medical care. This policy only addresses those ambulance services rendered by an air ambulance.

Air ambulance transportation services are provided by fixed (plane) or rotary (helicopter) wing equipment.

<u>Air ambulance transport may involve</u>

- The emergency transportation of an individual to the nearest hospital with the appropriate facilities for the treatment of the individual's illness or injury; or
- The non-emergent medical transport of a registered hospital inpatient to another location to obtain medically necessary, specialized diagnostic or therapeutic services.

<u>Ambulance Services are rendered for Emergent, Urgent or Non-Emergent Reasons</u>

- Emergent services are defined as services for a medical or behavioral condition with acute symptoms of sufficient severity that the absence of immediate medical attention would result in

placing the health of the individual in serious jeopardy, serious impairment of bodily function or serious dysfunction of any body organ or part. In the case of a behavioral condition, lack of immediate medical attention may also place the health of others in serious jeopardy.

- Urgent services are defined as services for a medical or behavioral condition that require immediate attention, although the condition may not be an emergency situation. An urgent care condition has the potential to become emergent in the absence of treatment.
- Non-emergent services are defined as services for a medical or behavioral condition that are not considered to be of an emergent or urgent nature (e.g., elective surgery).

Examples of individuals who may qualify for hospital-to-hospital air transport (e.g., emergency room to tertiary care facility) include, but are not limited to:

- Individuals with dissecting aortic aneurysms, who are receiving intravenous pressor drug titration or invasive monitoring;
- Individuals with unstable vital signs, who require enroute pharmacologic interventions that would not be available or medically advisable by ground transport; or
- Transplantation individuals who are unable to tolerate prolonged out-of-hospital times or who have acute organ rejection.

SUPPORTIVE LITERATURE

Not Applicable

PROFESSIONAL GUIDELINES

National Association of Emergency Medical Service Physicians (NAEMSP) states that some conditions (e.g., flail chest) can be clearly diagnosed in the field, while others (e.g., suspected cardiac injury or findings) requiring providers to act on clinical judgement. Air transport is generally indicated when it enables faster arrival to the appropriate facility or quicker access to advanced care by the helicopter crew. This position statement has been endorsed by the Air Medical Physician Association (AMPA).

According to the NAEMSP Guidelines for Air Medical Dispatch (Thomson et al 2003), the following are the indicated clinical situations for triage to air transport at the scene of an emergency:

<u>Trauma</u>

Scene response to injured patients probably represents the mode of helicopter utilization with the best supporting evidence.

- General and mechanism considerations:
  - Trauma score less than 12 (Glasgow Coma Scale, Systolic Blood Pressure, Respiratory);
  - Unstable vital signs (e.g., hypotension or tachypnea);
  - Significant trauma in patients less than 12 years old, greater than 55 years old, or pregnant;

- Multisystem injuries (e.g., long-bone fractures in different extremities; injury to more than two body regions);
- Ejection from vehicle;
- Pedestrian or cyclist struck by motor vehicle;
- Death in same passenger compartment as patient;
- Ground provider perception of significant damage to patient's passenger compartment;
- Penetrating trauma to the abdomen, pelvis, chest, neck, or head;
- Crush injury to the abdomen, chest, or head; or
- Fall from significant height.

- Neurologic considerations:
  - Glasgow Coma Scale score less than 10*;
  - Deteriorating mental status;
  - Skull fracture; or
  - Neurologic presentation suggestive of spinal cord injury.
- Thoracic considerations:
  - Major chest wall injury (e.g., flail chest);
  - Pneumothorax/hemothorax; or
  - Suspected cardiac injury.
- Abdominal/pelvic considerations:
  - Significant abdominal pain after blunt trauma;
  - Presence of a "seatbelt" sign or other abdominal wall contusion;
  - Obvious rib fracture below the nipple line; or
  - Major pelvic fracture (e.g., unstable pelvic ring disruption, open pelvic fracture, or pelvic fracture with hypotension).
- Orthopedic/extremity considerations:
  - Partial or total amputation of a limb (exclusive of digits);
  - Finger/thumb amputation when emergent surgical evaluation (i.e., for replantation consideration) is indicated, and rapid surface transport is not available;
  - Fracture or dislocation with vascular compromise;
  - Extremity ischemia;
  - Open long-bone fractures; or

- Two or more long-bone fractures.

- Major burns:
  - Greater than 20% body surface area;
  - Involvement of face, head, hands, feet, or genitalia;
  - Inhalational injury;
  - Electrical or chemical burns; or
  - Burns with associated injuries.
- Patients with near drowning injuries.

Non-trauma

The literature support for primary air ambulance transport of non-injured patients is limited to logistical considerations. It is conceivable that clinical indications for scene air response may be identified in the future. However, at this time prehospital providers should incorporate logistical considerations, clinical judgment, and medical oversight in determining whether primary air transport is appropriate for patients with non-trauma diagnoses.

* The Glasgow Coma Scale (GCS) [Internet] [accessed 2026 Jan 23] Available from: https://www.glasgowcomascale.org/

REGULATORY STATUS

Please refer to the Reference Section for the New York State Department of Health Regulations regarding Emergency Medical Services.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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HCPCS Codes

Code	Description
A0140	Non-emergency transportation and air travel (private or commercial); intra- or inter-state
A0430	Ambulance service, conventional air services, transport, one way (fixed wing)
A0431	Ambulance service, conventional air services, transport, one way (rotary wing)
A0435	Fixed wing air mileage, per statute mile
A0436	Rotary wing air mileage, per statute mile
S9960	Ambulance service, conventional air services, nonemergency transport, one way (fixed wing)
S9961	Ambulance service, conventional air services, nonemergency transport, one way (rotary wing)
T2007	Transportation waiting time, air ambulance and non-emergency vehicle, one-half (1/2) hour increments

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

American College of Emergency Physicians. Appropriate interfacility patient transfer [Internet]. Ann Emerg Med. 2022 Jan;79(6):e121–e123. [Accessed 2026 Feb 19] Available from: https://www.annemergmed.com/article/S0196-0644(22)00166-4/fulltext

American College of Surgeons (ACS). [Internet] National guidelines for field triage of injured patients: recommendations of the national expert panel on field triage, 2021. [Revised 2021; accessed 2026 Jan 16]. Available from: https://www.facs.org/quality-programs/trauma/systems/field-triage-guidelines/

Bekelis K, et al. Prehospital helicopter transport and survival of patients with traumatic brain injury. Ann Surg. 2015 Mar;261(3):579-85.

Brown JB, et al. External validation of the Air Medical Prehospital Triage (AMPT) score for identifying trauma patients likely to benefit from scene helicopter transport. J Trauma Acute Care Surg. 2017 Feb;82(2):270-279.

Joseph AM, et al. Helicopter versus ground ambulance transport for interfacility transfer of critically ill children. American Journal of Emergency Medicine. 2022;61: 44–51.

Nasser AH, et al. The Impact of Prehospital Transport Mode on Mortality of Penetrating Trauma Patients. Air Med J. 2020 Nov;39(6):502-505.

National Association of EMS Physicians (NAEMSP). [Internet] Position Paper: Medical direction of interfacility transports. [Original 2000 Feb, reaffirmed 2009 Jul; accessed 2026 Jan 23]. Available from: https://naemsp.org/position-statement/medical-direction-of-interfacility-transports/

New York State Department of Health (NYS DOH). [Internet] Guidelines for helicopter utilization criteria for scene response. Policy statement #05-05. [2005 Sep 12; accessed 2026 Jan 23] Available from: https://www.health.ny.gov/professionals/ems/policy/05-05.htm

New York State Department of Health (NYS DOH). [Internet] Bureau of Emergency Medical Services: New York State Trauma Program [Revised 2024 Aug; accessed 2026 Jan 23] Available from: https://www.health.ny.gov/professionals/ems/state_trauma/

New York State Department of Health (NYS DOH). [Internet] Bureau of Emergency Medical Services: EMS policies, laws and regulations. [Revised 2024 Jun; accessed 2026 Jan 23]. Available from: https://www.health.ny.gov/professionals/ems/policies_laws_regs/

New York State Insurance Laws: § 3216 (i) (24) (a). [Internet] [accessed 2026 Jan 23] Available from: https://www.nysenate.gov/legislation/laws/ISC/3216

New York State Insurance Laws: § 3221 (1) (15) (a). [Internet] [accessed 2026 Jan 23] Available from: https://www.nysenate.gov/legislation/laws/ISC/3221

New York State Insurance Laws: § 4303 (aa) (1). [Internet] [accessed 2026 Jan 23] Available from: https://www.nysenate.gov/legislation/laws/ISC/4303

Stewart K, et al. Association of interfacility helicopter versus ground ambulance transport and in-hospital mortality among trauma patients. Prehosp Emerg Care. Sep-Oct 2021;25(5):620-628.

Thomson DP and Thomas SH. [Internet] Guidelines for air medical dispatch: prehospital emergency care 2003. Apr-Jun;7(2):265-271 [Published online July 2009; accessed 2026 Jan 23] Available from: https://naemsp.org/position-statement/guidelines-for-air-medical-dispatch/

Van Tuyl A, et al. Characteristics and demographics of patients requiring emergent air medical. Emerg Med Int. 2022 Mar 1;2022:3044891:7 pages.

Webb T, et al. Validation of air medical prehospital score in determining resource utilization at level I trauma centers. Air Medical Journal. 2024;43:101-105.

SEARCH TERMS

Medevac

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Ambulance Services are not addressed in National or Regional Medicare coverage determinations or policies.

Please refer to the Medicare Benefit Policy Manual, Chapter 10 - Ambulance Services. [Last updated 2025 Nov 26; accessed 2026 Jan 23] Available from: Medicare Benefit Policy Manual Chapter 10-Ambulance Services

PRODUCT DISCLAIMER

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- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- CDPHP utilizes the New York State Medicaid Transportation Manual Policy Guidelines to determine ambulance coverage availability for Medicaid: https://www.emedny.org/ProviderManuals/Transportation/PDFS/Transportation_Manual_Policy_Section.pdf
- CDPHP utilizes the New York State Medicaid Transportation Manual Policy Guidelines to determine air ambulance coverage availability for Child Health Plus: https://www.emedny.org/ProviderManuals/Transportation/PDFS/Transportation_Manual_Policy_Section.pdf

POLICY HISTORY/REVISION

Committee Approval Dates

New: 10/92

Revised: 08/94, 04/97, 05/98, 04/99, 01/00, 10/02, 09/03, 04/04, 01/05, 10/05,07/08, 05/09, 5/10, 11/10, 05/11, 05/12, 07/12, 11/12, 05/13, 11/13, 01/14, 05/14, 05/15, 05/16, 05/18, 05/19, 04/20 (regulatory revision), 5/22, 1/23, 5/23, 11/23, 3/24, 5/26

Reviewed: 03/93, 08/95, 06/96, 03/01, 10/06, 09/06, 09/07, 05/17, 05/21, 5/24, 5/25

Date	Summary of Changes
6/1/2026	• Transitioned Ambulance and Transport Services policy, 1370/20.000092 to Lifetime HealthCare Companies policy template • Annual review, removing emergent or urgent conditions from policy statements
3/1/2024	• Added additional information under paramedic intercept section in regard to non-volunteer BLS entities
6/1/2023	No Criteria changes:

	• Clarified air ambulance services for interfacility transports • Added verbiage in regards to reviewing medical necessity of air ambulance services • Under the Medicare section added the following Medicare Language: o air ambulance transportation for deceased members and o utilizing air ambulance vs ground ambulance
5/12/2023	• Removed expanded coverage added for the COVID-19 public health emergency
1/1/2023	• Added coverage criteria for air ambulance to the Child Health Plus section
9/1/2022	• Clarified paramedic intercept service
04/01/2020	• Updates related to COVID-19 pandemic

MEDICAL POLICY

Medical Policy Title	**Ambulance: Land/Ground**
Policy Number	**10.01.07**
Current Effective Date	**September 1, 2026**
Next Review Date	**March 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Emergency land/ground ambulance transportation is considered **medically appropriate** (when the New York State (NYS) mandate does not apply), when **ALL** of the following criteria are met:

- A. The services must be provided by an ambulance service that is issued a certificate under the NYS Public Health Law;
- B. The ambulance must have the necessary patient-care equipment and supplies;
- C. The individual's condition must be such that any other form of transportation would be medically contraindicated; **and**
- D. The individual is transported to the nearest hospital with the appropriate facilities for the treatment of the patient's illness or injury.

II. Non-emergent ambulance services for medical transport are considered **medically appropriate** when **ALL** of the following criteria are met:

- A. The services must be provided by an ambulance service that is issued a certificate under the NYS Public Health Law;
- B. The ambulance must have the necessary patient-care equipment and supplies;
- C. The individual's condition must be such that any other form of transportation would be medically contraindicated;
- D. The provider of the specialized service is the nearest facility with the required capabilities;

  and

- E. **One** of the following indications:
  1. From a non-participating hospital to a participating hospital;
  2. To a hospital that provides a higher level of care that was not available at the original hospital;
  3. When individual has been approved for interfacility transfer (CMP #11.01.18 Interfacility Transfer of a Registered Patient); **or**

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4. From an acute care facility to a sub-acute setting.

III. Elective or convenience ambulance transportation (e.g., patient/patient's family desire, transportation from one facility to another facility within the same health care system for capacity management) is considered **not medically necessary**.

RELATED POLICIES

Corporate Medical Policy

11.01.06 Air Ambulance Services

Administrative Policy

54 Ambulance-Transport Service

POLICY GUIDELINE(S)

I. When the NYS mandate does not apply to ambulance transportation, contractual distance restrictions may apply. Refer to the member's subscriber contract regarding specific limitations.

II. The non-emergent medical transport of a bed-confined patient, when specialized medical services during transport are not necessary, is considered to be a non-ambulance transportation and is **ineligible for coverage** as non-ambulance transportation, such as ambulette, van or taxicab is generally excluded by contract.

III. Transportation services utilizing vehicles that are not equipped and certified under the New York Public Health Law to provide emergency medical services (e.g., ambulette, van, or taxicab) are **ineligible for coverage** as they do not provide medical care or monitoring during transportation.

IV. Ambulance services for deceased members may be **eligible for coverage** if the patient is legally pronounced dead after the ambulance is called, but before pick-up or enroute to the hospital. These services are **ineligible for coverage** if the patient is pronounced dead before the ambulance is called.

V. Prior authorization for interfacility transfer is contract-dependent, and, where a member's subscriber contract so requires, authorization must be obtained prior to transfer of the patient. Some members' subscriber contracts exclude coverage for the transfer of its members between health care facilities.

VI. Accepting the transfer of a registered inpatient from another facility through the emergency department, when the patient is not in need of emergent services, does not negate the requirement for prior authorization of the transfer if the member contract requires prior authorization for inpatient admissions.

DESCRIPTION

Ambulance services involve the assessment and administration of care to the ill or injured individual by specially trained personnel and transportation of the individual in specially designed and equipped

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vehicles within an appropriate, safe and monitored environment. The emergency medical personnel, ambulances, and equipment must follow New York State laws, codes, rules and regulations not addressed in this policy. Ambulance services are frequently the initial step in the chain of the delivery of medical care.

Ambulance and Medical Transport may involve:

- The emergency transportation of an individual to the nearest hospital with the appropriate facilities for the treatment of the individual's illness or injury; or
- The non-emergent medical transport of a registered hospital inpatient to another location to obtain medically necessary, specialized diagnostic, or therapeutic services.

Ambulance Services: Emergent, Urgent or Non-Emergent Reasons

I. An Emergency Condition is defined as services for a medical or behavioral condition that manifests itself by acute symptoms of sufficient severity, including severe pain, such that a prudent layperson, possessing an average knowledge of medicine and health, could reasonably expect the absence of immediate medical attention to result in:
   A. Placing the health of the person afflicted with such condition or, with respect to a pregnant woman, the health of the woman or her unborn child in serious jeopardy, or in the case of a behavioral condition, placing the health of such person or others in serious jeopardy;
   B. Serious impairment to such person's bodily function;
   C. Serious dysfunction of any body organ or part of such person; or
   D. Serious disfigurement of such person.

II. Urgent services are defined as services for a medical or behavioral condition that require immediate attention, although the condition may not be an emergency situation. An urgent care condition has the potential to become emergent in the absence of treatment.

III. Non-emergent services are defined as services for a medical or behavioral condition that are not considered to be of an emergent or urgent nature (e.g., elective surgery).

SUPPORTIVE LITERATURE

Not Applicable

PROFESSIONAL GUIDELINE(S)

In an updated Joint Position Statement of the Recommended Essential Equipment for Basic Life Support and Advanced Life Support Ground Ambulances 2020 co-authored by National Association of Emergency Medical Services (EMS) Physicians (NAEMSP)/American Academy of Pediatrics (AAP)/ American College of Surgeons Committee on Trauma (ACSCOT)/EMS for Children Innovation and Improvement Center (EIIC)/Emergency Nurses Association (ENA)/National Association of State EMS Officials (NASEMSO) and endorsed by National Association of Emergency Medical Technicians (NAEMT), Lyng et al (2021b) stated that the delivery of high-quality and effective EMS care is

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dependent on several factors, including but not limited to:

- Credentialed providers, who have demonstrated appropriate knowledge, ability, psychomotor skills, and critical thinking.
- Clinical protocols or guidelines supported by the best available scientific evidence.
- Equipment and supplies necessary to deliver appropriate care as indicated by clinical protocols/guidelines for patients of all ages.

The purpose of this statement is to review and revise the 2014 version of the joint position statement to include a review of equipment lists established by individual state/territory rules and statutes for all U.S. states and territories and to establish recommended equipment standards to build consistency across the EMS system of care and to facilitate advances in the delivery of quality and cost-effective EMS care. The statement also establishes that EMS agencies should include in their routine quality assurance practices efforts to assess that:

- Their EMS providers are outfitted with all necessary equipment for them to perform clinical care.
- All equipment and supplies undergo appropriate preventive maintenance and routine function checks.
- Malfunctioning or missing equipment issues are quickly addressed to preserve readiness to respond and provide patient care continuously.

The statement includes a list of required equipment for basic life support (BLS) Emergency Ground Ambulances and Advanced Life Support (ALS) Emergency Ground Ambulances, a list of optional equipment that should be used based on local needs and resources and a list of optional medications.

REGULATORY STATUS

The NYS Insurance Law mandates coverage for pre-hospital emergency services and land transportation provided by ambulance services certified under the NYS Public Health Law. The mandate requires coverage of pre-hospital emergency services and ground ambulance transport when a prudent layperson, possessing an average knowledge of medicine and health, could reasonably expect the absence of such transportation to result in:

- Placing the health of the person afflicted with such condition (or with respect to a pregnant woman, placing the health of the woman or her unborn child), in serious jeopardy, or in the case of a behavioral condition, placing the health of such person or others in serious jeopardy;
- Serious impairment to such person's bodily function;
- Serious dysfunction of any bodily organ or part of such person; or
- Serious disfigurement of such person.

The NYS mandate does not require coverage of air ambulance transportation and explicitly excludes ambulance transportation between hospitals or health care facilities.

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The NYS mandate applies to all major medical or similar comprehensive-type contracts, including Health Maintenance Organization (HMO) contracts and Child Health Plus contracts.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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HCPCS Codes

Code	Description
A0021	Ambulance service, outside state per mile, transport (Medicaid only)
A0080-A0130	Non-emergency transportation; ground vehicle (code range)
A0160-A0210	Non-emergency transportation (code range)
A0225	Ambulance service, neonatal transport, base rate, emergency transport, one way
A0380	BLS mileage (per mile)
A0382-A0384	BLS disposable supplies (code range)
A0390	ALS mileage (per mile)
A0392-A0398	ALS disposable supplies (code range)
A0420	Ambulance waiting time (ALS or BLS), one-half (1/2) hour increments
A0422	Ambulance (ALS or BLS) oxygen and oxygen supplies, life sustaining situation
A0424	Extra ambulance attendant, ground (ALS or BLS) or air (fixed or rotary winged)
A0425	Ground mileage, per statute mile
A0426	Ambulance service, ALS, non-emergency transport, level 1 (ALS 1)
A0427	Ambulance service, ALS, emergency transport, level 1 (ALS 1 – emergency)
A0428	Ambulance service, BLS, non-emergency transport (BLS)

Code	Description
A0429	Ambulance service, BLS, emergency transport (BLS, emergency)
A0432	Paramedic intercept, rural area, transport furnished by a volunteer ambulance company which is prohibited by state law from billing third-party payors
A0433	Advanced life support, level 2 (ALS2)
A0434	Specialty care transport (SCT)
A0888	Non-covered ambulance mileage, per mile (e.g., for miles traveled beyond closest appropriate facility)
A0998	Ambulance response and treatment, no transport
A0999	Unlisted ambulance services
S0207	Paramedic intercept, non-hospital-based ALS service (non-voluntary), non-transport
S0208	Paramedic intercept, hospital-based ALS service (non-voluntary), non-transport
S0215	Non-emergency transportation; mileage, per mile
T2001-T2007	Non-emergency transportation (code range)
T2049	Non-emergency transportation; stretcher van, mileage; per mile

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

Al Badawi AK and Nashwan AJ. The future of prehospital emergency care: embracing AI applications in ambulance services. International Emergency Nursing 2024;72:10138.

American College of Emergency Physicians. Appropriate interfacility patient transfer [Internet]. Ann Emerg Med. 2022 Jan;79(6):e121–e123. [accessed 2026 Feb 19] Available from: https://www.annemergmed.com/article/S0196-0644(22)00166-4/fulltext

Centers for Disease Control and Prevention (CDC). [Internet] Morbidity and mortality report: guidelines for field triage of injured patients: recommendations of the National Expert Panel on field triage, 2011. [original 2012 Jan 13; accessed 2026 Jan 27] Available from: https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6101a1.htm

Dixon M, et al. A systematic review of ambulance service-based randomised controlled trials

in stroke. Neurological Sciences 2023;44:4363–4378.

Elkbuli A, et al. Emergency medical service transport time and trauma outcomes at an urban level 1 trauma center: evaluation of prehospital emergency medical service response. The American Surgeon 2022;88(6):1090-1096.

Groth-Rasmussen Koch MA, et al. Interhospital transfers in elderly trauma patients. Injury 2025;56: 111998.

Kai TR, et al. The effect of emergency medical system transport time on in route clinical decline in a rural system. J Trauma Acute Care Surg 2020 Apr;88(6):734-741.

Lyng J, et al. Recommended essential equipment for basic life support and advanced life support ground ambulances 2020: a joint position statement. Prehosp Emerg Care. 2021b May-Jun;25(3):451-459.

Nasser AH, et al. The impact of prehospital transport mode on mortality of penetrating trauma patients. Air Med J 2020 Nov;39(6):502-505.

National Association of EMS Physicians/American College of Emergency Physicians. Alternate ambulance transportation and destination. Joint position paper. Approved Jan 2001, reaffirmed Jan 2007. Prehosp Emerg Care 2001 Jul-Sep;5(3):289.

National Association of Emergency Medical Service Physicians. [Internet]. Position statement: medical direction of interfacility transports. [original 2000 Feb, reaffirmed 2005 Oct; accessed 2026 Jan 27] Available from: https://www.tandfonline.com/doi/abs/10.1080/10903120090941128

National Highway Traffic Safety Administration (NHTSA). [Internet]. Guide for interfacility patient transfer. DOT HS 810 599 [original 2006 Apr; accessed 2026 Jan 27] Available from: https://www.ems.gov/assets/Interfacility_Transfers.pdf

New York State Department of Health (NYS DOH). [Internet]. Bureau of EMS and Trauma Systems. [original date not available, revised 2021 May; accessed 2026 Jan 27] Available from: http://www.health.ny.gov/professionals/ems/

New York State Department of Health (NYS DOH). [Internet]. Chapter VI of Title 10 (Health) of the official compilation of codes, rules and regulations. State emergency medical services (EMS) code. Part 800. [original 2019 Jan, updated effective date 2024 Jun 5; accessed 2026 Jan 27] Available from: https://regs.health.ny.gov/content/part-800-emergency-medical-services

New York State Department of Health (NYS DOH). [Internet]. Medical transportation. bureau of EMS. Policy statement 99-08. [original 1999 Oct; accessed 2026 Jan 27] Available from: https://www.health.ny.gov/professionals/ems/policy/99-08.htm

New York State Department of Health (NYS DOH). [Internet]. Regional EMS councils. [revised 2026 Dec; accessed 2026 Jan 27] Available from: http://www.health.ny.gov/professionals/ems/regional

New York State Insurance Law. § 3216 (i) (24) (a) [Internet] [accessed 2026 Jan 27] Available from: https://www.nysenate.gov/legislation/laws/ISC/3216

New York State Insurance Law. § 3221 (1) (15) (a) [Internet] [accessed 2026 Jan 27] Available from: https://www.nysenate.gov/legislation/laws/ISC/3221

New York State Insurance Law. § 4303 (aa) (1) [Internet] [accessed 2026 Jan 27] Available from: https://www.nysenate.gov/legislation/laws/ISC/4303

Stewart K, et al. Association of interfacility helicopter versus ground ambulance transport and in-hospital mortality among trauma patients. Prehosp Emerg Care Sep-Oct 2021;25(5):620-628.

Takeuchi A, et al. Ambulance transport intervals for children and adults with anaphylaxis: a retrospective analysis. Cureus. 2025 Jul 13;17(7):e87819.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Ambulance Services are not addressed in National or Regional Medicare coverage determinations or policies.

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- CDPHP utilizes the New York State Medicaid Transportation Manual Policy Guidelines to determine air ambulance coverage availability for Child Health Plus: https://www.emedny.org/ProviderManuals/Transportation/PDFS/Transportation_Manual_Policy_Section.pdf

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 10/92 **Revised**: 08/94, 04/97, 05/98, 04/99, 01/00, 10/02, 09/03, 04/04, 01/05, 10/05,07/08, 05/09, 5/10, 11/10, 05/11, 05/12, 07/12, 11/12, 05/13, 11/13, 01/14, 05/14, 05/15, 05/16, 05/18, 05/19, 04/20 (regulatory revision), 5/22, 1/23, 5/23, 11/23, 3/24, 5/26 **Reviewed**: 03/93, 08/95, 06/96, 03/01, 10/06, 09/06, 09/07, 05/17, 05/21, 5/24, 5/25	
Date	**Summary of Changes**
6/1/2026	• Transitioned Ambulance and Transport Services policy, 1370/20.000092 to Lifetime HealthCare Companies policy template. • Annual review. Removal of criteria for urgent ambulance transportation, and removal of criteria addressing cost effectiveness.
3/1/2024	• Added additional information under paramedic intercept section in regard to non-volunteer BLS entities.
6/1/2023	No Criteria changes: • Clarified air ambulance services for interfacility transports • Added verbiage in regards to reviewing medical necessity of air ambulance services • Under the Medicare section added the following Medicare Language: o Air ambulance transportation for deceased members and • Utilizing air ambulance vs ground ambulance
5/12/2023	• Removed expanded coverage added for the COVID-19 public health emergency
1/1/2023	• Added coverage criteria for air ambulance to the Child Health Plus section
9/1/2022	• Clarified paramedic intercept service
04/01/2020	• Updates related to COVID-19 pandemic

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: AMBULATORY ELECTROENCEPHALOGRAPHY (EEG)

POLICY EFFECTIVE DATE:	11/1/2024
Policy Control #:	1370/20.000519
Next Annual Review:	July 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

Ambulatory Electroencephalography (EEG): 95700, 95705, 95706, 95707, 95708, 95709, 95710, 95711, 95712, 95713, 95714, 95715, 95716, 95717, 95718, 95719, 95720, 95721, 95722, 95723, 95724, 95725, 95726

Routine "Resting" Electroencephalography (EEG): 95812, 95813, 95816, 95819, 95822

DESCRIPTIONS

An electroencephalogram (EEG) is a diagnostic test that measures the electrical activity of the brain (brainwaves) using highly sensitive recording equipment attached to the scalp by fine electrodes. It is used to diagnose neurological conditions.

EEGs can be recorded by ambulatory cassette. Ambulatory cassette-recorded EEGs offer the ability to record the EEG on a long-term, outpatient basis. Electrodes for at least four (4) recording channels are placed on the patient. The cassette recorder is attached to the patient's waist or on a shoulder harness. Recorded electrical activity is analyzed by playback through an audio amplifier system and video monitors.

Ambulatory EEG monitoring may facilitate the differential diagnosis between seizures and syncopal attacks, sleep apnea, cardiac arrhythmias or hysterical episodes. The test may also

allow the investigator to identify the epileptic nature of some episodic periods of disturbed consciousness, mild confusion, or peculiar behavior, where resting EEG is not conclusive. It may also allow an estimate of seizure frequency, which may at times help to evaluate the effectiveness of a drug and determine its appropriate dosage.

POSITION STATEMENT

CDPHP considered ambulatory electroencephalography (EEG) medically necessary for the following indications:

- Inconclusive EEGs;
- Experiencing episodic events where epilepsy is suspected but the history, examination, and routine EEG do not resolve the diagnostic uncertainties;
- Patients with confirmed epilepsy who are experiencing suspected non-epileptic events or for classification of seizure type (only ictal recordings can reliably be used to classify seizure type (or types) which is important in selecting appropriate anti-epileptic drug therapy);
- Differentiating between neurological and cardiac related problems;
- Adjusting anti-epileptic medication levels;
- Localizing seizure focus for enhanced patient management;
- Identifying and medicating absence seizures;
- For suspected seizures of sleep disturbances;
- Seizures which are precipitated by naturally occurring cyclic events or environmental stimuli which are not reproducible in the hospital or clinic setting.

Ambulatory monitoring is not necessary to evaluate most seizures, which are usually readily diagnosed by routine EEG studies and history.

POLICY CONSIDERATIONS

Ambulatory electroencephalography (EEG) should always be preceded by a routine EEG. A routine EEG is described by Current Procedural Terminology (CPT) codes 95812, 95813, 95816, 95819, or 95822 and refers to a routine EEG recording of less than a 24-hour continuous duration.

A routine "resting" (EEG) (as described by CPT codes 95812, 95813, 95816, 95819 or 95822) must be performed prior to performing an ambulatory continuous EEG. A claim for the routine EEG must have been submitted to CDPHP with a date of service (DOS) within one year of the DOS of the ambulatory EEG.

Requirements for a routine "resting" EEG is waived for medically necessary continuous EEG performed in an intensive care unit (ICU).

POLICY NAME: AMBULATORY ELECTROENCEPHALOGRAPHY (EEG)

EXCLUSIONS

Ambulatory EEG is considered not medically necessary in circumstances including but not limited to the following:

- Study of neonates or unattended, non-cooperative patients;
- Localization of seizure focus/foci when the seizure symptoms and/or other EEG recordings indicate the presence of bilateral foci or rapid generalization.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP:	Subject to all terms and conditions noted above in the policy.

SOURCES

1. Other payers
2. CMS Local Coverage Determination : EEG-Ambulatory Monitoring (L33399): https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33399&ver=14&bc=0

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: AMBULATORY ELECTROENCEPHALOGRAPHY (EEG)

POLICY APPROVAL DATES

New: 7/24

Revised:

Reviewed: 7/25, 7/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
11/1/2024	New

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BEHAVIORAL HEALTH RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.
(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: AMBULATORY MENTAL HEALTH PROGRAMS

POLICY EFFECTIVE DATE:	1/1/23
Policy Control #:	1370/20.000488
Next Annual Review:	March 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice

PROCEDURE CODES

H0002, H0040, H2012, H2018, H2019, H2015, T1015, T2034

DESCRIPTION

Ambulatory mental health programs include the following:

- **Assertive Community Treatment (ACT) and Youth Assertive Community Treatment (Youth ACT)** – These comprehensive services are for individuals with serious mental illness whose needs have not been met by traditional service delivery approaches. ACT is an evidence-based practice that incorporates treatment, rehabilitation, case management, and support services delivered by a mobile, multi-disciplinary mental health team. ACT supports recipient recovery through an individualized approach that provides recipients with the tools to obtain and maintain housing, employment, relationships, and relief from symptoms and medication side effects. The nature and intensity of ACT services are developed through a person-centered service planning process and adjusted as needed in daily ACT team meetings.

- **Continuing Day Treatment (CDT)** – A program which provides seriously mentally ill adults with the skills and supports necessary to remain in the community or work toward a more

independent level of functioning. Participants often attend several days per week with visits lasting more than an hour.

- **Personalized Recovery Oriented Services (PROS) –** A comprehensive recovery oriented program for individuals with severe and persistent mental illness. Through a single plan of care, the program model integrates treatment, support, and rehabilitation in a manner that facilitates the individual's recovery. The PROS model is person-centered, strength-based, and comprised of a menu of group and individual services designed to assist a participant to overcome mental health barriers and achieve a desired life role.

- **Crisis Residential Services –** Crisis Residence Programs provide short-term interventions to individuals experiencing psychiatric crisis. These programs address the cause of the individual's psychiatric crisis and avert or delay the need for emergency department stabilization or acute psychiatric inpatient hospitalization. Programs provide supports to stabilize and transition individuals back to the community.

RELATED POLICIES/DOCUMENTS

None

POSITION STATEMENT

CDPHP does not provide coverage for Assertive Community Treatment (ACT), Continuing Day Treatment (CDT), or Personalized Recovery Oriented Services (PROS), except for Select Plan/HARP as described below.

POLICY CONSIDERATIONS

SELECT PLAN/HARP:

Benefits are provided for Assertive Community Treatment (ACT), Continuing Day Treatment (CDT), Personalized Recovery Oriented Services (PROS), and Crisis Residential Services when criteria outlined below is met.

POLICY NAME: AMBULATORY MENTAL HEALTH PROGRAMS

Assertive Community Treatment (ACT)

Eligibility Requirements
Enrollee is 18 years of age or older and meets either of the conditions outlined below.

Enrollee with serious functional impairments demonstrates at least one of the following conditions:

- Inability to consistently perform practical daily living tasks required for basic adult functioning in the community without significant support or assistance from others such as family, relatives or friends;
- Inability to be consistently employed at a self-sustaining level or inability to consistently carry out the homemaker role;
- Inability to maintain a safe living situation (e.g., repeat evictions or loss of housing).

OR

Enrollee with continuous high-service needs demonstrates one or more of the following conditions:

- Inability to participate or succeed in traditional, office-based services or case management
- High use of acute psychiatric hospitals (two hospitalizations within one year, or one hospitalization of 60 days or more within one year)
- High use of psychiatric emergency or crisis services
- Persistent severe major symptoms (e.g., affective, psychotic, suicidal or significant impulse control issues)
- Co-existing substance abuse disorder (duration greater than 6 months).
- Current high risk or recent history of criminal justice involvement
- Court ordered pursuant to MHL §9.60 to participate in Assisted Outpatient Treatment
- Inability to meet basic survival needs or homeless or at imminent risk of becoming homeless
- Residing in an inpatient bed or in a supervised community residence, but clinically assessed to be able to live in a more independent setting if intensive community services are provided
- Currently living independently but clinically assessed to be at immediate risk of requiring a more restrictive living situation (e.g., community residence or psychiatric hospital) without intensive community services

Admission/Continuing Stay
ACT serves persons who have a severe and persistent mental illness listed in the diagnostic nomenclature (current diagnosis per DSM IV) that seriously impairs their functioning in the community. Priority is given to people with schizophrenia, other psychotic disorders (e.g., schizo-affective disorder), bipolar disorder and/or major or chronic depression, because these illnesses more often cause long-term psychiatric disability. Priority is also given to individuals with continuous high-service needs that are not being met in more traditional service settings. Individuals with a primary diagnosis of a personality disorder(s), substance abuse disorder, or mental retardation are not appropriate for ACT.

Youth Assertive Community Treatment (Youth ACT)

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POLICY NAME: AMBULATORY MENTAL HEALTH PROGRAMS

Youth Assertive Community Treatment (Youth ACT)
Youth Assertive Community Treatment (ACT) is a program designed to address the significant needs of children ages 10 up to 21, who are at risk of entering, or returning home from high intensity services, such as inpatient settings or residential services, through the use of a multi-disciplinary team. Children with significant psychiatric needs, who are at risk of institutional level of care, require intensive interventions in order to adequately support the child and family's complex needs, to avoid high end services or facilitate and support a successful transition back to community. Youth ACT serves as a critical component in the children's continuum of care.

Eligibility Requirements
- Enrollee is at least 10 at the time of enrollment and may be served up to the age of 21
- Enrollee must have a determination of Serious Emotional Disturbance (SED) defined as:
    - A child or adolescent having a designated mental illness diagnosis according to the most current Diagnostic and Statistical Manual of Mental Disorders AND has experienced functional limitations due to emotional disturbance over the past 12 months on a continuous or intermittent basis.
- Enrollee must have continuous high service needs that are not being met in more traditional service settings
- Enrollee's county of residence must be within the Youth ACT program's catchment area (i.e., county(ies) licensed to serve)

Referral, Admission, Continuing Stay, and Discharge
Admission to Youth ACT is managed through a local Children's Single Point of Access (C-SPOA). There are specific considerations for transition aged youth (TAY ages 18-21), as both Youth and Adult ACT teams can serve TAY individuals. For individuals on Assisted Outpatient Treatment (AOT), C-SPOA must make a referral to an Adult ACT team, as they have the expertise to serve these individuals. However, for those individuals not on an AOT, C-SPOA should take into consideration individual choice and the developmental and clinical needs of the individuals.

Enrollees/Families that meet any of the following criteria may be discharged:
- Enrollee and family no longer want to receive services through Youth ACT
- All parties involved concur that the enrollee has met the goals of his/her Individualized Service Plan and no longer requires Youth ACT services
- Enrollee no longer meets the definition of SED or has complex mental health needs requiring ACT level of care
- Enrollees who are hospitalized or locally incarcerated for three months or longer
- Enrollee has been admitted to another program (e.g., Community Residence, RTF)
- Enrollee turns 21
- Enrollee/family moves out of the geographic area served by the Youth ACT team in which they are enrolled. The Youth ACT team is responsible for transfer of mental health service to an appropriate provider and must maintain contact with the child/family until the provider and child/family are engaged in this new service arrangement.

Continuing Day Treatment (CDT)

Eligibility Requirements
- Enrollee is 18 years of age or older; **and**
- Enrollee has a designated mental illness diagnosis; **and**

- Enrollee has a function disability due to the severity and duration of mental illness; **and**
- Services are recommended by a licensed practitioner of healing arts

Admission
Enrollee must (all of the following):
- Have three or more areas of significant impairment in functioning
- Be experiencing symptoms impairing thought, mood, behavior or perception that interfere with the ability to function with a lesser level of service.
- Have cognitive capacity to engage in and benefit from this level of treatment
- Reasonably be expected to benefit in improved functioning at work, school, or social relationships
- Need a highly structured, focused treatment approach to accomplish improvement and to avoid relapse requiring higher level of treatment

Continuing Stay
For enrollee to continue treatment, the following criteria must be met (all of the following):
- Condition continues to meet admission criteria
- Treatment plan contains specific goals and documented measurable progress toward goals
- An active discharge plan is in place
- Attempts to coordination care and transition to other services are documented, as clinically indicated
- Interventions provided and enrollee's response documented in the enrollee's daily record

Personalized Recovery Oriented Services (PROS)

Eligibility Requirements
- Enrollee is 18 years of age or older; **and**
- Enrollee has a designated mental illness diagnosis; **and**
- Enrollee has a function disability due to the severity and duration of mental illness; **and**
- Services are recommended by a licensed practitioner of healing arts

Pre-Admission
The provider does not need to submit an initial service recommendation (ISR) for the pre-admission phase.

Admission
PROS provider will have 60 days from admission to develop an *Individualized Recovery Plan* (IRP). Services identified in the IRP may include:
- Intensive Rehabilitation (IR);
- Ongoing Rehabilitation and Supports (ORS);
- Clinical Treatment (CT);
- Community Rehabilitation and Support (CRS)

Active Rehabilitation
Once the IRP is completed, the enrollee is now in active rehabilitation. The IRP is reviewed and updated, at a minimum, every six months.
- For enrollees receiving Intensive Rehabilitation or Ongoing Rehabilitation and Supports, these

services identified in the IRP are to be assessed, at a minimum, every three months for continued need.
- Community Rehabilitation and Support (CRS) and clinic treatment (CT) services are reviewed, at a minimum, every six months.

Continued coverage is available when documentation confirms one of the following:
- Enrollee has an active recovery goal and shows progress toward achieving it; **or**
- Enrollee has met and is sustaining a recovery goal, but would like to pursue a new goal; **or**
- Enrollee requires a PROS level of care in order to maintain psychiatric stability and there is not a less restrictive level if care that is appropriate; **or**
- Without PROS services, the enrollee would require a higher level of care

Crisis Residential Services

There are two Crisis Residential Service Programs available to individuals aged 18 and older.

Residential Crisis Support Programs

Voluntary residential program for individuals experiencing symptoms of mental illness and/or challenges in daily life that create risk for an escalation of symptoms that cannot be managed in the individual's home and community environment without onsite supports. Individuals receive Residential Crisis Support Program services for up to 28 days.

Mental health diagnosis is not required to receive Residential Crisis Support Program services.

Service Components:
- Service Planning
  - Engagement with identified supports
  - Safety planning
  - Integration of direct care and support services
- Care Coordination
  - Case management activities that emphasize discharge planning
  - Collaboration and linkages with service options in the community that provide continuation of ongoing treatment and rehabilitation
- Peer Support
- Assistance in personal care and activities of daily living
- Medication management, monitoring, and training
- Crisis Respite
- For individuals 18-20:
  - Mental Health Assessment
  - Individual and Family Counseling
  - Family Support

Intensive Crisis Residence Programs

Voluntary residential treatment program for individuals experiencing a psychiatric crisis, including acute escalation of mental health symptoms. The program is short-term (up to 28 days). Individuals in need of this program are at imminent risk for loss of functional abilities and may raise safety concerns for themselves and others without this level of care. The immediate goal of this program is to provide treatment and supports to help the individual stabilize and return to previous levels of functioning.

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POLICY NAME: AMBULATORY MENTAL HEALTH PROGRAMS

Intensive Crisis Residence Programs can also be used as an inpatient hospitalization step-down service after discharge.

Mental health diagnosis is required to receive Intensive Crisis Residence Program services.

Service Components:

- Comprehensive Assessment
- Service Planning
  - Engagement with identified supports
  - Safety planning
  - Integration of direct care and support services
- Care Coordination
  - Case management activities that emphasize discharge planning
  - Collaboration and linkages with service options in the community that provide continuation of ongoing treatment and rehabilitation
- Individual and family counseling
  - Medication therapy
  - Individual and group counseling
  - Engagement and support to address co-occurring disorders
- Assistance in personal care and activities of daily living
- Medication management, monitoring, and training
- Crisis respite

EXCLUSIONS

Individuals with a primary diagnosis of a personality disorder(s); substance abuse disorder or mental retardation are not appropriate for ACT.

Individuals with a primary diagnosis of a personality disorder(s), or solely a substance use disorder without having co-occurring and significant mental health needs and diagnosis, are not appropriate for Youth ACT.

Children with Developmental Disabilities: Children with an IQ of 51 and above may be eligible for Youth ACT. Youth ACT is equipped to serve children whose IQ is 80 and above. For children whose IQ is 51-69, determinations will be made on a case by case basis. Children whose IQ is below 51 are not appropriate for Youth ACT.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	Child Health Plus provides coverage for Assertive Community Treatment (ACT), Youth ACT, and select Crisis Intervention services under Children and Family Treatment and Support Services (CFTSS). See Ambulatory Mental Health Programs for Children Policy for additional information. Child Health Plus does not provide coverage for Continuing Day

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POLICY NAME: AMBULATORY MENTAL HEALTH PROGRAMS

	Treatment (CDT) and Personalized Recovery Oriented Services (PROS)
MEDICARE ADVANTAGE:	Medicare Choices does not provide coverage for Assertive Community Treatment (ACT), Continuing Day Treatment (CDT), or Personalized Recovery Oriented Services (PROS), or Crisis Residential Services.
SELECT PLAN/HARP:	Subject to all terms and conditions noted above in the policy.

SOURCES

1. Transition of Behavioral Health Benefit into Medicaid Managed Care and Health and Recovery Program Implementation, October 2015, NYS DOH OMH OASAS
2. Crisis Intervention Benefit: Adult Crisis Residence Benefit and Billing Guidance, October 2020

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POLICY APPROVAL DATES

New: 05/16

Revised: 05/18, 05/19, 05/20, 12/20, 12/22, 5/23

Reviewed: 05/17, 05/21, 05/22, 4/25, 4/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
1/1/2023	Added CHP benefit
12/1/2020	Addition of Crisis Residential Services description, coverage criteria, and code T2034

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POLICY NAME: AMBULATORY MENTAL HEALTH PROGRAMS

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: AMNIOTIC MEMBRANE PLACEMENT FOR TREATMENT OF OCULAR SURFACE DISORDERS

POLICY EFFECTIVE DATE:	1/1/2026
Policy Control #:	1370/20.000507
Next Annual Review:	January, 2027

DISCLAIMER

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PROCEDURE CODES

65778	Placement of amniotic membrane on the ocular surface; without sutures
65779	Single layer, sutured
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers
65781	Limbal stem cell allograft (e.g., cadaveric or living donor)
65782	Limbal conjunctival autograft (includes obtaining graft)
V2790	Amniotic membrane for surgical reconstruction, per procedure

DESCRIPTIONS

Human amniotic membrane is a unique collagenous membrane derived from the innermost submucosa of the placenta. It consists of a collagen-rich thick basement membrane and an avascular stroma. Amniotic tissue has been used in a variety of surgical procedures to cover a defect on the surface of the eye and facilitate wound healing as well as decreasing inflammation. Some defects are created by the surgical excision of lesions or necrotic tissue while others result from injury, infection, or degeneration. The usefulness of amniotic membrane has been attributed to its anti-inflammatory, anti-fibrotic, anti-vascularization, and anti-scarring effects, and also to its ability to enhance epithelial healing.

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POLICY NAME: AMNIOTIC MEMBRANE PLACEMENT FOR TREATMENT OF OCULAR SURFACE DISORDERS

Amnion can be prepared for implantation several ways. Heat or air-dried amniotic membrane loses some of its biologic properties and is not ideal for ocular surface rehabilitation. The tissue can be lyophilized (freeze dried), which induces minimal change in its properties. Amnion can be preserved in cold glycerol and cryopreserved and stored frozen at -80 degrees. The cryopreservation method allows for greater retention of the membrane's structural, physiological, and biochemical properties responsible for its dramatic healing and easier handling intraoperatively.

RELATED POLICIES/DOCUMENTS

Payment Policies:

Adjunct and Non-Standard Technologies, 1550/20.000187

POSITION STATEMENT

CDPHP considers preserved human amniotic membrane transplantation medically necessary for the treatment of ocular surface defects including, but not limited to:

- There may be circumstances where there is a severe condition requiring acute treatment with amniotic membrane such as chemical, thermal or radiation injuries, or Stevens Johnson Syndrome, or limbal stem cell failure.
- Band keratopathy after treatment with other therapy such as surgery, topical medications, bandage contact lens, or patching.
- Bullous keratopathy associated with an epithelial defect.
- Scleral melting.
- Corneal ulcer following initiation of anti-infective therapy and demonstration of clinical response for the purpose of healing the persistent epithelial defect.
- Chemical burns of the ocular surface.
- Conjunctival defects after treatment with other therapy such as surgery or topical medications.
- Corneal melting.
- Limbal Stem Cell Deficiency.
- Pterygium
- Recurrent corneal erosions after treatment failure with other therapy such as bandage contact lens, patching, and topical medications.

In addition to the criteria above, the following ICD-10 codes support medical necessity for amniotic membrane transplantation:

POLICY NAME: AMNIOTIC MEMBRANE PLACEMENT FOR TREATMENT OF OCULAR SURFACE DISORDERS

Code	Description
H04.131 - H04.139	Lacrimal cyst, right lacrimal gland - Lacrimal cyst, unspecified lacrimal gland
H11.001 – H11.069	Pterygium of eye
H15.89 - H15.9*	Other disorders of sclera - Unspecified disorder of sclera
H16.001 - H16.079*	Unspecified corneal ulcer, right eye - Perforated corneal ulcer, unspecified eye
H16.121 - H16.129	Filamentary keratitis, right eye - Filamentary keratitis, unspecified eye
H16.231 - H16.239	Neurotrophic keratoconjunctivitis, right eye - Neurotrophic keratoconjunctivitis, unspecified eye
H18.10 - H18.13	Bullous keratopathy, unspecified eye - Bullous keratopathy, bilateral
H18.421 - H18.429	Band keratopathy, right eye - Band keratopathy, unspecified eye
H18.831 - H18.839	Recurrent erosion of cornea, right eye - Recurrent erosion of cornea, unspecified eye
H18.891 - H18.899	Other specified disorders of cornea, right eye - Other specified disorders of cornea, unspecified eye
L51.0	Nonbullous erythema multiforme
L51.1	Stevens-Johnson syndrome
L51.3	Stevens-Johnson syndrome-toxic epidermal necrolysis overlap syndrome
L51.9	Erythema multiforme, unspecified
T26.00XA - T26.92XS	Burn of unspecified eyelid and periocular area, initial encounter - Corrosion of left eye and adnexa, part unspecified, sequela

Amniotic membrane transplantation is considered experimental and investigational for all other indications.

* The unspecified diagnosis codes in these ranges (H15.89-H15.9 and H16.001-H16.079) should only be used if no other more specific diagnosis code exists that describes the condition being treated. If one of these diagnosis needs to be used, the supporting documentation must clearly describe in detail the indication the membrane is being used to treat.

POLICY CONSIDERATIONS

Amniotic membrane must be cleared by, or registered with, the U.S. Food and Drug Administration (FDA) for application of the eye.

- The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation, title 21, parts 1270 and 1271.

HCPCS code V2790 (amniotic membrane for surgical reconstruction, per procedure) is included in the allowance for CPT procedure code 65778. Therefore, V2790 should not be billed

separately when this code is billed.

EXCLUSIONS

Application for dry eye syndrome is non-covered, given no demonstrated impact on long term outcome.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. Other payers
2. FDA

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POLICY APPROVAL DATES

New: 1/21

Revised: 3/22, 5/24, 9/25

Reviewed: 1/22, 1/23, 1/24, 1/25. 1/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: AMNIOTIC MEMBRANE PLACEMENT FOR TREATMENT OF OCULAR SURFACE DISORDERS

1/1/2026	Added additional criteria for billing unspecified diagnosis codes H15.89-H15.9 and H16.001-H16.079.
6/1/2024	Added pterygium of the eye to the list of covered diagnoses.
7/1/2022	Added ICD-10 criteria to Position Statement.
1/12/21	New

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BEHAVIORAL HEALTH RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: APPLIED BEHAVIOR ANALYSIS

POLICY EFFECTIVE DATE:	9/1/24
Policy Control #:	1370/20.000477
Next Annual Review:	9/2025

DISCLAIMER

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PROCEDURE CODES

97151, 97152, 97153, 97154, 97155, 97156, 97157, 97158

DESCRIPTION

According to the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM 5), the essential features of Autism Spectrum Disorder (ASD) are persistent impairment in reciprocal social communication and social interaction (Criterion A), and restricted, repetitive patterns of behavior, interests or activities (Criteria B). These symptoms are present from early childhood and limit or impair everyday functioning (Criteria C and D). Manifestations of the disorder also vary greatly depending on the severity of the autistic condition, developmental level, and chronological age. Autism spectrum disorder encompasses disorders previously referred to as early infantile autism, childhood autism, Kanner's autism, high-functioning autism, atypical autism, pervasive developmental disorder not otherwise specified, childhood disintegrative disorder, and Asperger's disorder.

The Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Review (2011) defines applied behavior analysis (ABA) as an umbrella term describing principles and techniques used in the assessment, treatment, and prevention of challenging behaviors and the promotion of new desired behaviors. The goal of ABA is to teach new skills, promote

generalization of these skills, and reduce challenging behaviors with systematic reinforcement.

As a treatment modality for ASD, ABA involves a systematic analysis of behavior, utilizing careful observation to identify those behaviors that are triggered by environmental factors and are interfering with socialization and learning. An individualized treatment plan is designed using positive reinforcement and rewards designed to change behavior. ABA focuses on explaining behaviors in terms of environmental events that can be manipulated and modified rather than biological forces that are beyond the individual's control.
ABA may also be referred to as, Lovaas therapy or early intensive behavioral intervention (EIBI).

RELATED POLICIES/DOCUMENTS

N/A

POSITION STATEMENT

In accordance with New York State law, CDPHP administers benefits for ABA therapy when necessary to develop, maintain, or restore, to the maximum extent practicable, the functioning of an individual when all of the following criteria are met:

1.
2. Benefits for Applied Behavior Analysis (ABA) are available to individuals of any age and for any diagnosis where Applied Behavior Analysis (ABA) is an appropriate treatment modality.
3. Interventions are consistent with ABA techniques and are provided or supervised by a board certified behavior analyst, or other qualified health professional.
4. There is documentation of severe behavior that:
   - Presents a health or safety risk to self or others; or
   - Significantly interferes with home or community activities.
5. Less intensive behavior treatment has been unsuccessful in managing or treating the behaviors.
6. There has been established a reasonable expectation on the part of the therapist that the ABA treatment will significantly improve the behaviors.
7. Documentation supports the position that therapy will achieve functional gains beyond those expected as a result of growth and maturation.
8. The treatment plan is built on individual and measurable goals and interventions that emphasize generalization of skills learned.
9. Caregiver training and support is a part of the treatment plan.
10. Treatment intensity (i.e., number of hours per day or per week) and duration (i.e., length of service intervention) is individualized and designed to meet needs of the patient and adjusted as clinically appropriate.
11. Treatment plan addresses comorbid medical and psychiatric disorders, and includes

coordination of care with other providers and community based-resources, as appropriate.

POLICY CONSIDERATIONS

Care rendered by a non-network applied behavior analyst will be subject to the Plan's out-of-network benefit.

*** APPLICABLE CODES:**

ICD-10 Description	ICD-10 codes
Autistic disorder	F84.0
Rett's syndrome	F84.2
Other childhood disintegrative disorder	F84.3
Asperger's syndrome	F84.5
Other pervasive developmental disorders	F84.8
Pervasive developmental disorder, unspecified	F84.9

EXCLUSIONS

ABA services are no longer considered medically necessary when any of the following occur:

- The individual has achieved adequate stabilization and less intensive modes of treatment are appropriate and indicated.
- There has been no meaningful improvement in the patient's behavior after a significant period of treatment.
- The treatment is making the behaviors worse.
- The treatment has demonstrated the inability to maintain long-term gains.
- Medical conditions or impairments are present that would prevent beneficial utilization of ABA services.

ABA treatment will **not** be certified for the following services:

- Vocational rehabilitation
- Supportive respite care
- Recreational therapy
- Orientation and mobility
- Equine therapy
- Hippotherapy
- Dolphin therapy

ABA therapy that duplicates services already being provided by a federal or state agency (i.e., Early Intervention Program) or by a school district (under an Individualized Educational Program) that are sufficient in meeting the needs of an individual.

BEHAVIORAL HEALTH
RESOURCE COORDINATION POLICY

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POLICY NAME: APPLIED BEHAVIOR ANALYSIS

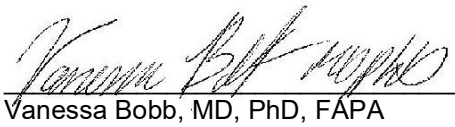
CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP:	ABA services are provided by Licensed Behavior Analyst (LBA), Certified Behavior Analyst Assistant (CBAA) working under the supervision of LBAs, or other individuals specified under Article 167 of NYS education law

SOURCES

1. NYS Autism Mandate, 2012; updated 2014
2. Other Payers
3. American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM 5).
4. MCG Health Care Guidelines for Applied Behavioral Analysis (B-806-T) – Edition 24.0, 2020

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Vanessa Bobb, MD, PhD, FAPA Date
VP, Behavioral Health and Medical Integration

POLICY APPROVAL DATES

New: 09/12

Revised: 09/17, 09/20, 9/21, 12/22, 10/23, 4/24, 8/24

BEHAVIORAL HEALTH
RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: APPLIED BEHAVIOR ANALYSIS

Reviewed: 09/13, 09/14, 09/15, 09/16, 09/18, 05/19, 09/19, 01/21,

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
9/1/24	Changed policy name to "Applied Behavioral Analysis" (removed "For Autism Spectrum Disorders) as ABA is covered for appropriate DSM-V diagnoses. Added ABA allowed for any age and for any diagnosis where Applied Behavior Analysis (ABA) is an appropriate treatment modality, for all LOB
6/1/23	Medicaid allowed for coverage of ABA for all ages and appropriate diagnoses.
4/1/23	Medicaid added coverage for 97154 & 97157. Medicaid now covers all codes listed in this policy.
1/1/2023	Added coverage for Medicaid
10/1/2021	Removed limits for ABA testing Added coverage for Medicaid per NYS update effective 10/1/21 - ONLY Codes 97151, 97152, 97153, and 97155 Added per 8/10/2021 MMC Plan Update: "Additional providers have been added to the list of providers that may diagnose/refer for ABA services. The providers added are pediatric nurse practitioners and physician assistants."
1/1/2020	Updated maximum hour limits for ABA Services in Policy Considerations section.

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POLICY NAME: APPLIED BEHAVIOR ANALYSIS

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MEDICAL POLICY

Medical Policy Title	**Aqueous Drainage Devices (Stents and Shunts) for Glaucoma**
Policy Number	**9.01.18**
Current Effective Date	**August 1, 2026**
Next Review Date	**January 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Insertion of an aqueous drainage device that has been approved by the United States Food and Drug Administration (FDA) is considered **medically appropriate** in patients with glaucoma for **EITHER** of the following indications:

   A. Medical therapy has failed to adequately control the intraocular pressure (IOP);

   B. Oral or topical medications are not tolerated by the patient (e.g., oral medications cause significant gastrointestinal (GI) effects or topical medications cause contact sensitivity or systemic effects).

II. Implantation of one (1) or two (2) FDA-approved micro-stents (e.g., iStent or iStent Inject) in conjunction with cataract surgery is considered **medically appropriate** when the **ALL** of the following criteria are met:

   A. Diagnosed with mild-to-moderate open-angle glaucoma (OAG);

   B. Currently being treated with ocular hypotensive medication(s).

III. The use of aqueous drainage devices inserted into the suprachoroidal space or supraciliary space in patients with glaucoma are considered **investigational**.

IV. All other uses of aqueous drainage devices, including but not limited to use in patients with glaucoma when IOP is adequately controlled by medications, are considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

Payment Policies:

Adjunct and Non-Standard Technologies, 1550/20.000187

POLICY GUIDELINE(S)

Not Applicable

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

DESCRIPTION

Glaucoma is a chronic disorder involving increased pressure in the eye due to fluid build-up. There are several forms of glaucoma, with OAG being the most common. The increased pressure associated with OAG can lead to optic neuropathies characterized by visual field loss and structural damage to the optic nerve fiber. If left untreated, glaucoma can result in partial or complete visual impairment. Currently, IOP is the only treatable risk factor for glaucoma, and lowering IOP has proven beneficial in reducing the progression of loss of vision.

In most cases, topical or oral medication is the first treatment of choice. Glaucoma surgery (e.g., trabeculectomy) is intended to reduce IOP when the target IOP cannot be reached with medications. Due to complications with established surgical approaches such as trabeculectomy, a variety of devices, including aqueous shunts, are being evaluated as alternative surgical treatments for patients with inadequately controlled glaucoma. Microstents are also being evaluated in patients with mild to moderate OAG that is currently treated with ocular hypotensive medication.

Aqueous shunts, also known as aqueous drainage devices, glaucoma drainage devices, setons, tube implants, and tube shunts, are implanted into the eye to create an alternate path for aqueous humor to drain from the anterior or posterior chamber of the eye to a space between the conjunctiva and the sclera where it is absorbed into the blood, thereby lowering the IOP. These devices differ depending on explant surface areas, shape, plate thickness, presence or absence of a valve, and details of surgical installation. Generally, the risk of hypotony (low pressure) is reduced with aqueous shunts, in comparison with trabeculectomy, but IOP outcomes are higher than after standard guarded filtration surgery. Complications of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva. The risk of post-operative infection is lower than after trabeculectomy, and failure rates are similar, with about 10% of devices failing each year. The primary indication for aqueous shunts is that prior medical or surgical therapy has failed, although some ophthalmologists have advocated their use as a primary surgical intervention, particularly for selected conditions such as congenital glaucoma, trauma, chemical burn, or pemphigoid.

Other aqueous stents (e.g., microstents) are being developed as minimally penetrating methods to drain aqueous humor from the anterior chamber into Schlemm's canal or the suprachoroidal space. These include the iStent (Glaukos), which is a 1-mm long stent inserted into the end of Schlemm's canal by an internal approach through the cornea and anterior chamber, and the third generation iStent supra, which is designed for ab interno implantation into the suprachoroidal space. An advantage of ab interno shunts is that they may be inserted into the same incision while cataract surgery is being performed. In addition, most devices do not preclude subsequent trabeculectomy if needed. It may also be possible to insert more than one shunt to achieve the desired IOP.

SUPPORTIVE LITERATURE

Sheybani et al (2023) conducted a prospective, randomized, multicenter, noninferiority trial comparing gel stent (XEN45) versus trabeculectomy in patients (N=139) with open angle glaucoma and IOP of 15 to 44 mm Hg while receiving topical IOP medication. Patients were randomized 2:1 to gel stent implantation or trabeculectomy. At 12 months XEN45 was noninferior to trabeculectomy in

terms of surgical success which was defined as at least a 20% reduction in IOP without a medication increase, clinical hypotony, vision loss, or secondary surgical intervention (between group difference, -6.1%; 95% CI, -22.9% to 10.8%). XEN45 resulted in fewer in-office postoperative interventions and faster visual recovery, and greater six-month improvements in visual function problems than trabeculectomy.

Randomized, controlled trials (RCTs) have shown that the use of large, externally placed shunts with extraocular reservoirs results in success rates as good as standard filtering surgery (trabeculectomy). Shunts have a different side effect profile and avoid some of the most problematic complications of trabeculectomy.

Gedde and colleagues (2012) reported five-year follow-up from an open-label, multicenter, randomized tube versus trabeculectomy (TVT) study. The study included 212 eyes of 212 patients (aged 18 to 85 years) who had previous trabeculectomy and/or cataract extraction with intraocular lens implantation, uncontrolled glaucoma with IOP of 18 mm Hg or greater, as well as 40 mm Hg or lower on maximal-tolerated medical therapy. Patients were assigned either a tube shunt (Baervelt implant, n=107) or trabeculectomy with mitomycin C (n=105). Excluding patients who had died, the study had 82% follow-up at five years, with a similar proportion of patients in the tube and trabeculectomy groups. At five years, neither IOP (14.3 mm Hg in the tube group and 13.6 mm Hg in the trabeculectomy group) nor number of glaucoma medications (1.4 in the tube group and 1.2 in the trabeculectomy group) were significantly different with intent-to-treat analysis. The cumulative probability of failure over the five years was lower in the tube group than the trabeculectomy group (29.8% versus 46.9%), and the rate of reoperation was lower (9% versus 29%). The rate of loss of two or more lines of visual acuity was similar in the two groups (46% in the tube group and 43% in the trabeculectomy group).

Implantation of the Ex-PRESS mini shunt under a scleral flap was compared with standard trabeculectomy in a randomized study of 78 patients (80 eyes) with a diagnosis of OAG that could not be controlled with maximal-tolerated medical therapy (de Jong 2009). The two groups were similar after randomization, with the exception of difference in the mean age (62 years for the Ex-PRESS group and 69 years for the trabeculectomy group). At an average 12 months' follow-up, mean IOP had improved from 23 to 12 mm Hg in the Ex-PRESS group and from 22 to 14 mm Hg in the trabeculectomy group. Both groups of patients used fewer anti-glaucoma medications post-operatively than before the procedure (from 2.8 at baseline to 0.3 in the Ex-PRESS group and from 3.0 at baseline to 0.6 in the trabeculectomy group). Twelve-month Kaplan-Meier success rates (defined as an IOP of > 4 mm Hg and $\leq$ 18 mm Hg without use of anti-glaucoma medications) were 82 percent for the Ex-PRESS shunt and 48 percent for trabeculectomy. There was a similar level of postoperative complications in the two groups.

A 2017 Cochrane Systematic Review (Tseng 2017) found that there was insufficient information to conclude whether aqueous shunts or trabeculectomy yielded superior results, with heterogenous methodology and data quality across studies. Therefore, the selection of aqueous shunts or trabeculectomy should be left to the discretion of the treating ophthalmologist, in consultation with the individual patient. The term minimally invasive glaucoma surgery, or MIGS, refers to a group of surgical procedures that are performed using an ab interno approach and involve minimal trauma to

ocular tissues. Limited long-term data is currently available for MIGS, given its relatively recent introduction. Modest IOP reduction has been reported following MIGS, and postoperative pressures are typically in the middle to upper teens. Although less effective in lowering IOP than trabeculectomy and aqueous shunt surgery, MIGS appears to have a more favorable safety profile in the short term. Currently available MIGS includes procedures targeting the trabecular meshwork/Schlemm's canal and the subconjunctival space. They are commonly combined with phacoemulsification; some are only FDA approved to be performed concurrently with phacoemulsification.

Use of microstents has been studied in patients with both cataracts and less advanced glaucoma, where the IOP is at least partially controlled with medication. Results from these studies indicate that IOP may be lowered below baseline with decreased need for medication, although the benefit appears to diminish after the first year. Samuelson et al (2011) conducted a multi-center RCT to assess the safety and efficacy of cataract surgery with iStent (n=111) compared to cataract surgery without iStent (control group) (n=123). Patients had OAG and a plan to undergo phacoemulsification for cataracts. Follow-ups occurred for up to 12 months. The primary outcome measure was IOP less than or equal to 21 mmHg without ocular hypotensive medication, and the secondary measure was greater than or equal to 20 percent reduction in IOP from baseline without medication. Additional efficacy measures included medication use and visual acuity. Compared to the control group, significantly more patients in the treatment group achieved primary and secondary outcomes ($p<0.001$, $p=003$, respectively). At the 12-month follow-up, 70 percent of the treatment group versus 50 percent of the control group had achieved both the primary and secondary outcomes. There was a significant delay in the introduction of medication in the treatment group versus the control group ($p<0.001$), and significantly more patients in the control group required medication at 12 months ($p=0.001$). The overall adverse events were similar in both groups. Both groups improved in vision, with no significant differences between the groups.

Craven and colleagues (2012) reported two-year follow-up of the above-noted iStent study. There were 199 of the original 239 patients (83%) remaining in the study. The primary endpoint, IOP of 21 mm Hg or less without use of medication, was reached by 61 percent of patients in the treatment group, compared to 50 percent of patients in the control group ($p=0.036$). The secondary outcomes of IOP reduction of 20 percent or more without medication (53% versus 44%) and mean number of medications used (0.3 versus 0.5) were no longer significantly different between the groups at two years. As noted by the FDA, this study was conducted in a restricted population of patients who had an unmedicated IOP of 22 mm Hg or higher and 36 mm Hg or lower. The results of this study indicate that treatment of this specific population with a microstent is likely to improve outcomes at one year, compared to cataract surgery alone.

Chen and colleagues (2020) performed a meta-analysis to evaluate the effectiveness of iStent as a standalone operation in patients with OAG. Prospective and retrospective clinical studies written in English that investigated the effect of iStent in at least five eyes were included. A total of 17 studies involving 978 eyes with 599 eyes implanted with the first-generation iStent and 379 eyes with the second-generation iStent were analyzed. Follow-up duration varied among studies with the longest follow-up extending 42 months. The number of iStents varied from one to three stents per eye with

75.5% of eyes implanted with two stents. All studies reported a reduction in IOP after iStent implantation. Pooled result demonstrated a significant standardized mean difference (SMD) of −2.64. The majority of studies also reported a reduction in the number of medications at the end point compared to baseline with an overall SMD of -1.71. The authors determined moderate heterogeneity in studies evaluating the SMDs of IOP, as well as the number of medications. Most of the studies had a complication rate of less than 20%. Subgroup analyses revealed the higher number of iStents resulted in a greater IOP reduction. The authors concluded iStent can reduce the IOP and the number of medications in patients with OAG as a standalone procedure. Limitations include potential publication bias with several industry sponsored studies and substantial heterogeneity among studies. Included studies tended to have small sample sizes and lacked a control group.

Fan Gaskin et al (2024) reported on a prospective, randomized, assessor-masked controlled trial with 87 patients (n=101 eyes) that compared the effectiveness of cataract surgery plus iStent Inject implantation versus cataract surgery alone in patients with mild-to-moderate glaucoma. At the 24-month follow-up, the iStent Inject group used significantly fewer medications compared to the cataract surgery alone group (mean, 0.7 vs. 1.5; p=.008) and had a higher proportion of patients taking no glaucoma medications (57% vs. 36%). At 4 weeks post-surgery, a lower IOP was observed in the iStent group (mean difference, -2.8 mmHg [95% CI, -4.7 to -1]) but there was no difference in subsequent follow-up assessments. Both groups showed improvement in patient-reported outcomes from baseline levels (Ocular Surface Disease Index score and Glaucoma Activity Limitation Questionnaire), with no significant differences between groups. The safety profiles were similar between the two groups. The authors concluded this study showed combined cataract surgery with iStent Inject achieved a clinically- and statistically-significantly greater reduction in ocular hypotensive medication usage at 24-months compared to cataract surgery alone, with no significant difference in IOP.

Hengerer et al (2024) conducted a prospective, non-randomized, unmasked, longitudinal study (n=125) which evaluated 7-year effectiveness and safety of second-generation trabecular micro-bypass implantation (iStent inject) either in combination with cataract surgery or as a standalone procedure (combined or standalone subgroups, respectively) in eyes with open-angle glaucoma. Patients had considerable preoperative disease burden, with mean intraocular pressure (IOP) of 23.5 mmHg, 84.8% of eyes on C 2 medications, and 38.4% of eyes with prior glaucoma surgery. IOP, medications, adverse events, and secondary surgeries were assessed through 7 years in the overall cohort and in combined (n = 81) and standalone (n = 44) subgroups. Over 7-year follow-up, mean IOP decreased by 36.2–40.0% in Overall eyes, 34.1–38.9% in Combined eyes, and 39.5–43.5% in Standalone eyes. Mean medications decreased by 59.3–71.3% in Overall eyes, 57.9–69.0% in Combined eyes, and 62.1–76.2% in Standalone eyes. At last follow-up versus preoperative, 100% of eyes in all groups had the same or lower IOP and 100% had the same or lower medication regimen. The authors concluded this study showed iStent inject implantation with or without phacoemulsification produced significant and durable 7-year reductions in IOP (34–44% reduction) and medications (58–76% reduction) while preventing filtering surgery with favorable safety outcomes.

Sarkisian et al (2023) published the results of an open-label, single-arm, pivotal study evaluating

iStent infinite in patients with OAG uncontrolled by prior surgical or medical therapy. A total of 72 patients were enrolled from 15 sites in this trial. All patients were implanted with the iStent infinite System and received 3 stents. The majority of patients had failed prior surgery (n=61), and the remainder were uncontrolled on medical therapy (n=11). At 12 months the proportion of patients achieving at least 20% reduction in IOP and receiving the same or fewer medications was 76.1% (95% CI, 66.2% to 86.1%). The mean reduction in IOP at12 months was 5.9 mm Hg (standard error, 0.6; 95% CI, 4.8 to 7.1). No serious device-related adverse events were reported; however, blepharitis (4.2%), IOP increase requiring surgical intervention (4.2%), loss of best spectacle corrected visual acuity of 2 lines or more (8.3%), ocular surface disease (9.7%), and visual field loss of at least 2.5 dB were commonly reported adverse events. Stent migration and stent obstruction were each reported in 2 patients. Although this trial indicates positive outcomes with iStent infinite, the small sample size and lack of a control group are significant limitations.

Shultz et al (2025) conducted a manufacturer sponsored, multicenter study to evaluate the effectiveness and safety of iStent infinite, a trabecular microbypass implant, combined with phacoemulsification (n=233 eyes). In all eyes with 12-month follow-up data (n = 96, consistent cohort), the mean IOP reduced from 17.2 ± 4.2 mmHg preoperatively to 13.8 ± 3.0 mmHg at Month 12 ($p = 0.001$), while the mean number of medications reduced from 1.24 ± 0.91 preoperatively to 0.61 ± 0.96 at month 12 ($p = 0.001$). The proportions of eyes achieving IOP ≤ 18/15/12 mmHg increased from 63.5%, 34.4%, and 14.6% preoperatively to 92.7%, 71.9%, and 37.5%, respectively at month 12, (all $p = 0.001$). The proportions of eyes off medication increased from 16.7% preoperatively to 62.5% at Month 12 ($p = 0.001$). A noted limitation of the data analysis is that cases were completed in combination with cataract surgery, so it was not possible to delineate the potentially IOP-lowering effect of lens extraction from that of iStent infinite implantation. The authors conclude that this manufacturer sponsored study demonstrates reductions in IOP and the number of topical glaucoma medications required following iStent infinite trabecular micro-bypass and phacoemulsification.

PROFESSIONAL GUIDELINE(S)

The American Academy of Ophthalmology (AAO) published a technology assessment on commercially available aqueous shunts, including the Ahmed, Baerveldt, Krupin, and Molteno devices (Minckler 2008). This review indicated that the IOP will generally settle at higher levels (approximately 18 mm Hg) with aqueous shunts than after standard trabeculectomy (14-16 mm Hg) or after trabeculectomy with antifibrotic agents 5-fluorouacil or mitomycin C (8-10 mm Hg). In one study, IOPs with the Baerveldt shunt and adjunct medications were found to be equivalent to trabeculectomy with mitomycin C (13 mm Hg). Five-year success rates for the two procedures were found to be similar (50%). The assessment concluded that, based on level 1 evidence, aqueous shunts were comparable to trabeculectomy for IOP control and duration of benefit. The risk of postoperative infection was lower with aqueous shunts than after trabeculectomy. Complications of aqueous shunts were noted to include immediate hypotony after surgery; excessive capsule fibrosis and clinical failure; erosion of the tube or plate edge; strabismus; and, very rarely, infection. The most problematic long-term consequence of anterior chamber tube placement was described as accelerated damage to the

corneal endothelium over time.

AAO published a technology assessment on aqueous shunts with extraocular reservoir for open-angle adult glaucoma (Chopra 2024). They concluded that the implantation of aqueous shunts with extraocular reservoir, including valved or nonvalved devices, has been shown to be an effective strategy to lower IOP. Strong level I evidence supports the use of aqueous shunts with extraocular reservoir by clinicians for the management of adult OAG.

AAO Primary Open-Angle Glaucoma Preferred Practice Pattern (2020) states the indications for using aqueous shunts have been broadening, and these devices are being increasingly used in the surgical management of glaucoma. Several studies have compared aqueous shunts with trabeculectomy.

The American Glaucoma Society (Fellman 2020) published a position paper on microinvasive glaucoma surgery. The society supports efforts that facilitate patient access to these procedures, including more flexible regulatory pathways for new devices, expansion of the indications for already approved devices, and greater availability of information obtained by regulatory authorities.

The National Institute for Health and Care Excellence (NICE) issued interventional procedural guidance for trabecular stent bypass microsurgery for open angle glaucoma (NICE 2017). They report, "Current evidence on the safety of trabecular stent bypass microsurgery for open-angle glaucoma raises no major safety concerns. Evidence on efficacy is adequate in quality and quantity. Therefore, this procedure may be used."

NICE also issued procedural guidance for microinvasive subconjunctival insertion of trans-scleral gelatin stents for primary open-angle glaucoma (NICE 2018). They report, "evidence on the safety and efficacy of microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma is limited in quantity and quality…NICE encourages further research into microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma, including randomized studies. Further research should include details of patient selection and long-term outcomes."

REGULATORY STATUS

The first-generation Ahmed (New World Medical), Baerveldt (Advanced Medical Optics), Krupin (Eagle Vision), and Molteno (Molteno Ophthalmic) aqueous shunts received marketing clearance from the FDA between 1989 and 1993; modified Ahmed and Molteno devices were cleared in 2006. Their indication for use is "in patients with intractable glaucoma to reduce IOP where medical and conventional surgical treatments have failed."

The AquaFlow Collagen Glaucoma Drainage Device received premarket approval from the FDA in 2001 for the maintenance of sub-scleral space following nonpenetrating deep sclerectomy.

The Ex-PRESS Mini Glaucoma Shunt received Section 510(k) marketing clearance in 2003. The Ex-PRESS shunt is placed under a partial thickness scleral flap and transports aqueous fluid from the anterior chamber of the eye into a conjunctival filtering bleb.

Alcon (a division of Novartis) received FDA approval for its CyPass micro-stent in July 2016. CyPass is a micro-invasive glaucoma surgical (MIGS) device to treat patients with mild to moderate primary

OAG in conjunction with cataract surgery. The CyPass Micro-Stent is designed to control IOP by creating a drainage pathway from the anterior chamber to the suprachoroidal space. The FDA approval was based on the COMPASS Study, which included two-year follow-up of over 500 patients undergoing cataract surgery. On August 29, 2018, Alcon Research, LTD voluntarily issued a recall of the CyPass Micro-Stent and withdrew this product from the global market. The decision for the withdrawal was based on five-year post-surgery data from the COMPASS XT long-term safety study. The study demonstrated a clinically and statistically significant increase in corneal endothelial cell loss in patients who received the CyPass Micro-Stent. Based upon its review of this data, the FDA issued a Safety Communication notifying physicians and patients of the risk associated with this device and recommended that the use of this device be discontinued. The FDA recalled the CyPass device on August 28, 2018; therefore, it is no longer available for use.

On November 21, 2016, the FDA cleared Allergen's XEN Glaucoma Treatment System (consisting of the XEN45 Gel Stent and the XEN Injector). The XEN45 Gel Stent is a glaucoma implant designed to reduce IOP in eyes suffering from refractory glaucoma, including cases where previous surgical treatment has failed, in cases of primary OAG, and in cases of pseudo-exfoliative or pigmentary glaucoma with open angles that are unresponsive to maximal-tolerated medical therapy. The device creates a permanent channel through the sclera, allowing flow of aqueous humor from the anterior chamber into the subconjunctival space. The XEN45 Gel Stent is inserted via an ab interno approach, through a small corneal incision.

In 2012, the FDA approved the Glaukos Corporation's iStent Trabecular Micro-Bypass Stent, as indicated for use in conjunction with cataract surgery for the reduction of IOP in adult patients with mild to moderate OAG that is currently treated with ocular hypotensive medication.

In 2018, the iStent Inject device (Glaukos), was approved by the FDA through the 515(d) process for use in conjunction with cataract surgery for the reduction of IOP in adults with mild-to-moderate OAG currently treated with ocular hypotensive medication. The iStent Inject trabecular micro-bypass system contains two preloaded intraocular stents in the injector.

In August 2022 Glaukos' iStent Infinite was approved by the FDA to be inserted as a stand-alone procedure. iStent infinite consists of three micro stents on a single preloaded injector. The stents are designed to be implanted ab interno in three separate areas of the trabecular meshwork, creating a patent bypass through the trabecular meshwork into Schlemm canal to increase physiological aqueous outflow and reduce IOP.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0253T (E/I)	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the suprachoroidal space
0449T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; initial device
0450T	Insertion of aqueous drainage device, without extraocular reservoir, internal approach, into the subconjunctival space; each additional device (List separately in addition to code for primary procedure)
0474T (E/I)	Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space
0671T	Insertion of anterior segment aqueous drainage device into the trabecular meshwork, without external reservoir, and without concomitant cataract removal, one or more
66179	Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft
66180	Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft
66183	Insertion of anterior segment aqueous drainage device, without extraocular reservoir, external approach
66184	Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft
66185	Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (1 stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more

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HCPCS Codes

Code	Description
C1783	Ocular implant, aqueous drainage assist device
L8612	Aqueous shunt

ICD10 Codes

Code	Description
E08.36	Diabetes mellitus due to underlying condition with diabetic cataract
E09.36	Drug or chemical induced diabetes mellitus with diabetic cataract
E10.36	Type 1 diabetes mellitus with diabetic cataract
E11.36	Type 2 diabetes mellitus with diabetic cataract
E13.36	Other specified diabetes mellitus with diabetic cataract
H25.011-H25.9	Age-related cataract (code range)
H26.011-H26.069	Infantile and juvenile cataract (code range)
H26.101-H26.139	Traumatic cataract (code range)
H26.20	Unspecified complicated cataract
H26.211-H26.219	Cataract with neovascularization (code range)
H26.221-H26.229	Cataract secondary to ocular disorders (degenerative) (inflammatory) (code range)
H26.231-H26.239	Glaucomatous flecks (subcapsular) (code range)
H26.30-H26.33	Drug-induced cataract (code range)
H26.40	Unspecified secondary cataract
H26.411-H26.419	Soemmering's ring (code range)

Code	Description
H26.491-H26.499	Other secondary cataract (code range)
H26.8	Other specified cataract
H26.9	Unspecified cataract
H28	Cataract in diseases classified elsewhere
H40.001-H40.009	Preglaucoma, unspecified (code range)
H40.011-H40.029	Open angle with borderline findings (code range)
H40.031-H40.039	Anatomical narrow angle (code range)
H40.041-H40.049	Steroid responder (code range)
H40.051-H40.059	Ocular hypertension (code range)
H40.061-H40.069	Primary angle closure without glaucoma damage (code range)
H40.10x0-H40.10x4	Unspecified open-angle glaucoma (code range)
H40.1111-H40.1134	Primary open-angle glaucoma (code range)
H40.1210-H40.1294	Low tension glaucoma (code range)
H40.1310-H40.1394	Pigmentary glaucoma (code range)
H40.141-H40.1494	Capsular glaucoma with pseudoexfoliation of lens (code range)
H40.151-H40.159	Residual stage of open-angle glaucoma (code range)

Code	Description
H40.20x0-H40.20x4	Unspecified primary angle-closure glaucoma (code range)
H40.211-H40.219	Acute angle-closure glaucoma (code range)
H40.2210-H40.2294	Chronic angle-closure glaucoma (code range)
H40.231-H40.239	Intermittent angle-closure glaucoma (code range)
H40.241-H40.249	Residual stage of angle-closure glaucoma (code range)
H40.30x0-H40.33x4	Glaucoma secondary to eye trauma (code range)
H40.40x0-H40.43x4	Glaucoma secondary to eye inflammation (code range)
H40.50x0-H40.53x4	Glaucoma secondary to other eye disorders (code range)
H40.60x0-H40.63x4	Glaucoma secondary to drugs (code range)
H40.811-H40.819	Glaucoma with increased episcleral venous pressure (code range)
H40.821-H40.829	Hypersecretion glaucoma (code range)
H40.831-H40.839	Aqueous misdirection (code range)
H40.89	Other unspecified glaucoma
H40.9	Unspecified glaucoma
H42	Glaucoma in diseases classified elsewhere
Q15.0	Congenital glaucoma

REFERENCES

Ahmed II, et al. A prospective randomized trial comparing Hydrus and iStent microinvasive glaucoma surgery implants for standalone treatment of open-angle glaucoma: The COMPARE Study. American Academy of Ophthalmology. 2020 Jan; 127(1): 52-61.

Ahmed IIK, et al., HORIZON Investigators. Three-Year Findings of the HORIZON Trial: a Schlemm canal microstent for pressure reduction in primary open-angle glaucoma and cataract. Ophthalmology. 2021 Jun;128(6):857-865.

Agency for Healthcare Research and Quality. Comparative effectiveness review number 60. Treatment for glaucoma: comparative effectiveness [Internet]. 2013 May [accessed 2025 Oct 20]. Available from: https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/glaucoma-treatment_surveillance.pdf

Belovay GW, et al. Using multiple trabecular micro-bypass stents in cataract patients to treat open-angle glaucoma. J Cataract Refract Surg. 2012 Nov;38(11):1911-7.

Center for Devices and Radiological Health. "Medical Device Recalls - Alcon Research, LTD. recalls CyPass® micro-stent systems due to risk of endothelial cell loss." U S Food and Drug Administration Home Page, Center for Devices and Radiological Health [Internet]. 2020 Mar 19 [accessed 2025 Oct 20]. Available from: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/alcon-announces-voluntary-global-market-withdrawal-cypass-micro-stent-surgical-glaucoma

Chen Y, et al. Use of iStent as a standalone operation in patients with open-angle glaucoma. Journal of Ophthalmology. 2020 May 24;2020:8754730.

Chopra V, et al. Aqueous shunts with extraocular reservoir for open-angle adult glaucoma: a report by the American Academy of Ophthalmology. Ophthalmology. 2024 Feb;131(2):227-239.

Craven ER, et al. Cataract surgery with trabecular micro-bypass stent implantation in patients with mild-to-moderate open-angle glaucoma and cataract" two-year follow-up. J Cataract Refract Surg. 2012 Aug;38(8):1339-45.

De Jong LA, et al. Five-year extension of a clinical trial comparing the EX-PRESS glaucoma filtration device and trabeculectomy in primary open-angle glaucoma. Clin Ophthalmol. 2011;5:527-33.

Denis P, et al. Two-year outcomes of the MINIject drainage system for uncontrolled glaucoma from the STAR-I first-inhuman trial. Br J Ophthalmol. 2020;0:1-6.

Falkenberry S, et al. Excisional goniotomy vs trabecular microbypass stent implantation: a prospective randomized clinical trial in eyes with mild to moderate open-angle glaucoma. J Cataract Refract Surg. 2020 Aug; 46(8):1165-1171.

Fan Gaskin JC, et al; Glaucoma Investigation and Research Unit, Royal Victorian Eye and Ear Hospital. Prospective, randomized controlled trial of cataract surgery vs combined cataract surgery with insertion of iStent Inject. Ophthalmol Glaucoma. 2024 Jul-Aug;7(4):326-334.

Fellman RL, et al. American Glaucoma Society Position Paper: Microinvasive Glaucoma Surgery.

Ophthalmol Glaucoma. 2020 Jan-Feb;3(1):1-6.

Ferguson TJ, et al. iStent Trabecular micro-bypass stent implantation with phacoemulsification in patients with open-angle glaucoma: 6-year outcomes Clinical Ophthalmology. 2020 July; 2020 (14): 1859-1866.

Francis BA, et al. Novel glaucoma procedures: a report by the American Academy of Ophthalmology. Ophthalmology. 2011 Jul;118(7):1466-80.

Gedde SJ, et al. Postoperative complications in the Tube Versus Trabeculectomy (TVT) study during five years of follow-up. Am J Ophthalmol. 2012 May;153(5):804-14.

Gedde SJ, et al, on behalf of the American Academy of Ophthalmology. Primary open-angle glaucoma preferred practice pattern [Internet]. 2020 Nov [accessed 2025 Oct 20]. Available from: https://www.aao.org/preferred-practice-pattern/primary-open-angle-glaucoma-ppp

Hengerer FH, et al. 7-Year efficacy and safety of iStent inject trabecular micro-bypass in combined and standalone usage. Adv Ther. 2024 Apr;41(4):1481-1495.

Lee RM, et al. The implications of an ab interno versus ab externo surgical approach on outflow resistance of a subconjunctival drainage device for intraocular pressure control. Trans Vis Sci Tech. 2019;8(3):58.

Minckler DS, et al. Aqueous shunts in glaucoma: a report by the American Academy of Ophthalmology. Ophthalmology. 2008 Jun;115(6):1089-98.

Molteno AC, et al. Long-term results of primary trabeculectomies and Molteno implants for primary open-angle glaucoma. Arch Ophthalmol. 2011 Nov;129(11):1444-50.

National Institute for Health and Clinical Excellence. Microinvasive subconjunctival insertion of a trans-scleral gelatin stent for primary open-angle glaucoma [Internet]. 2018 Apr 24 [accessed 2025 Oct 20]. Available from: https://www.nice.org.uk/guidance/ipg612/resources/microinvasive-subconjunctival-insertion-of-a-transscleral-gelatin-stent-for-primary-openangle-glaucoma-pdf-1899873918817477

National Institute for Health and Clinical Excellence. Trabecular stent bypass microsurgery for open angle glaucoma [Internet]. 2017 Feb 22 [accessed 2025 Oct 20]. Available from: https://www.nice.org.uk/guidance/ipg575/resources/trabecular-stent-bypass-microsurgery-for-openangle-glaucoma-1899872109871045

Philip R, et al. Intermediate-term outcome of aurolab aqueous drainage implant. Indian J Ophthalmol. 2019 Feb;67(2):233–238.

Samet S, et al. Hydrus microstent implantation for surgical management of glaucoma: a review of design, efficacy, and safety. Eye and Vision. 2019;6:32.

Samuelson TW, et al. Randomized evaluation of the trabecular micro-bypass stent with phacoemulsification in patients with glaucoma and cataract. Ophthalmology. 2011 Mar 118(3):459-67.

Sarkisian SR, et al. Effectiveness and safety of iStent infinite trabecular micro-bypass for uncontrolled glaucoma. J Glaucoma. 2023 Jan; 32(1): 9-18.

Sheybani A, et al. Gel stent versus trabeculectomy: the randomized, multicenter, gold-standard pathway study (GPS) of effectiveness and safety at 12 months. Am J Ophthalmol. 2023 Aug;252:306-325.

Shultz M, et al. Third-generation trabecular micro-bypass implantation and phacoemulsification in patients with glaucoma: a multicenter study. Vision (Basel). 2025 Jul 19;9(3):61.

Sponsel WE, et al. Efficacy of a Novel Retrobulbar Extension Shunt to Rescue Eyes with Fibrotic Encapsulated Blebs and Uncontrolled Ocular Hypertension. Graefe's Arch Clin Exp Ophthalmol. 2019;257:791–798.

Tseng VL, et al. Aqueous shunts for glaucoma. Cochrane database Syst Rev. 2017 July 28;7:CD004918.

Wijesinghe HK, et al. Incidence and outcomes of suprachoroidal hemorrhage following aurolab aqueous drainage implant in adult and pediatric glaucoma. J Glaucom. 2021 Jun 1;30(6):497-501.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Micro-Invasive Glaucoma Surgery (MIGS) (LCD L37244) [accessed 2024 December 18].

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 1/20

Revised: 1/22, 1/24, 1/25, 7/26

Reviewed: 1/21, 1/23, 1/26

Date	Summary of Changes
8/1/2026	• Transitioned Aqueous Shunts/Stents for Glaucoma policy, 1370/20.000504

	to Lifetime HealthCare Companies policy template.
5/1/2025	• Updated Position Statement and Policy Considerations sections with new criteria and coding guidelines.
1/1/2024	• Added additional procedure codes 66989 and 66991. • Added Schocket Shunt to list of FDA- approved devices. • Added information on iSTENT Inject.
1/1/2022	• Under Policy Considerations, moved the statement that Cypass is non covered to the Exclusions section. • Removed from exclusions codes 0376T and 0450T as these are payment related and are on the Adjunct and Non-Standard Technology Payment Policy. • Effective 1/1/2022: Removed deleted code 0191T and updated with replacement code 0671T.
2/1/2020	• New – criteria in policy aligns with Medicare local coverage determination.

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: **ARTIFICIAL INTELLIGENCE ENABLED CT BASED QUANTITATIVE CORONARY TOPOGRAPHY (AI-QCT) CORONARY PLAQUE ANALYSIS (AI-CPA)**

POLICY EFFECTIVE DATE:	7/1/2026
Policy Control #:	1370/20.000523
Next Annual Review:	January 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice

PROCEDURE CODES

75577

DESCRIPTIONS

Coronary plaque analysis (AI-QCT/AI-CPA) is an adjunctive tool for the quantification and characterization to assess the severity of coronary disease. This is derived from augmentative software analysis of data from a coronary computed tomographic angiography.

RELATED POLICIES/DOCUMENTS

Coronary Fractional Flow Reserve Using Computed Tomography, 1370/20.000511

POSITION STATEMENT

Coronary CT plaque quantification or coronary plaque analysis using data from CCTA is medically necessary when ALL of the following conditions exist:

POLICY NAME: **ARTIFICIAL INTELLIGENCE ENABLED CT BASED QUANTITATIVE CORONARY TOPOGRAPHY (AI-QCT) CORONARY PLAQUE ANALYSIS (AI-CPA)**

- The patient has acute or stable chest pain with no known CAD, prior to current workup, and is eligible for CCTA, **AND**

  After the CCTA is performed and interpreted, it indicates any of the risk categories below:
  - Intermediate risk;
  - CAD-RADS 1;
  - CAD-RADS 2;
  - CAD-RADS 3; **AND**

- Cardiac evaluation is negative or inconclusive for acute coronary syndrome

*The below details CAD-RADS stenosis scoring:
- CAD-RADS 0: No Stenosis
- CAD-RADS 1: < 25% stenosis
- CAD-RADS 2: 25-49% stenosis
- CAD-RADS 3: 50-69% stenosis
- CAD-RADS 4A: 70-99% stenosis in one or two vessels
- CAD-RADS 4B: 70-99% stenosis in three vessels or the left main artery
- CAD-RADS 5: 100% stenosis or total occlusion

EXCLUSIONS

Coronary CTA plaque quantification or coronary plaque analysis using data from CCTA is considered not medically necessary in ANY of the following clinical scenarios:

- Unstable coronary syndromes;
- In conjunction with invasive coronary catheterization;
- For the purpose of screening or disease surveillance;
- Within 30 days of a myocardial infarction;
- Current completed and interpreted CCTA documents **any** of the following results:
  - Normal CCTA;
  - CAD-RADS-0;
  - High-grade stenosis (> 70%);
  - CAD-RADS 4; **or**
  - CAD-RADS 5

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CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP:	Subject to all terms and conditions noted above in the policy.

SOURCES

1. Other payers
2. Evicore Cardiac Imaging Guidelines
3. Medicare Billing Article: Artificial IntelligenceEnabled CT Based Quantitative CoronaryTopography (AI-QCT)/Coronary PlaqueAnalysis (AI-CPA)

CPT® is a registered trademark of the American Medical Association

POLICY APPROVAL DATES

New: 3/26

Revised: 7/26

Reviewed:

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
7/1/2026	Further clarified first bullet of criteria

RESOURCE COORDINATION POLICY

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POLICY NAME: ARTIFICIAL INTELLIGENCE ENABLED CT BASED QUANTITATIVE CORONARY TOPOGRAPHY (AI-QCT) CORONARY PLAQUE ANALYSIS (AI-CPA)

4/15/2026	Clarified first bullet of criteria
3/1/2026	New Policy

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MEDICAL POLICY

Medical Policy Title	**Assisted Reproductive Technologies**
Policy Number	**4.01.05**
Current Effective Date	**September 1, 2026**
Next Review Date	**December 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

Additional coverage for MEDICAID MANAGED CARE/HARP MEMBERS is addressed at the end of this document.

POLICY STATEMENT(S)

All Assisted Reproductive Technologies (ART), including but not limited to, in vitro fertilization (IVF) and artificial insemination, are contract dependent. All ART services must be provided by health care professionals who are qualified to provide such services, in accordance with the guidelines established and adopted by the American Society for Reproductive Medicine.

I. IVF, a type of ART, is considered **medically appropriate** when the following criteria are met:

   A. A diagnosis of infertility has been made, as defined by NYS Insurance Law §4303 (see Description V); **and**

   B. For individuals younger than 35 years of age, when a successful pregnancy has not been achieved after six to 12 cycles of assisted insemination (e.g., artificial insemination or therapeutic donor insemination);

   OR

   C. For individuals 35 years or older, when a successful pregnancy has not been achieved after three to six cycles of assisted insemination (e.g., artificial insemination or therapeutic donor insemination); **and**

   D. Failure of other reasonable, less expensive, and medically appropriate infertility treatments have not resulted in a successful pregnancy (e.g., treatment of ovulatory dysfunction, surgical treatment, etc.).

II. ART are **not medically necessary** for members who have undergone permanent birth control procedures (e.g. bilateral tubal ligation or vasectomy) as they do not meet the definition of infertility (refer to Policy Guideline VII).

III. ART are **not medically necessary** when the reversal of an elective sterilization does not restore fertility (e.g., a male member who remains azoospermic following the reversal of a prior elective sterilization), or either partner has undergone an elective sterilization in the past.

IV. IVF cycles initiated for the sole purpose of embryo banking are considered **not medically necessary**.

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V. The following are considered **investigational**:

A. Assisted embryo hatching; (CPT 89253)

B. Hyaluronan binding assay (HBA);

C. Co-culture of embryos; (CPT 89251)

D. Sperm DNA integrity tests (e.g., sperm chromatin structure assay [SCSA], sperm chromatin dispersion test [SCD], sperm DNA fragmentation assay [SDFA], deoxynucleotidyl transferase-mediated deoxyuridine triphosphate-biotin nick end labeling [TUNEL], single cell electrophoresis assay [COMET]); **and**

E. Reproductive medicine (endometrial receptivity analysis [ERA]), RNA gene expression profile, 238 genes by next-generation sequencing, endometrial tissue, predictive algorithm reported as endometrial window of implantation (e.g., pre-receptive, receptive, post-receptive).

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

Pharmacy Policies:

Infertility Medications, 1350/20.000567

POLICY GUIDELINE(S)

I. A cycle of assisted insemination consists of:

1. Monitoring for ova production and ovulation (e.g., lab tests and ultrasound);
2. Monitoring the uterine lining prior to insemination (e.g., ultrasound);
3. Preparation of fresh or frozen semen;
4. Intracervical (ICI) or intrauterine (IUI) insemination.

II. IVF is considered a cycle of treatment rather than a procedure at a single point in time.

A. An IVF cycle consists of:

1. taking medication to stimulate production of ova;
2. retrieval of ova;
3. fertilization of ova with sperm to create embryo(s);
4. fertilized embryo(s) transferred to the uterus;

OR

5. taking medication to prepare the endometrium

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6. thawing and transfer of previously cryopreserved embryo(s)

III. All cryopreserved embryos that are suitable for transfer must be transferred prior to initiating another ovarian stimulation. Each transfer of an embryo(s) (either fresh or cryopreserved) is considered the completion of an IVF cycle.

IV. If a member undergoes ovarian stimulation, ova retrieval and fertilization, that does not result in any viable embryos, this will still constitute an IVF cycle.

V. Preimplantation genetic testing is not an indication for IVF.

VI. Peer-reviewed, published studies and professional society guidelines do not provide data concerning the appropriate number of cycles. Therefore, based upon specialty clinician input, when coverage is available for ART services and cycle limitations are not stipulated in the member's subscriber contract, the following will be considered medically appropriate:

A. Artificial insemination is limited to a lifetime maximum of six (6) cycles; and

B. IVF is limited to a lifetime maximum of three cycles. A "cycle" is considered all treatment that starts when: preparatory medications are administered with the intent of undergoing IVF with embryo transfer.

VII. There may be certain clinical situations where IVF could be considered first-line therapy for infertility (e.g., azoospermia, hysterosalpingogram demonstrating blocked fallopian tubes). These scenarios will be reviewed on a case-by-case basis for determination of medical necessity.

VIII. Methods of permanent birth control (e.g., bilateral tubal ligation or vasectomy) will not be considered causes of infertility.

IX. Infertility treatments for a partner who is not a member of the Health Plan are **ineligible for coverage.**

X. Gestational Carrier/Surrogacy/Use of Host Uterus: Ovarian stimulation and the retrieval of eggs are covered for individuals with a known medical cause of infertility, who meet the criteria for IVF, and have IVF benefit coverage. The implantation of eggs, donor sperm, or embryo(s) into a gestational carrier/surrogate/host uterus, regardless of their Health Plan member status is not covered. A Health Plan member's pregnancy, as a result of acting as a gestational carrier/surrogate/host uterus, would be covered per the gestational carrier/surrogate/host uterus Health Plan member's benefit contract.

XI. Reciprocal IVF: In cases where both the egg donor and gestational carrier are both uterus and/or ovary bearing individuals and intended parents, ovarian stimulation and egg retrieval are covered dependent on the egg donor's IVF benefit contract. Both the egg donor and gestational carrier must meet criteria in policy statement I to proceed with IVF unless failure of other medically appropriate infertility treatments have not resulted in a successful pregnancy (e.g., treatment of ovulatory dysfunction, surgical treatment, use of donor sperm for assisted insemination, etc.).

XII. Fertility Preservation: Refer to Description V.B.

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XIII. Clinical contraindications to infertility treatment include:

A. Use of prescription medication detrimental to or contraindicated for pregnancy; or

B. Any coexisting medical conditions that place the patient and/or fetus at unacceptable risk (e.g., uncontrolled diabetes mellitus, poorly controlled hypertension, clinically severe obesity).

XIV. Contract Exclusions and Limitations:

A. IVF and other forms of ART are contract-dependent. Please refer to the terms of the member's contract or service agreement prior to review.

B. The following services may be **ineligible for coverage**:

1. Procurement of donor sperm or ova;
2. Cryopreservation of eggs, sperm or semen, embryo, oocyte, testicular or ovarian reproductive tissue.
3. Monitoring and storage of cryopreserved eggs, embryo, oocyte, sperm or semen, testicular or ovarian reproductive tissue or previously frozen embryos;
4. Thawing of cryopreserved eggs, embryo, oocyte, sperm or semen, testicular or ovarian reproductive tissue;
5. Cloning services and procedures;
6. Reversal of tubal ligations;
7. Reversal of vasectomies;
8. Travel expenses.

DESCRIPTION

The American Society for Reproductive Medicine (ASRM, 2023) has defined infertility as a "disease, condition, or status characterized by the inability to achieve a successful pregnancy based on a patient's medical, sexual, and reproductive history, age, physical findings, diagnostic testing, or any combination of those factors; or the need for medical intervention, including, but not limited to, the use of donor gametes or donor embryos in order to achieve a successful pregnancy either as an individual or with a partner; or in patients having regular, unprotected intercourse and without any known etiology for either partner suggestive of impaired reproductive ability, evaluation should be initiated at 12 months when the female partner is under 35 years of age and at six months when the female partner is 35 years of age or older. Nothing in this definition shall be used to deny or delay treatment to any individual, regardless of relationship status or sexual orientation."

I. There are many causes of infertility, and may include:

A. Ovulatory dysfunctions such as: amenorrhea, oligoovulation, oligomenorrhea, or hyperprolactinemia;

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B. Uterine anomalies and abnormalities, such as unicornate, septate or bicornate uteri, endometrial polyps, submucous myomas, or synechiae;

C. Peritoneal factors, such as endometriosis or pelvic/adnexal adhesions;

D. Anatomic tubal damage or disease;

E. Cervical factors, such as abnormal cervical mucus production or poor sperm-mucous interaction;

F. Azoospermia - the absence of spermatozoa/sperm;

G. Oligospermia - low sperm count;

H. Low sperm motility; and

I. Teratospermia - abnormal semen morphology.

II. ART procedures involve the laboratory handling of human ova, sperm and embryos in response to diagnosed infertility. ART procedures include, but are not limited to, the following:

A. Assisted insemination procedures in which fertilization takes place within the human body:

1. Artificial Insemination - a process involving the non-coital introduction of sperm into the cervical canal (intracervical) or uterine cavity (intrauterine), to produce conception. Intrauterine insemination can be used with ovulation stimulation.

2. Therapeutic Donor insemination- a process that requires the use of donor sperm, for assisted insemination.

B. Procedures in which fertilization takes place outside the human body:

1. In-Vitro Fertilization (IVF) - a process in which mature ova are removed from the ovaries by various methods, placed in a laboratory medium with sperm, and incubated. The embryo(s) are then placed into the uterus through the cervix.

2. Cryopreserved Embryo Transfer (CET) - the transfer of embryo(s) that were previously cryopreserved (frozen) in the laboratory, thawed, and then transferred into the uterus.

3. Intracytoplasmic Sperm Injection (ICSI) - the micromanipulation of sperm performed in a laboratory, and involving the injection of a single sperm directly into the cytoplasm of a mature ovum using a microinjection pipette.

C. Natural oocyte retrieval (NORIVF) - the harvesting of ova from the ovary following natural ovulation (ovulation without hormone therapy).

III. Co-culture of embryos involves an effort to improve the culture media for embryos, so that a greater proportion of embryos will reach the blastocyst stage and, hopefully, improve the implantation and pregnancy rate. In the co-culture procedure, "helper" cells are grown along with the developing embryo. A variety of co-culture techniques have been investigated, involving the use of feeder cell layers derived from a range of tissues (e.g., human oviducts, fetal bovine uterine or oviduct cells), to established cell lines.

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IV. Assisted hatching involves a procedure intended to thin or perforate the zona pellucida. It has been investigated as a method of improving the implantation and subsequent pregnancy rates following IVF. Several techniques have been used to mechanically or chemically weaken the zona pellucida, including drilling, dissection, application of acid solutions or proteinases, and laser energy.

V. New York Insurance Law §4303 defines infertility as "a disease or condition characterized by the incapacity to impregnate another person or to conceive, due to the failure to establish a clinical pregnancy after 12 months of regular, unprotected sexual intercourse or therapeutic donor insemination, or after six months of regular unprotected sexual intercourse or therapeutic donor insemination for a female 35 years of age or older." The law also mandates the following benefits for treatment of infertility, under most insured managed care and indemnity health plans.

   A. Policies that provide coverage of hospital care or surgical and medical care must cover the following services:

      1. Services in relation to surgical and medical procedures to correct malformation, disease or dysfunction resulting in infertility; and
      2. Services in relation to diagnostic tests and procedures necessary:
         a. To determine infertility; or
         b. In connection with any surgical or medical treatments or prescription drug coverage included in the mandate.

   B. In 2020, the law was expanded to require coverage of the following fertility preservation services under most insured managed care and indemnity health plans.

      1. Standard fertility preservation services when a medical treatment is necessary to correct malformation, disease or dysfunction that may, directly or indirectly, cause iatrogenic infertility; or when fertility is impaired by surgery, radiation, chemotherapy or other medical treatment affecting reproductive organs or processes. Standard fertility preservation services include the collecting, preserving, and storage of ova or sperm.
      2. Basic infertility treatments (e.g., intrauterine insemination procedures) must be provided to individuals who are unable to conceive due to their sexual orientation or gender identity.
      3. Standard fertility preservation services will be covered for individuals whose medical treatment for gender dysphoria will directly or indirectly result in iatrogenic infertility.
      4. Cryopreservation will be covered in connection with an intended IVF procedure if medically necessary, until the three covered IVF cycles are provided.

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Under the statute, fertility preservation services solely for the purpose of delaying reproduction are not eligible for coverage. The statute does not require coverage of procedures to reverse a previous voluntary sterilization procedure or infertility treatment for a person in connection with such reversal.

C. Policies providing coverage for prescription drugs that also cover hospital or medical/surgical services must provide coverage for FDA approved drugs for the diagnosis and treatment of infertility.

1. Also excluded from the mandate are medical or surgical services or procedures that are deemed experimental in accordance with the guidelines and standards of the American College of Obstetricians and Gynecologists (ACOG) and the American Society for Reproductive Medicine (ASRM), which state: "A procedure for the treatment of infertility is considered experimental until there is adequate scientific evidence of safety and efficacy from appropriately designed, peer-reviewed, published studies by different investigator groups."
2. The diagnosis of infertility must be made, and treatment must be prescribed by a physician and documented in plan of care.
3. The determination of appropriate candidates for the treatment of infertility, and the identification of the required training, experience and other standards for health care providers who wish to diagnose and treat infertility, are governed by the standards and guidelines adopted by ACOG and ASRM.

VI. Endometrial Receptivity Analysis (ERA)-ERA has been proposed for women with repeat implantation failures. The goal of ERA is to identify an individual's window of implantation (WOI) during an IVF transfer cycle. This requires a biopsy of the endometrium during a mock transfer cycle of IVF, where the individual undergoes the preparatory steps of IVF, including medications. No transfer of embryos occurs at this time. After endometrial biopsy, the receptivity is measured by the presence of exogenous and/or endogenous progesterone after oestradiol priming and is analyzed through next-generation sequencing to identify each endometrial stage: proliferative, pre-receptive, receptive, and post-receptive. The identification of the receptive stage might push forward or back the date of embryo transfer.

VII. Surrogacy/Gestational Carrier/Host Uterus- Traditional surrogacy is defined as the use of an individual who has a biological connection to the intended parents to receive eggs, or donor sperm to have a biologically related child when infertility is diagnosed. This can be accomplished through assisted insemination or IVF. A gestational carrier is a third-party individual without any familial/biological connection to intended parents who are infertile, who agrees to act as a host uterus, to receive eggs, donor sperm, or embryo(s) to achieve and carry a pregnancy. This is typically accomplished via IVF, unless the gestational carrier also provides the donor eggs, which would allow for attempts at assisted insemination.

VIII. Reciprocal IVF is a process that allows two uterus-bearing people to participate biologically in a pregnancy in which both the egg donor and gestational carrier are the intended parents.

SUPPORTIVE LITERATURE

This policy is based upon Health Plan contract benefits and is intended to clarify those benefits.

Assisted Hatching (AH)

The AH procedure has been utilized by clinicians, but this practice is not strongly supported by the evidence. In 2012, Carney et al published an update of a 2009 Cochrane systematic review and meta-analysis on AH, to determine the effect of AH of embryos from assisted conception on live birth and multiple pregnancy rates. Randomized, controlled trials (RCTs) of AH (mechanical, chemical or laser disruption of the zona pellucida prior to embryo replacement) versus no AH that reported live birth or clinical pregnancy were reviewed for quality assessments and data extraction. Thirty-one trials reported clinical pregnancy data, including 1992 clinical pregnancies in 5728 women. The authors concluded that, while AH does appear to offer a significantly increased chance of achieving a clinical pregnancy, the extent to which it may do so only just reaches statistical significance; the "take home" baby rate was still not proven to be increased by AH; and the included trials provided insufficient data to investigate the impact of AH on several important outcomes and most trials still failed to report on live birth rates. The current data do not support the use of AH as a routine practice to improve IVF outcomes.

A 2021 Cochrane review, by Lacey et al, was conducted to determine the effects of AH of embryos services from assisted conception on live birth and multiple pregnancies. The review included 39 RCTs, comprised of 7,249 women and 2,486 clinical pregnancies. Authors concluded that routine use of AH is not supported by strong evidence. The effects of AH on live birth rates are uncertain and AH may lead to increased risk of multiple pregnancy. AH may offer a slightly increased chance of achieving a clinical pregnancy, but data quality was low grade. Alteri et al (2024) published a randomized controlled trial that evaluated whether laser-mediated assisted hatching performed on vitrified/warmed blastocysts before embryo transfer can improve live birth rate. 698 participants met the inclusion criteria and were randomized: 352 patients were assigned to the AH arm and 346 to the control arm. Inclusion criteria were women at oocyte retrieval aged greater than or equal to 40 years, first or second frozen cycle using vitrified blastocysts, first or second oocyte retrieval, and collapsed blastocysts vitrified after laser-assisted artificial shrinkage. Patients transferring frozen blastocysts obtained from frozen oocytes could be included. Patients were not enrolled in the presence of any of the following exclusion criteria: preimplantation genetic testing cycle, body mass index (BMI) of >35 kg/m2, uterine abnormalities (e.g., adenomyosis, submucous myoma, septate uterus, and endometrial polyps), unoperated hydrosalpinx, and severe male factor (use of surgically retrieved spermatozoa). The primary outcome was the live birth rate. Secondary end points included clinical pregnancy, miscarriage, multiple pregnancies, preterm births, obstetric and neonatal complications, and congenital anomalies. Of the participants, 105 (29.8%) and 101 (29.2%), respectively, achieved a live birth after treatment. The relative risk of live birth in patients with vitrified/warmed blastocysts treated with AH was 1.02 (95% confidence interval, 0.86–1.19). Exploratory subgroup analyses for women's age, recruiting centers, indications for in vitro fertilization, method of insemination, blastocyst quality, and days of blastocyst development failed to highlight any clinical situation that

could benefit from AH in thawed blastocysts. Authors concluded, in patients undergoing frozen embryo transfer with vitrified/warmed blastocysts, laser AH does not improve the live birth rate. Further studies are required to rule out milder but potentially interesting benefits in specific subgroups of patients.

The most recently updated guideline from the American Society of a Reproductive Medicine that addresses AH (2022) states, "In studies evaluating pregnancy rates in an unselected patient population, there is moderate evidence that live birth rates are not significantly different between embryos that have undergone AH vs. those that have not. In patients with a poor prognosis, the data are mixed regarding improvement in live birth rates with laser-AH." The data is insufficient to make recommendations regarding the use of laser-AH in frozen embryo transfer cycles (Strength of evidence: B; strength of recommendation: moderate).

Co-Culture of Embryos

There is no standardized method of co-culture, and few clinical trials have evaluated outcomes. Most studies have not found improved implantation or pregnancy rates after co-culture. One 2015 randomized, controlled trial reported on a novel co-culture method, and an interim analysis of the trial found a higher clinical pregnancy rate with co-culture than with standard practice control group. Additional studies are needed to evaluate this novel co-culture technique. No studies have reported on the impact of co-culture on live birth rates.

ERA

To date, only one RCT has been identified comparing ERA (personalized embryo transfer [pET]) with IVF conducted with frozen (FET) or fresh embryo transfer (ET) (Simon et al 2020). The study included 458 patients over 16 centers, who were less than 37 years of age undergoing IVF with blastocyst transfer. The study reported significantly higher cumulative pregnancy and live birth rates but there were several limitations. The intention to treat analysis demonstrated comparable clinical outcomes across the three transfer types, individuals with repeated infertility failures were excluded, and there was a 50% drop out rate causing the study to be underpowered. The evidence does not demonstrate that personalized embryo transfer utilizing the ERA test improves the net health outcome.

PROFESSIONAL GUIDELINE(S)

The American Urological Association (AUA), in collaboration with the American Society for Reproductive Medicine, released the 2024 Male Infertility Guideline. This guideline provides a comprehensive framework for evaluating and managing the male partner in an infertile couple. It emphasizes the importance of obtaining a thorough history and conducting a physical examination, followed by appropriate diagnostic testing when necessary. The guideline also covers medical treatments, surgical techniques, and the use of intrauterine insemination and assisted reproductive technologies to ensure optimal patient care.

The American Society for Reproductive Medicine (ASRM) has several committee opinions that address assistive reproductive technologies (see reference section). ASRM does not recommend ERA, AH or co-culture of embryos for routine IVF patients.

The American College of Obstetricians and Gynecologists (ACOG) committee opinion number 671 (reaffirmed 2020) does not recommend ERA, AH, or co-culture for routine IVF patients. Their guidance focuses on patient safety and counseling rather than endorsing adjunctive lab techniques.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) is responsible for ensuring the safety, efficacy, and quality of drugs sold in the United States. This includes both prescription and over-the-counter medications. Refer to the FDA Drug website. Available from: https://www.fda.gov/drugs [accessed 2025 Nov 6]

The FDA maintains information for consumers and health professionals on new drug warnings and other safety information, drug label changes, and shortages of medically necessary drug products. Available from: Drug Safety and Availability [accessed 2025 Nov 6]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
58321	Artificial insemination; intra-cervical
58322	Artificial insemination; intra-uterine
58323	Sperm washing for artificial insemination
58970	Follicle puncture for oocyte retrieval, any method
58974	Embryo transfer, intrauterine
58976	Gamete, zygote, or embryo intrafallopian transfer, any method
89250	Culture of oocyte(s)/embryo(s), less than 4 days

Code	Description
89251 (E/I)	Culture of oocyte(s)/embryo(s), less than 4 days; with co-culture of oocyte(s)/embryos
89253 (E/I)	Assisted embryo hatching, microtechniques (any method)
89254	Oocyte identification from follicular fluid
89255	Preparation of embryo for transfer (any method)
89257	Sperm identification from aspiration (other than seminal fluid)
89261	Sperm isolation; complex prep (e.g. Percoll gradient, albumin gradient) for insemination or diagnosis with semen analysis
89264	Sperm identification from testis tissue, fresh or cryopreserved
89268	Insemination of oocytes
89272	Extended culture of oocyte(s)/embryo(s), 4-7 days
89280	Assisted oocyte fertilization, microtechnique; less than or equal to 10 oocytes
89281	Assisted oocyte fertilization, greater than 10 oocytes
89258	Cryopreservation; embryo(s)
89259	Cryopreservation; sperm
89335	Cryopreservation, reproductive tissue, testicular
89337	Cryopreservation, mature oocyte(s)
89342	Storage, (per year); embryo(s)
89343	Storage, (per year); sperm/semen
89344	Storage, (per year); reproductive tissue, testicular/ovarian
89346	Storage, (per year); oocyte(s)
89352	Thawing of cryopreserved; embryo(s)
89353	Thawing of cryopreserved; sperm/semen, each aliquot

Code	Description
89354	Thawing of cryopreserved; reproductive tissue, testicular/ovarian
89356	Thawing of cryopreserved; oocytes, each aliquot
89398	Unlisted reproductive medicine laboratory procedure

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HCPCS Codes

Code	Description
S4011	In vitro fertilization; including but not limited to identification and incubation of mature oocytes, fertilization with sperm, incubation of embryo(s), and subsequent visualization for determination of development
S4013	Complete cycle, gamete intrafallopian transfer (GIFT), case rate
S4015	Complete in vitro fertilization cycle, not otherwise specified, case rate
S4016	Frozen in vitro fertilization cycle, case rate
S4017	Incomplete cycle, treatment cancelled prior to stimulation, case rate
S4018	Frozen embryo transfer procedure cancelled before transfer, case rate
S4020	In vitro fertilization procedure cancelled before aspiration, case rate
S4021	In vitro fertilization procedure cancelled after aspiration, case rate
S4022	Assisted oocyte fertilization, case rate
S4025	Donor services for in vitro fertilization (sperm or embryo), case rate
S4026	Procurement of donor sperm from sperm bank
S4027	Storage of previously frozen embryo
S4028	Microsurgical epididymal sperm aspiration (MESA)
S4030	Sperm procurement and cryopreservation services; initial visit
S4031	Sperm procurement and cryopreservation services; subsequent visit

Code	Description
S4035	Stimulated intrauterine insemination (IUI), case rate
S4037	Cryopreserved embryo transfer, case rate
S4040	Monitoring and storage of cryopreserved embryos, per 30 days
S4042	Management of ovulation induction (interpretation of diagnostic tests and studies, non-face-to-face medical management of the patient), per cycle

ICD10 Codes

Code	Description
E23.0	Hypopituitarism
N46.01-N46.9	Male infertility (code range)
N97.0-N97.9	Female infertility (code range)
Z31.83	Encounter for assisted reproductive fertility procedure cycle

REFERENCES

Alteri, Alessandra, et al. The effect of laser-assisted hatching on vitrified/warmed blastocysts: the ALADDIN randomized controlled trial. Fertil Steril. 2024.Jul;122(1):106-113.

American College of Obstetricians and Gynecologists Committee on Gynecologic Practice. ACOG committee opinion. No. 22. Anticipatory counseling regarding ovarian-factor fertility decline. Obstet Gynecol. 2025 Nov; 146(5).

American College of Obstetricians and Gynecologists Committee on Gynecologic Practice; Practice Committee of the American Society for Reproductive Medicine. Practice Bulletin No. 230: Obesity in Pregnancy. Obstet Gynecol. 2021 Jun;128(6):1450. Reaffirmed 2025.

American College of Obstetricians and Gynecologists Committee on Gynecologic Practice [Internet]. ACOG committee opinion. No.671. Perinatal risks associated with assisted reproductive technology [September 2016; reaffirmed 2020; accessed 2025 Nov 12]. Available from: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2016/09/perinatal-risks-associated-with-assisted-reproductive-technology.

American Society for Reproductive Medicine. [Internet]. Available from: https://www.asrm.org/practice-guidance/practice-committee-documents/ [accessed 2025 Nov 6].

- ASRM Standard Embryo Transfer Protocol Template: A Committee Opinion. 2017 Nov.

- Blastocyst Culture and Transfer in Clinical-Assisted Reproduction: A Committee Opinion. 2018 Dec.
- Definition Of Infertility: A Committee Opinion. 2023 Dec
- Fertility Evaluation of Infertile Women: A Committee Opinion. 2021 Nov.
- Diagnostic Evaluation of Sexual Dysfunction in the Male Partner in the Setting of Infertility. 2023 Nov.
- Diagnosis and Treatment of Infertility in Men: AUA/ASRM Guideline Part I And II. 2021 Jan
- Guidance on the Limits to the Number of Embryos to Transfer: A Committee Opinion. 2021 Sept.
- Intracytoplasmic Sperm Injection (ICSI) for Non-Male Factor Indications: A Committee Opinion. 2020 Aug.
- In Vitro Maturation. 2021 Feb.
- Optimizing Natural Fertility: A Committee Opinion. 2022 Jan.
- Recommendations for Practices Using Gestational Carriers. 2022 Jul.
- Minimum Standards for Practices Offering Assisted Reproductive Technologies: A Committee Opinion. 2020 Mar.
- The Role of Assisted Hatching in In Vitro Fertilization: A Guideline. 2022 Jun.

Brannigan RE, et al. Updates to male infertility: AUA/ASRM guideline (2024). J Urol. 2024 Aug.

Centers for Disease Control and Prevention [Internet]. Assisted reproductive technology. [Updated 2024 December 10; accessed 2025 Nov 7]. Available from: https://www.cdc.gov/ART/index.html].

Glujovsky D, et al. Cleavage stage versus blastocyst stage embryo transfer in assisted conception. Cochrane Database Syst Rev. 2022;(5):CD002118.

Lacey L, et al. Assisted hatching on assisted conception (in vitro fertilization (IVF) and intracytoplasmic sperm infection (ICSI)). Cochrane Database Syst Rev. 2021 Mar 17;CD001894.

New York Insurance Law [Internet]. §§ 3221(k)(6)(C) [Accessed 2025 Nov 7]. Available from: Laws of New York.

New York Insurance Law [Internet]. §§ 4303(s)(3) [Accessed 2025 Nov 7]. Available from: Laws of New York.

Salang L, et al. Luteal phase support for women trying to conceive by intrauterine insemination or sexual intercourse. Cochrane Database Syst Rev. 2022 Aug 24;(8) CD012396.

Simon, et al. A 5-year multicentre randomized controlled trial comparing personalized, frozen and fresh blastocyst transfer in IVF. RBMO. 2020 ;41(3):402-415.

Sini I, et al. Embryo banking with mild ovarian stimulation for IVF: an alternative strategy for poor prognosis patients. J Reprod Infertil. Jul-Sep 2020;21(3):176-182.

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Su H, et al. Fertility preservation in people with cancer: ASCO guideline update. J Clin Oncol. Apr 20 2025; 43(12): 1488-1515.

Teixeira DM, et al. Regular (ICSI) versus ultra-high magnification (IMSI) sperm selection for assisted reproduction. Cochrane Database Syst Rev. 2020;(2):CD010167.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Effective October 1, 2019, Medicaid Managed Care (MMC) and Health and Recovery Plan (HARP) benefits will include medically necessary ovulation enhancing drugs and medical services related to prescribing and monitoring the use of such drugs for individuals 21 through 44 years of age experiencing infertility.

For Medicaid purposes, infertility is a condition characterized by the incapacity to conceive, defined by the failure to establish a clinical pregnancy after:

1. Twelve months of regular, unprotected sexual intercourse for individuals 21 through 34 years of age, or
2. Six months for individuals 35 through 44 years of age.

Infertility benefits include:

1. Office visits;
2. Hysterosalpingograms;
3. Pelvic ultrasounds;
4. Blood testing;
5. Ovulation enhancing drugs.

The ovulation enhancing drugs included in the Medicaid formulary are:

1. Bromocriptine;
2. Clomiphene Citrate;
3. Letrozole;
4. Tamoxifen.

Benefits will be limited to coverage for three (3) cycles of treatment per lifetime.

October 2019 Medicaid Update Bulletin. Available from: https://www.health.ny.gov/health_care/medicaid/program/update/2019/2019-06.htm#ovulation [accessed 2025 Nov 06].

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

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POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 11/89 **Revised**: 02/93, 05/94, 03/95, 08/95, 06/96, 12/97, 09/98, 11/99, 05/00, 04/02, 11/02, 02/03, 1/04, 01/05, 11/05, 11/06, 04/07, 03/08, 09/08, 09/09, 11/09, 09/10, 09/11, 09/13, 09/14, 09/15, 11/15, 11/16, 07/17, 09/18, 09/19, 01/20, 03/20, 07/20, 09/20, 01/21, 3/21, 5/21, 7/21, 9/21, 11/21, 5/22, 9/22, 9/23, 11/23, 3/24, 7/24, 11/24, 1/25, 7/25, 9/25, 5/26 **Reviewed**: 08/94, 09/12, 09/16, 09/17	
Date	**Summary of Changes**
9/1/2026	• Transitioned Infertility Services policy, 1370/20.000050 to Lifetime HealthCare Companies policy template.
9/1/2025	• Updated information throughout the policy referencing new pharmacy policy, Infertility Medications, 1350/20.000567.
2/1/2025 * No change to effective date of policy	• Removed reference to Avalon Healthcare Solutions and updated with current genetic vendor (HealthHelp).
2/1/2025	• Under exclusions added: Endometrial Receptivity Analysis (ERA) test, 0253U.
10/1/2024 *No change to effective date of policy	• Under IUI- removed cycle limits. • Under Advanced Infertility, updated verbiage for storage of ova/sperm.
10/1/2024	• Added pertinent codes to Procedure Codes Section
7/1/2024	• Under Fertility Preservation section added statement regarding collecting more than one sample and under exclusions added endometrial scratching/injury to improve uterine/endometrial receptivity.
3/1/2024	• Under the IVF section added the following statement: Prior authorization will need to be obtained for each individual cycle.

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12/1/2023	• Clarified verbiage for storage of oocytes/embryos. • Added statement on utilization of frozen embryos/oocytes prior to fresh retrieval for IVF. • Added exclusion for single members who have not demonstrated infertility.
9/1/2023	• Under Medicaid section: • removed reference to Clomiphene for Female Infertility policy as this policy is now obsolete. • added verbiage that effective 4/1/23 pharmacy benefit is administered by NYRx.
9/1/2022 * No change to effective date	• Added examples of conditions that may preclude a trial of artificial insemination/intrauterine insemination.
9/1/2022	• Removed the following statement as all providers are required to obtain prior authorization: Infertility services require authorization when rendered by providers other than the enrollee's primary care physician or designated obstetrical/gynecological practitioner.
01/18/2022	• Updated verbiage for preimplantation genetic testing: coverage for PGT in accordance with criteria outlined in policy, M2039 – Pre-Implantation Genetic Testing. Prior authorization is required through Avalon Healthcare Solutions (see Genetics & Molecular Diagnostics/1370/20.000210 policy).
12/1/2021	• Under Fertility Preservation Services and Exclusions sections, clarified fertility preservation benefit of embryos for members who are approved for advanced infertility services.
11/1/2021 *No change to effective date	• Under Advanced Infertility, updated criteria for eligibility of IVF services.

5/1/2021* *No change to effective date	• As result of DFS Circular Letter dated February 2021, updated Position Statement to include enrollees who are identified as gender non-binary or transgender, or who are a same-sex couple, which removes the "waiting period" of meeting the definition of infertility and removed information about surrogacy from the Exclusions section.
5/1/2021	• Added section to address coverage for intra-cytoplasmic sperm injection (ICSI). • Removed termed code 0058T and replaced with 89398.
3/11/2020 (Effective date on policy remains the same)	• Added infertility treatment in connection with reversal of a previous voluntary sterilization to the Exclusions section.
3/11/2020	• Added section to address preimplantation genetic testing relating to IVF procedure.
1/1/2020	• Added section on advanced infertility services and updated fertility preservation services section in accordance with NYS mandate effective 1/1/20.

MEDICAL POLICY

Medical Policy Title	**Autologous Hematopoietic Stem Cell Transplantation (Auto-HSCT)**
Policy Number	**7.02.03**
Current Effective Date	**July 1, 2026**
Next Review Date	**February 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Autologous hematopoietic stem cell transplant (auto-HSCT) is considered **medically appropriate** when **ALL** of the following criteria are met:

A. Candidates have met the transplanting institution's selection criteria;

B. The multidisciplinary team has evaluated the individual and recommends treatment (see policy guidelines for required documentation); **and**

C. The individual meets the following indication-specific criteria:

Blood/Plasma Cancers

1. Acute Promyelocyte Leukemia
   a. Adult ≥ age 18; in the following disease state:
      i. CR2, in molecular remission
   b. Child ≤ age 17; in the following disease state:
      i. Relapse;
2. Multiple Myeloma
   a. Adult ≥ age 18; in any of the following disease states:
      i. Initial response;
      ii. Sensitive relapse;
      iii. Refractory;
3. Plasma Cell Leukemia
   a. Adult ≥ age 18;
4. Amyloid Light-chain Amyloidosis
   a. Adult ≥ age 18

5. POEMS Syndrome
    a. Adult ≥ age 18
6. Relapse after Autologous Transplant
    a. Adult ≥ age 18
7. Hodgkin Lymphoma
    a. Adult ≥ age 18; in **any** of the following disease states:
        i. Primary refractory, sensitive;
        ii. First relapse, sensitive; **or**
        iii. Second or greater relapse
    b. Child ≤ age 17; in **any** of the following disease states:
        i. Primary refractory, sensitive;
        ii. First relapse, sensitive; **or**
        iii. Second or greater relapse;
8. Diffuse Large B-cell Lymphoma
    a. Child ≤ age 17; in **any** of the following disease states:
        i. Primary refractory, sensitive;
        ii. First relapse, sensitive; **or**
        iii. Second or greater relapse;
    b. Adult ≥ age 18; and in **any** of the following disease states
        iv. Primary refractory, sensitive;
        v. First relapse, sensitive; **or**
        vi. Second or greater relapse;
9. High-grade B cell Lymphoma, with MYC and BCL2 or BL6 rearrangements:
    a. Adult ≥ age 18; and in **any** of the following disease states
        i. CR1 (positron emission tomography negative);
        ii. Primary refractory, sensitive;
        iii. First relapse, sensitive; **or**
        iv. Second or greater relapse;
10. Primary Central Nervous System Lymphoma
    a. Adult ≥ age 18; in **either** of the following disease states:

i. CR1/first partial remission (consolidation); **or**
ii. Relapse, sensitive;

11. Follicular Lymphoma
    a. Adult ≥ age 18; in **any** of the following disease states:
        i. Primary refractory, sensitive;
        ii. First relapse, sensitive (including POD24);
        iii. Second or greater relapse; **or**
        iv. Transformation to high-grade lymphoma;
12. Mantle Cell Lymphoma
    a. Adult ≥ age 18; in **any** of the following disease states:
        i. First partial remission;
        ii. Primary refractory, sensitive;
        iii. First relapse, sensitive; **or**
        iv. Second or greater relapse;
13. T-Cell non-Hodgkin Lymphoma
    a. Adult ≥ age 18; in **any** of the following disease states:
        i. CR1/first partial remission;
        ii. Primary refractory, sensitive;
        iii. First relapse, sensitive; **or**
        iv. Second or greater relapse;
    b. Child ≤ age 17; in **any** of the following disease states:
        i. CR1, standard or high risk;
        ii. CR2; **or**
        iii. Third complete remission with additional therapy (CR3+);
14. Burkitt Lymphoma
    a. Adult ≥ age 18: in the following disease state:
        i. First or greater relapse, sensitive;
    b. Child ≤ age 17; in the following disease state:
        i. First or greater relapse, sensitive;
15. Cutaneous T Cell Lymphoma

a. Adult ≥ age 18; in relapse;

16. Lymphoplasmacytic lymphoma/Waldenstrom macroglobulinemia
    a. Adult ≥ age 18; in **any** of the following disease states:
        i. Primary refractory, sensitive; **or**
        ii. First or greater relapse, sensitive;
17. Plasmablastic Lymphoma
    a. Adult ≥ age 18; in relapse;
18. Chronic Lymphocytic Leukemia
    a. Adult ≥ age 18; in **any** of the following disease states:
        i. T cell prolymphocytic leukemia;
        ii. B cell, prolymphocytic leukemia; **or**
        iii. Transformation to high-grade lymphoma;

<u>Solid Tumors</u>

19. Germ cell tumors
    a. Adult ≥ age 18; in **either** of the following disease states:
        i. Relapse; **or**
        ii. Refractory;
    b. Child ≤ age 17; in **either** of the following disease states:
        i. Relapse; **or**
        ii. Refractory;
20. Neuroblastoma
    a. Child ≤ age 17; in **either** of the following disease states:
        i. High risk; **or**
        ii. Relapse;
21. Wilms Tumor
    a. Child ≤ age 17; in relapse;
22. Osteosarcoma
    a. Child ≤ age 17; in relapse;
23. Ewing's sarcoma
    a. Adult ≥ age 18; high risk;

b. Child ≤ age 17; in **either** of the following disease states:
    i. High risk; **or**
    ii. Relapse;

24. Medulloblastoma
    a. Adult ≥ age 18; high risk or recurrent;
    b. Child ≤ age 17; high risk or recurrent;
25. Pediatric brain tumors when **both** of the following criteria are met:
    a. High risk (e.g. rhabdoid tumors); **and**
    b. The intent is to avoid craniospinal radiation therapy;

Non-Malignant Conditions

26. Multiple Sclerosis (MS)
    a. Adult ≥ age 18; and ≤ 45 years; when **all** of the following criteria are met:
        i. Individual has a diagnosis of relapsing-remitting or secondary progressive MS;
        ii. Two (2) or more clinical relapses or one (1) relapse and MRI gadolinium-enhancing lesion(s) at an independent time point in the previous 12 months;
        iii. Continued disease activity despite use of one or more FDA-approved disease-modifying therapies (e.g., interferons, glatiramer acetate natalizumab, fingolimod, dethyl fumarate); **and**
        iv. Expanded Disability Status Scale (EDSS) score between 2.0 and 5.5 or less;
27. Systemic Sclerosis
    a. Adult ≥ age 18 with **either** of the following:
        i. Pulmonary Involvement with **both**:
            a) Active interstitial lung disease (i.e., bronchoalveolar cell composition or ground-glass opacities on computed tomography of the chest); **and**
            b) Forced vital capacity or a diffusing capacity of the lung for carbon monoxide of less than 70% of the predicted value;

            OR

            c) Renal involvement with previous scleroderma-related renal disease;
    b. Child ≤ age 17
28. Juvenile Rheumatoid Arthritis;
    a. Child ≤ age 17.

II. Autologous HSCT is considered **investigational** for all other indications.

RELATED POLICIES

Corporate Medical Policy

7.02.02 Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

7.02.11 Chimeric Antigen Receptor T-cell (CAR-T) Therapy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Each individual considered for autologous stem cell transplant will be evaluated by the transplant center for potential difficulties that would complicate and diminish the success of transplantation. Consideration will be given to the patient's risk of death without transplantation, along with the presence and severity of potential contraindications to transplantation.

I. Required documentation from the multidisciplinary team that includes the individual's eligibility and risk for autologous stem cell transplant should include:

   A. Clinical Evaluation

      1. Confirmation of diagnosis;
      2. Identification of co-morbidities;
      3. Current assessment of co-morbidities;
      4. Management of co-morbidities;
      5. Consult notes (if applicable);

   B. Psycho-Social Evaluation:

      1. Identification of stressors (e.g., family support, noncompliance issues, motivational issues, alcohol, or smoking/substance abuse).

   C. Performance Status:

      1. Karnofsky performance score;
      2. Palliative Performance Scale (PPS) score;
      3. Eastern Cooperative Oncology Group (ECOG) performance status; or
      4. Lansky Play-Performance Scale (for age 1 to 16 years)

   D. Oral Health Evaluation

   E. Lab Tests:

      1. CBC;
      2. Metabolic profile;

F. Cardiac Assessment:
   1. 12 Lead EKG;
   2. Echo or Muga Scan

G. Pulmonary Assessment:
   1. Chest x-ray;
   2. Pulmonary function tests (PFTs) for high-risk for respiratory failure (COPD, emphysema, a-1-antritrypsin deficiency, hepatopulmonary syndrome, or significant smoking history);

H. Age-Appropriate Screening Tests:
   1. Please refer to the U.S. Preventive Services Task Force (USPSTF) website for list of age-appropriate screening guidelines. https://uspreventiveservicestaskforce.org/uspstf/ [accessed 2025 Nov 24]

DESCRIPTION

In auto-HCT a portion of the patient's own stem cells are re-infused intravenously to rescue the patient by re-establishing his/her bone marrow which has been eradicated after high dose chemotherapy and/or total body irradiation has been given to destroy the malignant cells. Utilization of one's own cells avoids immunologic incompatibilities that can be seen with allogeneic stem cell transplants. This also permits subsequent engraftment and repopulation of the bone marrow with normal hematopoietic stem cells obtained from the patient before undergoing bone marrow ablation. Therefore, auto-HCT is typically performed as consolidation therapy when the patient's disease is in complete remission. Patients who undergo auto-HCT are also susceptible to chemotherapy-related toxicities and opportunistic infections before engraftment.

Disability Scores

I. The Karnofsky performance status score describes a patient's functional status as a comprehensive 11-point scale correlating to percentage values ranging from 100% (no evidence of disease, no symptoms) to 0% (death). Adapted from Peus, et al 2013:

A: Able to carry on normal activity and to work. No special care is needed.	100	Normal, no complaints, no evidence of disease.
	90	Able to carry on normal activity, minor signs or symptoms of disease.
	80	Normal activity with effort, some signs, or symptoms of disease.
B: Unable to work. Able to live at home, care for most personal needs.	70	Cares for self, unable to carry on normal activity or to do active work.

A varying degree of assistance is needed.	60	Requires occasional assistance but is able to care for most of personal needs.
	50	Requires considerable assistance and frequent medical care.
C: Unable to care for self. Requires equivalent of institutional or hospital care. Disease may be progressing rapidly.	40	Disabled, requires special care and assistance. [In bed more than 50% of the time]
	30	Severely disabled, hospitalization is indicated although death not imminent. [Almost completely bedfast]
	20	Very ill, hospitalization and active supportive treatment necessary. [Totally bedfast and requiring extensive nursing care by professionals and/or family]
	10	Moribund, fatal processes progressing rapidly. [Comatose or barely arousable]
	0	Dead.

II. Palliative Performance Scale (PPS) score; adapted from Fast Facts and Concepts (Wilner and Arnold 2004):

Percentage	**Ambulation**	**Activity Level/Evidence of Disease**	**Self-Care**	**Intake**	**Level of Consciousness**
100	Full	Normal No Disease	Full	Normal	Full
90	Full	Normal Some Disease	Full	Normal	Full
80	Full	Normal with Effort Some Disease	Full	Normal or Reduced	Full
70	Reduced	Can't do normal job or	Full	As above	Full

		work Some Disease			
60	Reduced	Can't do hobbies or housework Significant Disease	Occasional Assistance Needed	As above	Full or confusion
50	Mainly sit/lie	Can't do any work Extensive Disease	Considerable Assistance Needed	As above	Full or Confusion
40	Mainly in bed	As above	Mainly Assistance	As above	Full or Drowsy or Confusion
30	Bed Bound	As above	Total Care	Reduced	As above
20	Bed Bound	As above	As above	Minimal	As above
10	Bed Bound	As above	As above	Mouth care only	Drowsy or coma
0	Death	-	-	-	-

III. Eastern Cooperative Oncology Group (ECOG) performance status; adapted from ECOG-ACRIN Cancer Research group:

Grade	ECOG PERFORMANCE STATUS
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours

4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
5	Dead

IV. Lansky Play-Performance Scale (for age 1 to 16 years)

The Lansky play-performance scale is used for children aged 1-16 with any type of malignancy. It is typically rated by parents based on their child's activity over the past week. Adapted from: Performance status | HemOnc.org - A Hematology Oncology Wiki [accessed 2025 Nov 24]:

Rating	**Description**
100	Fully active, normal
90	Minor restrictions with strenuous physical activity
80	Active, but gets tired quickly
70	Both greater restriction of, and less time spent in, active play
60	Up and around, but minimal active play; keeps busy with quieter activities
50	Lying around much of the day, but gets dressed; no active play; participates in all quiet play activities
40	Mostly in bed; participates in quiet activities
30	Stuck in bed; needs help even for quiet play
20	Often sleeping; play is entirely limited to very passive activities
10	Does not play or get out of bed
0	Unresponsive

V. Kurtzke Expanded Disability Status Scale (EDSS)

The EDSS is one of the most widely used assessment instruments in MS. It is a clinical rating scale ranging from 0 (normal neurological examination) to 10 (death due to MS) in half point increments. It is used in conjunction with the Kurtzke Functional System Scores, observation, information concerning gait and use of assistive devices in order to rate the EDSS. The guidelines recommend that patients with an EDSS of 2.0-5.5 could be considered for auto-HSCT, with 2.0 defined as minimal disability in one functional system (FS) score, and 5.5 defined as ambulatory without aid or rest for about 100 meters; disability severe enough to preclude full daily activities.

SUPPORTIVE LITERATURE

Blood Plasma Cancers

Acute Myeloid Leukemia

A meta-analysis published by Nathan et al (2004) compared survival outcomes for auto-HCT in CR1 with standard chemotherapy or no further treatment in AML patients ages 15 to 55 years. Two types of studies were eligible: (1) prospective cohort studies in which patients with an available sibling donor were offered allogeneic hematopoietic stem cell transplantation (allo-HCT) (biologic randomization) with random assignment of all others to auto-HCT or chemotherapy (or no further treatment); and (2) randomized trials that compared auto-HCT with chemotherapy in all patients. Among a total of 4058 patients included in 6 studies, 2989 (74%) achieved CR1; 1044 (26%) were randomized to HCT (n=524) or to chemotherapy (n=520). Of the 5 studies for which overall survival (OS) data were available, outcomes with auto-HCT were better in three, and outcomes with chemotherapy were better in two. None of the differences were statistically significant, nor was the pooled estimate (fixed-effects model survival probability ratio, 1.01; 95% CI, 0.89 to 1.15; p=.86). In all six studies, disease free survival (DFS) was numerically superior using auto-HCT compared with chemotherapy (or no further treatment), but only one reported a statistically significant DFS probability associated with auto-HCT. The pooled estimate for DFS showed a statistically significant probability in favor of auto-HCT at 48 months posttransplant (fixed-effects model survival probability ratio, 1.24; 95% CI, 1.06 to 1.44; p=.006). This review comprised studies performed between 1984 and 1995, during which transplant protocols and patient management evolved significantly, particularly compared with current care.

A second meta-analysis, published by Wang et al (2010), evaluated auto-HCT plus further chemotherapy or no further treatment for patients with AML in CR1. A total of nine randomized trials involving 1104 adults who underwent auto-HCT and 1118 patients who received additional chemotherapy or no additional treatment were identified. Analyses suggested that auto-HCT in CR1 is associated with a statistically significant reduction of relapse risk (relative risk, 0.56; 95% CI, 0.44 to 0.71; p=.001) and significant improvement in DFS (HR, 0.89; 95% CI, 0.80 to 0.98), but at the cost of an increased non-relapse mortality rate (relative risk, 1.90; 95% CI, 1.34 to 2.70; p=.23). There were more deaths during the first remission among patients assigned to auto-HCT than among the chemotherapy recipients or further untreated patients. As a consequence of the increased non-relapse mortality rate, no statistical difference in OS (HR, 1.05; 95% CI, 0.91 to 1.21) was associated with the use of auto-HCT, compared with further chemotherapy or no further therapy. These results are concordant with the earlier meta-analysis.

A prospective, randomized phase 3 trial by Vellenga et al (2011) compared auto-HCT with intensive consolidation chemotherapy among patients (range, 16 to 60 years) with newly diagnosed AML of similar risk profiles in CR1. After two cycles of intensive chemotherapy (etoposide and mitoxantrone), patients in CR1 who were not a candidate for allo-HCT were randomized to a third consolidation cycle of the same chemotherapy (n=259) or auto-HCT (n=258). The HCT group experienced an upward trend toward superior regression free survival (RFS) (38%) compared with the chemotherapy group at five years (29%; p=.065). The HCT patients also had a lower relapse rate at five years (58%)

compared with chemotherapy recipients (70%; p=.02). The OS did not differ between the HCT group (44%) and the chemotherapy group (41%; p=.86). Non-relapse mortality rates were higher in the auto-HCT group (4%) than in the chemotherapy consolidation group (1%; p=.02). Despite this difference in non-relapse mortality, the relative equality of OS rates was attributed by the investigators to a higher proportion of successful salvage treatments (second-line chemotherapy, autologous or allo-HCT) in the chemotherapy consolidation recipients that were not available to the auto-HCT patients. This large trial has shown an advantage for post-remission auto-HCT in reducing relapse, but similar OS rates secondary to better salvage of chemotherapy-consolidated patients.

Miyamoto et al (2018) reported results of a randomized, multicenter phase 3 trial conducted in 24 centers in Japan from 2003 to 2011 that compared auto-HCT versus HiDAC consolidation as post-remission therapy in AML. This trial enrolled 240 patients between 15 and 64 years of age with newly diagnosed favorable- and intermediate-risk AML and Eastern Cooperative Oncology Group (ECOG) performance status of <3; 87 of those who achieved CR1 were randomized to auto-HCT or HiDAC. The study was powered to include 122 patients with 5 years of accrual and 3 years of post-accrual follow-up to detect a difference in DFS at 3 years of 40% versus 65%. Approximately one-third of the patients had favorable risk AML, and the remaining two-thirds had intermediate-risk AML. The median age was 48 years. Median follow-up was approximately 4.5 to 5 years. Three-year DFS rate was 41% (95% CI, 27% to 55%) in the HiDAC group and 55% (95% CI, 38% to 68%) in the auto-HCT group (p=.25). Three-year OS was 77% (95% CI, 61% to 87%) versus 68% (95% CI, 52% to 80%) (p=.67). Cumulative incidence of relapse was 54% versus 41% (p=.22). There were no differences between the HiDAC and auto-HCT groups in the incidence of liver or renal dysfunction. The incidence of life-threatening infectious complications (p=.003) and mucositis/diarrhea (p=.002) was significantly higher in the auto-HCT group.

Multiple Myeloma

Chakraborty et al (2022) conducted a meta-analysis investigating the impact of high-dose therapy (HDT) consolidation on survival outcomes in patients with newly diagnosed multiple myeloma, focusing on differences between those with standard-risk and high-risk cytogenetics. Researchers reviewed randomized controlled trials from 2000 to 2021 comparing HDT to standard-dose therapy (SDT). Six trials were included for progression-free survival (PFS) analysis and four for OS, with follow-ups ranging from 3.1 to 7.8 years. The results showed that HDT significantly improved OS in high-risk patients (HR 0.66) compared to standard-risk patients (HR 0.90), with a statistically significant interaction (P = .03). For PFS, HDT also showed benefits in both groups, but the difference between them was not statistically significant (P = .25). Overall, the study concluded that the survival benefit of HDT is influenced by cytogenetic risk, supporting the use of upfront HDT consolidation particularly in high-risk patients.

POEMS Syndrome

For individuals who have POEMS syndrome (Polyneuropathy, Organomegaly, Endocrinopathy, Monoclonal gammopathy, and Skin abnormalities Syndrome) who receive HCT, the evidence includes retrospective cohort studies, case reports, and case series. Relevant outcomes are OS and treatment-related morbidity. No RCTs of HCT of any type have been performed in patients with POEMS

syndrome of any severity, nor is it likely such studies will be performed because of the rarity of this condition. Available case reports and series are subject to selection bias and are heterogeneous concerning treatment approaches and peritransplant support. However, for patients with disseminated POEMS syndrome, a chain of evidence and contextual factors related to the disease and multiple myeloma would suggest improvement in health outcomes with auto-HCT. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Hodgkin Lymphoma (HL)

A systematic review and meta-analysis of the available RCTs on HCT for patients with relapsed or refractory HL were published by Rancea et al (2014). Reviewers included three RCTs, 2 (1993, 2002) of which compared HDC plus auto-HCT with conventional treatment. Both trials were judged to be at moderate risk of bias using the Cochrane criteria. Combined analysis for the outcome of OS demonstrated a hazard ratio of 0.67 for patients treated with auto-HCT, which was not statistically significant (95% CI, 0.41 to 1.07). For the outcome of progression-free survival (PFS), there was a significant improvement for auto-HCT treatment, with a hazard ratio of 0.55 (95% CI, 0.35 to 0.86).

A retrospective observational cohort study by Merryman et al (2021) evaluated auto-HCT after anti-programmed death-1 (PD-1) therapy for patients with relapsed or refractory HL. A total of seventy-eight patients who were identified underwent auto-HCT as a third-line (or later) treatment; 74% of patients underwent auto-HCT after anti-PD-1 treatment and 26% of patients received anti-PD-1 treatment along with additional therapy prior to auto-HCT. The 18-month PFS and OS after auto-HCT were 81% (95% CI, 69 to 89) and 96% (95% CI, 87 to 99), respectively. Favorable outcomes were reported for patients who had received greater than four systemic therapies before auto-HCT (18-month PFS, 73%), who were refractory to two consecutive therapies immediately prior to anti-PD-1 treatment (18-month PFS, 78%), and who had positive pre-HCT positron emission tomography (PET) (18-month PFS, 75%); patients who were non-responders to anti-PD-1 treatment had inferior outcomes (18-month PFS, 51%).

Diffuse Large B-Cell Lymphoma (DLBCL)

Results of a phase 3 multicenter randomized trial, Chemoradiotherapy and Peripheral Stem Cell Transplantation Compared with Combination Chemotherapy in Treating Patients with Non-Hodgkin's Lymphoma (SWOG-9704) of auto-HCT as consolidation for aggressive (high-intermediate or high-risk) DLBCL were published in 2013 (Stiff et al). In this trial, 253 patients received five cycles of induction chemotherapy (CHOP with [n=156 (47%)] or without rituximab). Those who had at least a PR to five cycles of induction therapy were randomized to three additional cycles of CHOP (n=128) or one additional cycle of CHOP followed by auto-HCT (n=125). The primary efficacy endpoints of the trial were 2-year PFS and OS. Two-year PFS rates were 69% and 55% in the HCT and control group, respectively (HR control vs. HCT, 1.72; 95% CI, 1.18 to 2.51; p=.005). The 2-year OS rates in the HCT and control group were 74% and 71%, respectively (HR, 1.26; 95% CI, 0.82 to 1.94; p=.30). Unplanned exploratory analyses showed a differential treatment effect by disease risk level. Among high-risk patients, the 2-year OS rate was 82% in the HCT group and 64% in the control group (p=.01). The main results of this trial are consistent with earlier study results in not discerning a significant effect of early auto-HCT on OS among a group of patients with high-, intermediate-, and

high-risk diffuse B-cell NHL. However, the survival curve appeared to plateau among the high-risk HCT patients out to 10 years after study registration. Although this evidence was from exploratory subset analysis, it further supports the efficacy of this approach in such cases compared with nontransplant strategies.

The pivotal trial that established the superiority of auto-HCT for relapsed DLBCL is the Autologous Bone Marrow Transplantation as Compared with Salvage Chemotherapy in Relapses of Chemotherapy-Sensitive Non-Hodgkin's Lymphoma (PARMA) (Philip et al 1995), a prospective randomized study in which 215 patients with chemosensitive disease in first or second relapse of aggressive lymphoma were given two courses of conventional chemotherapy. A total of 109 patients responded and were randomized to four courses of chemotherapy plus radiotherapy (n=54) or radiotherapy plus intensive chemotherapy and auto-HCT (n=55). The groups did not differ in baseline characteristics. Median follow-up was 63 months. The response rate was 84% in the HCT group and 44% in the nontransplant group. The event free survival (EFS) rate for the transplant group was 46% and 12% in the nontransplant group (p=.001); the OS rate was 53% in the transplant group and 32% in the nontransplant group (p=.038).

Follicular Lymphoma (FL)

Follicular lymphoma is the most common indolent Non-Hodgkin Lymphoma (NHL) (70% to 80% of cases), and often the terms indolent lymphoma and FL are used synonymously. Also included in the indolent NHL are small lymphocytic lymphoma/chronic lymphocytic lymphoma, lymphoplasmacytic lymphoma, marginal zone lymphomas, and cutaneous T-cell lymphoma.

Schaaf et al (2012) performed a systematic review of RCTs comparing auto-HCT with chemotherapy or immunochemotherapy in patients with previously untreated or relapsed FL concerning OS, PFS, treatment-related mortality, adverse events, and secondary malignancies. Five RCTs involving 1093 patients were included, with four trials in previously untreated patients and one in relapsed patients. The quality of the five trials was judged to be moderate. There was a statistically significant increase in PFS in previously untreated FL patients in the HCT arm (hazard ratio [HR], 0.42; 95% confidence interval [CI], 0.33 to 0.54; p<.001). However, there was no statistically significant OS advantage (HR, 0.97; 95% CI, 0.76 to 1.24; p=.81). In the four trials in previously untreated patients, there were no statistically significant differences between HCT and the control arm in terms of treatment-related mortality (relative risk [RR], 1.28; 95% CI, 0.25 to 6.61; p=.77), secondary acute myeloid leukemia/myelodysplastic syndromes (RR, 2.87; 95% CI, 0.7 to 11.75; p=.14), or solid cancers (RR, 1.20; 95% CI, 0.25 to 5.77; p=.82). Adverse events were rarely reported but were more frequent in patients who underwent HCT. For patients with relapsed FL, there was some evidence from one trial with 70 patients that HCT was advantageous regarding PFS (HR, 0.30; 95% CI, 0.15 to 0.61) and OS (HR, 0.40; 95% CI, 0.18 to 0.89). No results were reported from this trial for treatment-related mortality, adverse events, or secondary cancers.

In most patients with FL relapse, and with relapsed disease, a cure is unlikely, with a median survival of 4.5 years after recurrence. In the European CUP trial (Schouten et al 2004), 89 patients with relapsed, non-transformed FL with PR or CR after standard induction chemotherapy were randomized to one of three arms: three additional cycles of conventional chemotherapy (n=24), high-dose

chemotherapy and unpurged auto-HCT (n=33), or high-dose chemotherapy with purged auto-HCT (n=32). The OS rates at 4 years for chemotherapy versus unpurged versus purged arms were 46%, 71%, and 77%, respectively. Two-year PFS rates were 26%, 58%, and 55%, respectively. No difference was found between the auto-HCT arms. Although several studies have consistently shown improved DFS with auto-HCT for relapsed FL, this study was the first to show a difference in OS benefit.

Mantle Cell Lymphoma (MCL)

Zoellner et al (2021) conducted a post-hoc analysis of an open-label, multicenter, randomized phase 3 trial on previously untreated MCL patients. A total of 269 patients were randomized to receive myeloablative radiochemotherapy followed by auto-HCT (n=134) or interferon alfa maintenance after completion of a CHOP-like induction therapy (n=135) with or without rituximab. The median follow-up period was 14 years, with the intention-to-treat population consisting of 174 patients (93 in the auto-HCT group and 81 in the interferon alfa maintenance group) who responded to induction therapy. The median PFS in the auto-HCT group was 3.3 years (95% CI, 2.5 to 4.3 years) compared to 1.5 years (95% CI, 1.2 to 2.0 years) in the interferon alfa group (log-rank p<.0001; adjusted HR, 0.5 [95% CI, 0.36-0.69]). The median OS in the auto-HCT group was 7.5 years (95% CI, 5.7 to 12.0 years) and 4.8 years (95% CI, 4.0 to 6.6 years) in the interferon alfa group (log-rank p=.019; adjusted HR, 0.66 [95% CI, 0.46-0.95]). For patients treated with a rituximab-containing induction regimen, neither PFS nor OS was significantly different between the 2 groups.

Metzner et al (2023) reported long-term outcomes for a series of 65 individuals with MCL who received auto-HCT. 54 (83%) received first-line auto-HCT, 10 (15%) received second-line auto-HCT. The 10-year OS and PFS after first-line HCT were 64% and 52%, respectively. 10-year OS and PFS after second-line HCT was 50% and 20%. Treatment-related mortality 3 months after HCT was 1.5%. At the time of publication, 26 of the individuals who received first-line HCT remained in complete remission up to 19 years following HCT.

Dreyling et al (2024) conducted an RCT evaluating the impact of adding ibrutinib to standard immunochemotherapy in younger patients (aged ≤65 years) with MCL. The TRIANGLE study assessed whether ibrutinib-enhanced regimens could improve clinical outcomes compared to standard treatment involving auto-HCT or to an ibrutinib-containing regimen without auto-HCT. The trial included 870 patients with untreated stage II to IV MCL who were randomized 1:1:1 to a control group receiving alternative R-CHOP and rituximab, dexamethasone, cytosine-arabinoside, and platinum (R-DHAP) followed by auto-HCT (group A), an experimental group receiving the same regimen with added ibrutinib during induction and as maintenance therapy post- auto-HCT (group A+I), or another experimental group receiving ibrutinib without auto-HCT (group I). The primary outcome was failure-free survival (FFS). After a median follow-up of 31 months, group A+I demonstrated superior FFS compared to group A, with 3-year FFS rates of 88% vs 72%, respectively (HR, 0.52; 98.3% CI, 0 to 0.86; p=.0008). However, the superiority of group A over group I was not shown, with 3-year FFS rates of 72% vs 86%, respectively (HR, 1.77; 98.3% CI, 0 to 3.76; p=.9979). The comparison between groups A+I and I is ongoing. During maintenance or follow-up, grade 3 to 5 hematological adverse events occurred in 50% of patients in group A+I, 28% in group I, and 21% in group A. Infections were reported in 25% of patients in group A+I, 19% in group I,

and 13% in group A. The results of this study demonstrate that Auto-HSCT is no longer clearly superior to ibrutinib-containing immunochemotherapy without ASCT in first complete remission.

Peripheral T-Cell Lymphoma (PTCL)

Schmitz et al (2021) conducted a randomized, prospective phase 3 trial of autologous versus allo-HCT as part of first-line therapy in patients with PTCL. There were 104 patients enrolled, age 18 to 60 years, who were randomized to four cycles of CHOP without etoposide (CHOEP) and 1 cycle of DHAP followed by high-dose therapy and auto-HCT (n=54) or myeloablative conditioning and allo-HCT (n=49). A few study patients were unable to proceed with transplantation due to disease progression, toxicity, or other reasons, so the final patient population consisted of 41 patients who underwent auto-HCT and 26 patients who underwent allo-HCT. The median follow-up period was 42 months and the 3-year EFS was 38% (95% CI, 25% to 52%) in the auto-HCT group versus 43% (95% CI, 29% to 57%) in the allo-HCT group. The 3-year OS was 70% (95% CI, 57% to 82 %) in the auto-HCT group versus 57% (95% CI, 43% to 71%) in the allo-HCT group.

Girard et al (2024) published a meta-analysis including 17 studies (N=1798) that compared upfront auto-HCT in patients with PTCL achieving first CR post-chemotherapy, with chemotherapy treatment alone. Histological subtypes included in the studies were heterogeneous, though the majority of patients had nodal PTCL. Results demonstrated that among transplant-eligible patients in CR after chemotherapy, auto-HCT provided significant benefits in both PFS (9 studies; HR, 0.61; 95% CI, 0.47 to 0.81) and OS (3 studies; HR, 0.59; 95% CI, 0.36 to 0.95). Subgroup analysis showed that angioimmunoblastic T-cell lymphoma patients in CR derived a significant PFS benefit from auto-HCT (3 studies; HR, 0.43; 95% CI, 0.20 to 0.94), though no significant OS advantage was noted.

Solid Tumors

Matthay et al (1999) randomized 129 children with high-risk neuroblastoma to a combination of myeloablative chemotherapy, total body irradiation, and transplantation of autologous bone marrow and compared their outcomes with those of 150 children randomized to intensive nonmyeloablative chemotherapy; both groups underwent a second randomization to subsequent 13-cis-retinoic acid (cis-RA) or no further therapy. The 3-year event free survival (EFS) rate among patients assigned to transplantation was 43% and 27% among those assigned to continuation chemotherapy (p=.027). However, OS rates for both groups did not differ significantly, with 3-year estimates of 43% or 44% for those assigned to transplant and continued chemotherapy, respectively (p=.87). Long-term results from this trial were reported in 2009 after a median follow-up of 7.7 years (range, 130 days to 12.8 years). The 5-year EFS rate for patients who underwent auto-HCT was 30% and 19% for those who underwent nonmyeloablative chemotherapy (p=.04). Five-year OS rates from the second randomization of patients who underwent both random assignments were 59% for autologous transplant/cis-RA, 41% for auto-HCT/no cis-RA, and, for nonmyeloablative chemotherapy, 38% and 36% with and without cis-RA. Authors concluded that myeloablative chemotherapy and auto-HCT resulted in significantly better 5-year EFS and OS rates.

A systematic review by Żebrowska et al (2024) evaluated the survival benefits of myeloablative therapy (MAT) combined with auto-HCT in high-risk neuroblastoma. Analysis of RCTs revealed significant improvements in event-free survival (HR, 0.78; 95% CI, 0.67 to 0.91; p=.001) and a trend

toward OS benefit (HR, 0.86; 95% CI, 0.73 to 1.00; p=.05) with MAT+ auto-HCT compared to conventional chemotherapy or no further treatment. Tandem MAT+ auto-HCT demonstrated superior event-free survival and OS compared to single auto-HCT, particularly when followed by anti-disialoganglioside 2 immunotherapies. Limited evidence suggested an increased risk of relapse when MAT+ auto-HCT was omitted prior to anti-GD2 therapy, while MAT+ auto-HCT also appeared to improve OS in relapsed patients, though data were sparse.

Non- Malignant Conditions

Multiple Sclerosis

Ruiz-Argüelles et al (2019) conducted a single-center, prospective study of 617 consecutive patients with multiple sclerosis (MS) referred for autologous hematopoietic stem cell transplantation (HSCT) between June 2015 and March 2019. The goal was to assess the safety and efficacy of the "Mexican method," which uses a conditioning regimen based on cyclophosphamide and rituximab. Eligible patients included those with relapsing-remitting MS (RRMS), secondary progressive MS (SPMS), or primary progressive MS (PPMS), provided they had a Karnofsky performance status above 70% and an Expanded Disability Status Scale (EDSS) score of 8 or lower within two weeks prior to transplant. All patients underwent a washout period of at least three months from other immunosuppressive agents. Follow-up ranged from 3 to 42 months (median: 12 months). Primary endpoints were recovery of granulocyte and platelet counts and transplant-related mortality (TRM). Secondary endpoints included overall survival (OS) and clinical response, defined as improvement or stabilization of the self-reported EDSS score. Of the 617 participants, 216 were male (35%) and 401 female (65%), with a median age of 46 years (range: 18–73). MS subtypes included 259 RRMS (42%), 228 SPMS (37%), and 130 PPMS (21%). The median EDSS score was 5.5 (range: 0–8; interquartile range: 4–6.5). All transplants were performed on an outpatient basis; 32 patients required brief hospitalization (15 for neutropenic fever, six for MS flare, four for pneumothorax requiring chest tube). Eleven patients required red blood cell transfusions, and six needed platelet transfusions. Thirty-month survival was 100%. At 12 months, 78% of patients reported improvement or stabilization of EDSS scores, with the best outcomes in RRMS (83%). Disability progression-free survival was 82% overall. A limitation of the study was that MRI was not systematically used to confirm self-reported improvements. The authors concluded that HSCT is safe and effective, particularly for RRMS.

Nabizadeh et al (2022) reviewed 50 studies involving 4,831 patients to assess the safety and effectiveness of autologous hematopoietic stem cell transplantation (AHSCT) for multiple sclerosis (MS). The analysis found that AHSCT significantly improved disability scores and reduced relapse rates compared to pre-treatment. After transplantation, 73% of patients remained progression-free, 81% were relapse-free, and 63% had no disease-related events. MRI activity-free survival was 89%, with only 8% developing new lesions. Additionally, 68% achieved no evidence of disease activity (NEDA), and overall survival was high at 94%. However, transplant-related mortality was 4%, indicating some risk despite the generally favorable outcomes.

Scleroderma

An open-label, randomized, controlled phase 2 trial (Trial of High Dose Cyclophosphamide and Rabbit Antithymocyte Globulin [rATG] With Hematopoietic Stem Cell Support in Patients with Systemic Scleroderma: A Randomized Trial [ASSIST]; Burt et al 2011) evaluated the safety and efficacy of autologous nonmyeloablative HCT compared with standard cyclophosphamide therapy. The primary outcome was improvement at 12 months, defined as either a decrease in modified Rodnan skin score (mRSS) of at least 25% for patients with an initial mRSS >14, or an increase in forced vital capacity (FVC) of more than 10%. Patients in the control group who experienced disease progression (>25% increase in mRSS or >10% decrease in FVC) despite cyclophosphamide could switch to HCT after 12 months. Patients assigned to HCT (n=10) improved at or before the 12-month follow-up, compared with none of the nine patients assigned to cyclophosphamide (p<.001). Treatment failure (disease progression without improvement) occurred in eight of nine controls but in none of the HCT patients (p<.001). After a mean follow-up of 2.6 years, all but two HCT patients had sustained improvement in mRSS and FVC, with the longest follow-up reaching 60 months. Seven patients from the cyclophosphamide group switched to HCT at a mean of 14 months after enrollment and all improved without complications. Among four of these patients followed for at least one year, mRSS decreased from a mean of 27 (SD=15.5) to 15 (SD=7.4), FVC increased from 65% (SD=20.6%) to 76% (SD=26.5%), and total lung capacity rose from 81% (SD=14.0%) to 88% (SD=13.9%). Data for 11 patients with two years of follow-up after HCT suggested that improvements in mRSS (p<.001) and FVC (p<.03) persisted.

Sullivan et al (2018) conducted an RCT comparing auto-HCT with cyclophosphamide for the treatment of scleroderma (SCOT – A Randomized, Open-Label, Phase II Multicenter Study of High-Dose Immunosuppressive Therapy Using Total Body Irradiation, Cyclophosphamide, ATGAM, and Autologous Transplantation with Auto-CD34+HPC Versus Intravenous Pulse Cyclophosphamide for the Treatment of Severe Systemic Sclerosis [SCSSc-01]). The trial was originally designed for 226 patients, but due to low enrollment, 75 patients participated. Of the 36 patients randomized to HCT, 27 completed the trial per protocol (3 died and 6 withdrew early). Of the 39 patients randomized to cyclophosphamide alone, 19 completed per protocol (11 died and 9 withdrew early). The primary outcome was a global rank composite score, which does not measure disease activity directly but compares outcomes in pairs based on death, EFS, FVC, Disability Index of the Health Assessment Questionnaire, and mRSS. At 4 and 4.5 years of follow-up, more pairwise comparisons favored HCT over cyclophosphamide. Disease progression events were significantly higher in the cyclophosphamide group for initiating disease-modifying antirheumatic drugs, congestive heart failure requiring treatment, and pulmonary arterial hypertension. Events such as arrhythmia, pericardial effusion, renal crisis, and myositis did not differ significantly between groups.

PROFESSIONAL GUIDELINE(S)

In 2019, Cohen and colleagues published a position statement from the American Society for Blood and Marrow Transplantation (ASBMT) addressing the use of auto-HCT in treatment-refractory relapsing MS. The position statement is as follows:

"The ASBMT Task Force recommends revising the recommended indication for AHCT in MS to "standard of care, clinical evidence available", for patients with relapsing forms of MS (RRMS or

progressive MS with superimposed activity) who have prognostic factors that indicate a high risk of future disability, including ongoing clinical relapse or MRI lesion activity despite treatment with available DMTs, especially if disease activity continues despite treatment with high-efficacy DMTs and/or worsening disability."

In 2020, the American Society of Transplantation and Cellular Therapy (ASTCT) convened a guideline committee to make recommendations for the use of hematopoietic cell transplantation and immune effector cell therapy. Indications were categorized as (1) Standard of care, where indication is well defined and supported by evidence; (2) Standard of care, clinical evidence available, where large clinical trials and observational studies are not available but have shown to be effective therapy; (3) Standard of care, rare indication, for rare diseases where demonstrated effectiveness exists but large clinical trials and observational studies are not feasible; (4) Developmental, for diseases where preclinical or early-phase clinical studies show promising results, and (5) not generally recommended, where available evidence does not support the routine use of hematopoietic stem cell transplantation. The following indications have auto-HCT categorized as standard of care for pediatric patients under the age of 18:

- Hodgkin lymphoma, first relapse, sensitive;
- Ewing sarcoma, high risk or relapse;
- Neuroblastoma, high risk or relapse.

The following indications have auto-HCT categorized as standard of care for adult patients:

- Hodgkin lymphoma, first relapse (sensitive);
- Ewing sarcoma, high risk or relapse;
- Neuroblastoma, high risk or relapse;
- Acute promyelocytic leukemia, CR2, molecular remission;
- Myeloma, initial response, or sensitive relapse;
- Amyloid light-chain amyloidosis;
- Hodgkin lymphoma, primary refractory (sensitive), first relapse (sensitive), or second or greater relapse;
- Diffuse Large B cell lymphoma, primary refractory (sensitive); first relapse (sensitive), or second or greater relapse;
- Follicular lymphoma, primary refractory (sensitive), second or greater relapse, or transformation to high grade lymphoma;
- Mantle cell lymphoma, CR1, first partial remission, primary refractory (sensitive) first relapse (sensitive), or second or greater relapse;
- T cell lymphoma, CR1/first partial remission, primary refractory (sensitive), first relapse (sensitive);

- Lymphoplasmocytic lymphoma/Waldenstrom macroglobulinemia, first or greater relapse (sensitive);
- Chronic lymphocytic leukemia, transformation to high-grade lymphoma;
- Germ cell tumor, relapse, or refractory; and
- Systemic sclerosis.

In 2021, the ASTCT, Center of International Blood and Marrow Transplant Research (CIBMTR), and the European Society for Blood and Marrow Transplantation (EBMT) formulated consensus recommendations regarding auto-HCT, allo-HCT, and chimeric antigen receptor (CAR) T-cell therapy for patients with MCL (Munshi et al). The panel of experts, consisting of physicians and investigators, recommended the use of auto-HCT as consolidation therapy in newly diagnosed MCL patients (without TP53 mutation or bi-allelic deletion) who are in complete or partial remission after first-line therapies.

The ASTCT Committee on Practice Guidelines published guidance on transplantation and cellular therapies in DLBCL in 2023 (Epperla et al). The committee made the following recommendations:

- "The panel does not recommend auto-HCT in DLBCL (regardless of IPI score) as consolidation in complete remission after first-line (R-CHOP or similar) therapy." (Grading: A)
- "Autologous HCT may be considered for eligible patients with DLBCL with secondary CNS involvement at diagnosis achieving complete remission and with undetectable CNS disease after first-line therapy." (Grading: C)
- "The panel recommends consolidation with autologous HCT for eligible primary CNS lymphoma patients in CR1."(Grading: A)
- "In DLBCL patients with early relapse who achieve a complete remission with salvage therapy, the panel considers autologous HCT an acceptable consolidation therapy in eligible patients."(Grading: B)
- "In DLBCL patients with early relapse who achieve a partial remission with salvage therapy, the panel considers autologous HCT an acceptable consolidation therapy in eligible patients." (Grading: B)
- "In DLBCL patients with late relapse, the panel recommends autologous HCT consolidation therapy in eligible patients who have achieved a complete or partial remission after second-line therapies." (Grading: A)
- "The panel recommends allogeneic HCT in eligible DLBCL patients relapsing/progressing after CAR-T therapy if they achieve a complete or partial remission with subsequent antilymphoma therapies." (Grading: C)
- "The panel recommends allogeneic HCT in eligible relapsed or refractory DLBCL patients after autologous HCT failure in regions without access to CAR-T therapy, and in those with CAR T cell manufacturing failure, ideally after achieving a complete or partial remission with subsequent antilymphoma therapies." (Grading: C)

Grading of recommendations:

- A- There is good research-based evidence to support the recommendation;
- B- There is fair research-based evidence to support the recommendation;
- C- The recommendation is based on expert opinion and panel consensus;
- X- There is evidence of harm from this intervention.

The National Comprehensive Cancer Network (NCCN) V.2.2025 clinical practice guidelines for pediatric aggressive mature B-cell lymphomas recommends HSCT for the treatment of relapsed or refractory disease, and that "the decision regarding the type of HSCT [autologous versus allogeneic] should be based upon donor availability and physician preference." However, it is recommended that patients with a complete response to second-line therapy (e.g., rituximab, dexamethasone, cytarabine, and cisplatin) are better suited for an autologous HSCT.

In 2024, ASTCT and EBMT formulated consensus recommendations for HCT and cellular therapies in follicular lymphoma (Iqbal et al). The following consensus statements regarding auto-HCT were made:

"Front-line setting (i.e., HCT following first-line chemotherapy):

- The panel does not recommend autologous or allogeneic HCT as consolidation therapy in eligible follicular lymphoma patients in complete or partial remission after first-line therapies."

"Early first relapse/progression (i.e., first relapse occurred on or within 24 months from receiving front-line chemoimmunotherapy (post-operative day [POD] 24) and without evidence of histological transformation):

- The panel recommends autologous HCT as an option for consolidation therapy in eligible, relapsed POD24 follicular lymphoma patients who have achieved complete or partial remission after second-line therapies.
- The panel does not recommend autologous HCT as consolidation therapy in eligible, relapsed follicular lymphoma patients who do not achieve complete or partial remission after second or subsequent line therapies.

"Late first relapse, second relapse, and beyond settings:

- The panel does not recommend autologous HCT as consolidation therapy in eligible, relapsed follicular lymphoma patients who did not achieve complete or partial remission after second or subsequent line therapies.
- The panel does not recommend autologous HCT as consolidation therapy in eligible, relapsed follicular lymphoma patients who have relapsed after CAR T-cell therapy and did not achieve complete or partial remission to the most recent anti-lymphoma treatment."

In 2023, Fraint and colleagues published a report from the ASTCT Committee on practice guidelines for the evaluation of children with malignancies for blood and marrow transplantation. ASTCT states, "Children with malignancy who require HCT for cure have a unique set of psychosocial needs,

physical comorbidities, and disease risk features that differentiate them from adults. Given the inability for some of the important pre-HCT risk indices developed for adults to be applied to children, a specialized approach is needed, ideally with harmonization among centers." Although rigorous data on physiologic differences and randomized trials on management are lacking for children, the recommendations provided are meant to serve as a guide for pre-HCT preparations.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates vaccines, blood and blood products, and biologics via the Center for Biologics Evaluation and Research (CBER) which ensures the safety, efficacy, and quality of these products. Refer to the FDA vaccines/blood/biologics website. Available from: Vaccines, Blood & Biologics | FDA [accessed 2025 Nov 24]

The FDA maintains information for consumers and health professionals on vaccine, blood and biologics warnings and other safety information. Available from: Recalls (Biologics) | FDA [accessed 2025 Nov 24]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
38206	Blood-derived hematopoietic progenitor cell harvesting for transplantation, per collection; autologous
38210	Transplant preparation of hematopoietic progenitor cells; Specific cell depletion within harvest, T-cell depletion
38211	tumor cell depletion
38212	red blood cell removal
38213	platelet depletion
38232	Bone marrow harvesting for transplantation, autologous
38241	Hematopoietic progenitor cell (HPC); autologous transplantation

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HCPCS Codes

Code	Description
S2150	Bone marrow or blood-derived stem cells (peripheral or umbilical), allogeneic or autologous, harvesting, transplantation, and related complications; including: pheresis and cell preparation/storage; marrow ablative therapy; drugs, supplies, hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services; and the number of days of pre and post-transplant care in the global definition

ICD10 Codes

Code	Description
C26.0-C26.9	Malignant neoplasm of other and ill-defined digestive organs (code range)
C33	Malignant neoplasm of trachea
C34.00-C34.92	Malignant neoplasm of bronchus and lung (code range)
C38.1-C38.8	Malignant neoplasm of heart, mediastinum and pleura (code range)
C47.0-C47.9	Malignant neoplasm of peripheral nerves and autonomic nervous system (code range)
C48.0	Malignant neoplasm of retroperitoneum
C49.0-C49.9	Malignant neoplasm of other connective and soft tissue (code range)
C50.011-C50.919	Malignant neoplasm of breast (code range)
C62.00-C62.92	Malignant neoplasm of testis (code range)
C71.0-C71.9	Malignant neoplasm of brain (code range)
C81.00-C81.99	Hodgkin lymphoma (code range)
C82.00-C82.99	Follicular lymphoma (code range)
C83.00-C83.09	Non-follicular lymphoma (code range)
C83.10-C83.19	Mantle cell lymphoma (code range)
C83.30-C83.39	Diffuse large B-cell lymphoma (code range)

Code	Description
C83.50-C83.59	Lymphoblastic (diffuse) lymphoma (code range)
C83.70-C83.79	Burkitt lymphoma (code range)
C83.80-C83.99	Other non-follicular lymphoma (code range)
C84.60-C84.79	Anaplastic large cell lymphoma, ALK-positive or ALK-negative (code range)
C86.5	Angioimmunoblastic T-cell lymphoma
C86.6	Primary cutaneous CD30-positive T-cell proliferations
C88.2-C88.9	Malignant immunoproliferative diseases and certain other B-cell lymphomas (code range)
C90.00-C90.32	Multiple myeloma and malignant plasma cell neoplasms (code range)
C91.10-C91.12	Chronic lymphocytic leukemia of B-cell type (code range)
E85.0-E85.9	Amyloidosis (code range)
G35	Multiple sclerosis
M05.00-M05.09	Felty's syndrome (code range)
M05.20-M05.29	Rheumatoid vasculitis with rheumatoid arthritis (code range)
M05.30-M05.39	Rheumatoid heart disease with rheumatoid arthritis (code range)
M05.40-M05.59	Rheumatoid myopathy with rheumatoid arthritis (code range)
M05.60-M06.09	Rheumatoid arthritis with involvement of other organs and systems (code range)
M06.1	Adult-onset Still's disease
M06.4	Inflammatory polyarthropathy
M06.80-M06.9	Other specified rheumatoid arthritis (code range)

Code	Description
M08.00-M08.99	Juvenile arthritis (code range)
M12.00-M12.09	Other and unspecified arthropathy (code range)
M32.0-M32.9	Systemic lupus erythematosus (SLE) (code range)
M34.0-M34.9	Systemic sclerosis [scleroderma] (code range)

REFERENCES

American Society for Transplantation and Cellular Therapy (ASTCT) [Internet]. Indications for autologous and allogeneic hematopoietic cell transplantation. 2015 Aug 07. [Last updated 2025 Oct 18; accessed 2025 Oct 29]. Available from: https://www.guidelinecentral.com/guideline/26026/#section-336178

Anagnostopoulos A, et al. Stem cell transplantation (SCT) for Waldenstrom's macroglobulinemia (wm). Bone Marrow Transplant. 2002;29:943-7.

Balassa K, et al. Haematopoietic stem cell transplants: principles and indications. Br J Hosp Med (Lond). 2019 Jan 2;80(1):33-39.

Bishop MR, et al. Second-line tisagenlecleucel to standard care in aggressive B Cell Lymphoma. The England Journal of Medicine. 2022 Feb; 386(7):629-639.

Bose G, et al. Autologous hematopoietic stem cell transplantation improves fatigue in multiple sclerosis. Mult Scler. 2019 Nov;25(13):1764-1772.

Carreras, E, et al. (eds.), The EBMT handbook. 7th ed. Switzerland: Springer Nature. 2020.

Chakraborty R, et al. Impact of autologous transplantation on survival in patients with newly diagnosed multiple myeloma who have high-risk cytogenetics: A meta-analysis of randomized controlled trials. Cancer. 2022 Jun;128(12)2288-2297.

Cohen JA, et al. Autologous hematopoietic cell transplantation for treatment-refractory relapsing multiple sclerosis: position Statement from the American Society for Blood and Marrow Transplantation. Biol Blood Marrow Transplant. 2019 May;25(5):858-854.

Dalakas MC. Therapies in stiff-person syndrome. Neurol Neuroimmunol Neuroinflamm. 2023 Apr 14;10(3):e200109.

Dreyling M, et al. Ibrutinib combined with immunochemotherapy with or without autologous stem-cell transplantation versus immunochemotherapy and autologous stem-cell transplantation in previously untreated patients with mantle cell lymphoma (TRIANGLE): a three-arm, randomised, open-label, phase 3 superiority trial of the European Mantle Cell Lymphoma Network. Lancet. 2024 May 25;403(10441):2293-2306.

ECOG-ACRIN Cancer Research Group [Internet]. ECOG performance status scale. 2025 [accessed 2025 Nov 21]. Available from: ECOG Performance Status Scale - ECOG-ACRIN Cancer Research Group

Epperla N, et al. ASTCT clinical practice recommendations for transplantation and cellular therapies in diffuse large b cell lymphoma. Transplant and Cellular Therapy. 2023 Sep;29(9):548-555.

Fassas A, et al. Hematopoietic stem cell transplantation for multiple sclerosis a retrospective multicenter study. J Neurol. 2002;249:1088-97.

Girard L, et al. Role of upfront autologous transplant for peripheral T-cell lymphoma patients achieving a complete remission with first-line therapy: a systematic review and meta-analysis. Bone Marrow Transplant. 2024 Jun;59(6):838-848.

Henes J, et al. Autologous stem cell transplantation for progressive systemic sclerosis: a prospective non-interventional study from the European society for blood and marrow transplantation autoimmune disease working party. Haematologica. 2020 Jan 16.

Iqbal M, et al. Clinical practice recommendations for hematopoietic cell transplantation and cellular therapies in follicular lymphoma: a collaborative effort on behalf of the American Society for Transplantation and Cellular Therapy and The European Society for Blood and Marrow Transplantation. Transplant and Cellular Therapy. 2024 Sep;30(9):832-843.

Kruz KS, et al. Large B-Cell Lymphoma in the 5th edition of the WHO-Classification of Haematolymphoid neoplasm-updated classification and new concept. Cancer. 2023 Apr;15(8):2285.

Majhail NS, et al. Indications for autologous and allogeneic hematopoietic cell transplantation: guidelines from the American Society for Blood and Marrow Transplantation. Bio Blood Marrow Transplant. 2015 Nov;21(11):1863-1869.

Matthay KK, et al. Long-term results for children with high-risk neuroblastoma treated on a randomized trial of myeloblative therapy followed by 13-CIS-retinoic acid: a children's oncology group study. J Clin Oncol. 2009 Mar 01;27(7):1007-1013.

Matthay KK, et al. Treatment of high-risk neuroblastoma with intensive chemotherapy, radiotherapy, autologous bone marrow transplantation, and 13-CIS-retinoic acid. NEJM. 1999 Oct 14;341(16):1165-1173.

Merryman RW, et al. Autologous stem cell transplantation after anti-PD-1 therapy for multiply relapsed or refractory Hodgkin lymphoma. Blood Adv. 2021 Mar 12;5(6):1648–1659.

Metzner B, et al. Long-term outcome in patients with mantle cell lymphoma following high-dose therapy and autologous stem cell transplantation. Eur J Haematol. 2023 Aug;111(2):220-228.

Miyamoto T, et al. Prospective randomization of post-remission therapy comparing autologous peripheral blood stem cell transplantation versus high-dose cytarabine consolidation for acute myelogenous leukemia in first remission. Int J Hematol. 2018 Apr;107(4):468-477.

Munshi PN, et al. ASTCT, CIBMTR and EBMT Clinical Practice recommendations for transplant and cellular therapies in mantle cell lymphoma. Bone Marrow Transplant. 2021 Aug 20;56(12):2911–

2921.

Nabizadeh F, et al. Autologous hematopoietic stem-cell transplantation in multiple sclerosis: a systematic review and meta-analysis. Neurol Ther. 2022 Dec;11(4):1553-1569.

Nathan PC, et al. Consolidation therapy with autologous bone marrow transplantation in adults with acute myeloid leukemia: a meta-analysis. J Natl Cancer Inst. 20024 Jan 07;96(1):38-45.

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines for pediatric aggressive mature B-Cell lymphomas, version 2.2025. 2025 Apr 28 [accessed 2026 Jan 26]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/ped_b-cell.pdf

National Multiple Sclerosis Society. [Internet]. Functional systems scores (FSS) and expanded disability status scale (EDSS). 2025. [accessed 2025 Dec 18]. Available from: FSS and EDSS Assessment for MS | National MS Society

Peus D, et al. Appraisal of the Karnofsky Performance Status and proposal of a simple algorithmic system for its evaluation. BMC. 2013 Jul 19;72(2013):1-7.

Philip T, et al. Autologous bone marrow transplantation as compared with salvage chemotherapy in relapses of chemotherapy-sensitive non-Hodgkin's lymphoma. N Engl J Med. 1995 Dec 07;333(23):1540-1545.

Puyade M, et al. Health-related quality of life in systemic sclerosis before and after autologous haematopoietic stem cell transplant-a systematic review. Rheumatology (Oxford). 2020 Apr 1;59(4):779-789.

Rancea M, et al. High-dose chemotherapy followed by autologous stem cell transplantation for patients with relapsed or refractory Hodgkin lymphoma: a systematic review with meta-analysis. Critical Rev Onc. 2014 Apr 14;92(2014):1-10.

Richardson PG, et al. Triplet therapy, transplantation, and maintenance until progression in myeloma. New England Journal of Medicine. 2022 Jul;387(2):132-147.

Ruiz-Argüelles GJ, et al. Self-reported changes in the expanded disability status scale score in patients with multiple sclerosis after autologous stem cell transplants: real-world data from a single center. Clin Exp Immunol. 2019 Dec;198(3):351-358.

Schaaf M, et al. High-dose therapy with autologous stem cell transplantation versus chemotherapy or immuno-chemotherapy for follicular lymphoma in adults. Cochrane Database Syst Rev. 2012 Jan 18;1(1):CD007678.

Schmitz N, et al. A randomized phase 3 trial of autologous vs allogeneic transplantation as part of first-line therapy in poor-risk peripheral T-NHL. Blood. 2021 May 13;137(19):2646–2656.

Schouten HC, et al. High-dose therapy improves progression-free survival and survival in relapsed follicular non-Hodgkin's lymphoma: results from the randomized European CUP trial J Clin Oncol. 2003 Nov 01;21(21):3918-27.

Sharrack B, et al. Autologous hematopoietic stem cell transplantation and other cellular therapy in

multiple sclerosis and immune-mediated neurological diseases: updated guidelines and recommendations from the EBMT Autoimmune Diseases Working Party (ADWP) and the Joint Accreditation Committee of EBMT and ISCT (JACIE). Bone Marrow Transplant. 2020 Feb;55(2):283-306.

Sormani MP, et al. Autologous hematopoietic stem cell transplantation in multiple sclerosis: a meta-analysis. Neurology. 2017 May 30;88(22):2115-2122.

Stiff PJ, et al. Autologous transplantation as consolidation for aggressive non-Hodgkin's lymphoma. NEJM. 2013 Oct 13;369:1681-1690.

Traynor AE, et al. Hematopoietic stem cell transplantation for severe and refractory lupus analysis after 5 years and 15 patients. Arthrit Rheumat. 2002;46(11):2917-23.

Vallenga E, et al. Autologous peripheral blood stem cell transplantation for acute myeloid leukemia. Blood. 2011 Sep 14;118(23):6037-6042.

Vardhana S, et al. Outcomes of relapsed and refractory primary mediastinal (thymic) large B cell lymphoma treated with second-line therapy and intent to transplant. Biol Blood Marrow Transplant. 2018 Jun 07;24(2018):2133-2138.

Wang J, et al. Autologous Hematopoietic stem cell transplantation for acute myeloid leukemia in first complete remission: a meta-analysis of randomized trials. Acta Haematol. 2010 Jul 10;124(2):61-71.

Wilner FS and Arnold R. The palliative performance scale. fast facts and concepts #125 [Internet] November 2004 [accessed 2025 Nov 21]. Available from: https://www.jeffersonhealth.org/content/dam/health2021/documents/staff-and-student/palliative-care/fast-facts-palliative-performance-scale.pdf

Wulffraat M, et al. Autologous stem cell transplantation for refractory juvenile idiopathic arthritis: current results and perspectives. Transplant Proceed. 2002; 34:2925-26.

Zoellner AK, et al. Long-term survival of patients with mantle cell lymphoma after autologous haematopoietic stem-cell transplantation in first remission: a post-hoc analysis of an open-label, multicentre, randomised, phase 3 trial. Lancet Haematol. 2021 Sep;8(9):e648-e657.

SEARCH TERMS

Bone marrow transplant, BMT, peripheral blood stem cell transplant, PBCT, autogenous/autogenic transplant, high-dose chemotherapy with stem cell rescue

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Stem Cell Transplantation (Formerly 110.8.1) (NCD 110.23) [accessed 2025 Nov 13]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.

- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
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- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 3/26 **Revised:** **Reviewed:**	
Date	**Summary of Changes**
7/1/2026	• New

MEDICAL POLICY

Medical Policy Title	**Balloon Dilation of the Eustachian Tube (BDET)**
Policy Number	**7.01.101**
Current Effective Date	**January 1, 2026**
Next Review Date	**July 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Balloon dilation of the Eustachian tubes (BDET), unilateral or bilateral, is **medically appropriate** for the treatment of chronic obstructive Eustachian tube dysfunction (ETD) when **ALL** the following **criteria** are met:

   A. Age 18 years or older;

   B. Comprehensive diagnostic evaluation documents **all** of the following:

      1. abnormal tympanogram (Type B or C);
      2. abnormal tympanic membrane on examination (e.g., retracted membrane, effusion, or perforation); **and**
      3. other causes of aural fullness have been ruled out (e.g., temporomandibular joint disorders, extrinsic obstruction of the Eustachian tube, superior semicircular canal dehiscence, and endolymphatic hydrops);

   C. Symptoms of chronic obstructive ETD including **all** of the following:

      1. aural fullness and aural pressure;
      2. hearing loss or otalgia (earache/pain); **and**
      3. symptoms lasting (3) months or longer that are continuous and not episodic (e.g., symptoms occur only in response to barochallenge such as pressure changes while flying);

   D. Absence of any contraindication, including but not limited to:

      1. patulous ETD;
      2. dehiscence of carotid artery canal;

   E. No treatment history of prior BDET in the same ear for which the surgery is proposed;

   F. Treatment history includes the following, if applicable:

      1. failure to respond to appropriate medical management of coexisting conditions (e.g., allergic rhinitis, rhinosinusitis, and laryngopharyngeal reflux);

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2. symptoms of obstructive ETD must have improved following myringotomy with tympanostomy tube placement (trial is not required for BDET).

II. BDET, unilateral or bilateral, is **investigational** for **ALL** other indications, including but not limited to:

A. As a repeat procedure;

B. Performed concurrent with tympanoplasty (ear drum repair) or other middle ear surgery (e.g., mastoidectomy);

C. Aural fullness but normal examination and tympanogram;

D. Transtympanic BDET;

E. Age 17 years and younger;

F. Extrinsic cause of ETD (e.g., but not limited to enlarged adenoid pads, history of radiation therapy to the nasopharynx, craniofacial syndrome [e.g., cleft palate spectrum], nasopharyngeal or skull base neoplasm, neoplasms causing extrinsic obstruction of the Eustachian tube).

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Comprehensive diagnostic evaluation ensures proper patient selection, which may result in successful outcomes of BDET in patients with true primary obstructive ETD. Essential assessments include a history and physical exam, otoscopy, nasal endoscopy, audiometry, and tympanometry. All assessments are inadequate to secure a diagnosis when relied upon in isolation (Tucci et al 2019).

II. Tympanometry measures the mobility of the tympanic membrane and graphically displays results in tympanograms. Tympanograms are classified by the height and location of the tympanometric peak:

A. Type A indicates normal middle ear and Eustachian tube function;

B. Type B indicates poor tympanic membrane mobility ("flat" tympanogram);

C. Type C indicates the presence of negative middle ear pressure.

III. Failure to relieve symptoms despite a functioning myringotomy or tympanostomy tube suggests a diagnosis other than obstructive ETD (e.g., patulous ETD).

IV. Individuals undergoing BDET concurrent with sinus ostial dilation should meet the same diagnostic criteria for BDET as those undergoing BDET alone. Individuals with a middle ear effusion at the time of BDET may benefit from concurrent myringotomy with or without

tympanostomy tube placement.

BDET can only be performed with a balloon dilation device/system that is approved by the U.S. Food and Drug Administration (FDA).

DESCRIPTION

The Eustachian tube (ET) is a fibrocartilaginous duct connecting the nasopharynx to the middle ear space. In adults, the ET is approximately 36 millimeters (mm) in length. It functions primarily to equalize air pressure between the middle ear and atmosphere, crucial to the proper working of the eardrum. The ET opens during yawning, swallowing, and sneezing which aids in equalized air pressure, clearing secretions, and protects the middle ear from infection and nasopharyngeal contents.

Eustachian tube dysfunction (ETD) is a broad diagnostic category that involves the inability of the ET to open and close appropriately. Common ET disorders include:

- Patulous ETD: the functional valve of the ET is pathologically patent, creating an abnormally persistent state of pressure equalization between the middle ear and nasopharynx. Diagnosis of patulous ETD is suggested by symptoms of autophony of voice, audible respirations.
- Obstructive ETD: patency of the ET is decreased by a functional or anatomical obstruction.
- Baro-challenge-induced ETD: failure of the ET to adequately open and regulate middle-ear pressure during ambient pressure changes, although ET function may be normal in normobaric situations.

Medical management of obstructive ETD is directed by the underlying etiology. Decongestants and antihistamines can be used for rhinosinusitis to relieve inflammation and secretions. Nasal steroid sprays can also be used to aid in the relief of inflammation. The American Academy of Otolaryngology- Head and Neck Surgery (AAO-HNS) clinical consensus statement supports that there is no standard medical therapy for primary obstructive ETD, therefore, in the absence of extrinsic causes, there is no absolute role for a treatment trial of topical or systemic medical therapy in primary OETD (Tucci et al 2019). Patients who do not find relief with medical management may be treated with surgery.

Available surgical interventions include myringotomy with tympanostomy tube placement, in which a small incision is made to the tympanic membrane and a small tube is placed, to allow for drainage of secretions. These procedures create an alternative route for ventilation of the middle ear space but do not address the functional problem at the Eustachian tube. Tympanostomy tube placement may be a repeat procedure for the life of the patient, and the risk of complications from tympanostomy tubes increases with increasing numbers of tube placements and duration of tube placement.

Balloon dilation of the Eustachian tube (BDET) is novel, minimally invasive tuboplasty procedure intended to improve the patency of the cartilaginous Eustachian tube and ease the symptoms of chronic ETD by expanding the Eustachian tube. During this procedure, a saline-filled balloon catheter is introduced into the Eustachian tube trans-nasally using a minimally invasive endoscopic method. Once the balloon is placed, it is inflated. Pressure is maintained for approximately two minutes,

followed by deflation and removal. BDET allows for the drainage of secretions and equalization of pressure across the tympanic membrane, providing relief for those suffering from ETD.

This transnasal procedure can be performed unilaterally or bilaterally and done as a stand-alone procedure or in conjunction with other procedures such as adenoidectomy, intranasal surgery (e.g., septoplasty, turbinate procedures, or sinus surgery), surgery for obstructive sleep apnea or sleep disturbed breathing, and myringotomy with or without tympanostomy tube placement.

Transtympanic approach to accessing the ET is a proposed technique to overcome limitation of the transnasal approach to perform BDET. There is limited and conflicting evidence to support its use.

SUPPORTIVE LITERATURE

For adults with chronic obstruction Eustachian tube dysfunction (ETD) who have not responded to medical management (if applicable) and who undergo balloon dilation of the Eustachian tube (BDET), the evidence is sufficient to conclude that this technology leads to an improvement in net health outcomes. However, there is a lack of published evidence supporting the use of BDET in the pediatric population or for conditions such as patulous ETD, systemic mucosal diseases, or autoimmune inflammatory diseases affecting the nasopharyngeal mucosa. While the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) consensus statement acknowledges that patients with a history of recurrent barochallenge might indicate a diagnosis of obstructive ETD, and that these patients may benefit from BDET, the studies conducted on this subgroup are small and heterogeneous.

Adult Population

Oehlandt et al (2022) assessed the efficacy and safety of balloon Eustachian tuboplasty (BET) for patients with baro-challenge-induced ETD by conducting a systematic review of the existing literature in November 2020, along with a retrospective cohort study of baro-challenge-induced ETD patients who underwent BET between 2011 and 2020. Additionally, a meta-analysis was performed to evaluate the Valsalva maneuver, ETDQ-7 score, and subjective symptom improvement. The systematic review resulted in inclusion of eight publications and the cohort study included altogether 113 patients. The authors reported an overall improvement in subjective symptoms after BET, showing improvement in 81% of patients, with 22 out of 27 (81%) professionals (professional divers, aviators, or cabin crew members) being able to continue in their profession. Reported complications were rare and mild. Outcome measures appear to be long-lasting based on a mean follow-up period of 4 years and 8 months. Although the authors concluded that BDET seems to be effective in baro-challenged-induced ETD and enables professionals to resume careers (flying or diving), they noted several study limitations (risk of bias was high in all studies, all studies lacked a control group, missing patient data, varied follow-up time and method) and note the need for more controlled and blinded studies on long-term effects.

Froehlich et al (2020) conducted a systematic review and meta-analysis of balloon dilation for chronic ETD. Twelve studies were included in the meta-analysis, including 3 randomized controlled trials (RCTs), 5 prospective observational studies, and 4 case series. One RCT (Liang et al 2016) that compared balloon dilation to tympanic paracentesis reported tympanometry and otoscopy scores but

not symptoms. The other two RCTs compared balloon dilation plus medical management to medical management alone and used the ETDQ-7 to measure symptoms. Pooled analyses showed improvements in subjective and objective measures including ETDQ-7 scores, tympanograms, otoscopy exams, and ability to perform a Valsalva maneuver. Improvements appeared to be maintained in studies with longer-term follow-up (3 to 12 months).

Poe et al (2018) conducted a 2:1 randomized controlled trial (n=323) to assess the safety and efficacy of BDET. Patients included in the study were aged 22 years and older who had persistent ETD and who had failed medical management, which consisted of either a minimum of four weeks of continuous daily usage of any intranasal steroid spray or a minimum of one completed course of an oral steroid within 90 days of study enrollment. A positive diagnosis of persistent ETD was confirmed with both abnormal tympanometry and symptomatic dysfunction, as determined by the Eustachian Tube Dysfunction Questionnaire (ETDQ-7). BDET was performed in the operating room under general anesthesia. Each dilation was done at an inflation pressure of 10-12 atm, with a total time of two minutes. The primary effectiveness endpoint was normalization of tympanometry at six-week follow-up. At the six-week follow-up period, 51.8% of the investigational group had a normal tympanogram versus 13.9% in the control group. At 24-weeks postoperatively, tympanogram normalization in the treatment group was 62.2%, however, the majority of the failed control group subjects had crossed over, so no statistical comparison could be made. Improvement in tympanometry was also associated with normalization of the ETDQ-7 at six-weeks. There were no serious adverse effects noted in the study, but two subjects did develop mild symptoms of patulous ET, one of which resolved by the completion of the study. The authors concluded that the study shows BDET, with adjunctive medical management, is superior to medical management alone. Study limitations include the inability to blind patients, short term follow-up, small sample size, and most patients in the control group (82%) did opt to crossover and receive BDET before their 12-week follow-up. As a result of this crossover, the control group became relatively small and self-selecting in nature, likely biasing any statistical comparison between treatment groups.

Anand et al (2019) published the 52-week follow up data to the 2017 Poe study. At 52 weeks, the overall results of tympanograms and ETDQ-7 questionnaires of subjects who received balloon dilation remained comparable to the results at the six-week follow-up period. Tympanograms were done at six weeks, 12 weeks, 24 weeks, and 52 weeks. At six weeks, the tympanogram results were 51% normalized; at 52 weeks, 55.5% were normalized. There were many instances in which ears had normalized tympanograms, then reverted to non-normalized tympanograms, then normalized tympanograms again. In total, 63.6% of ears had normalized tympanograms at 52 weeks, either remaining normal throughout the study or converting to normal (failure then becoming normal or temporary failure but return to normal). The authors concluded that the beneficial effects of BDET with medical management at the 52-week follow-up demonstrate a durability that is clinically relevant.

Meyer et al (2018) conducted a randomized controlled trial to compare BDET to continued medical therapy for treating persistent ETD. Subjects were randomized in a 1:1 ratio to balloon dilation or control (medical management). Of the 60 patients in the study, 31 patients were randomized to the balloon dilation group, and 29 were randomized to the control group. Patients were required to follow

up at six-weeks, and then at three-, six-, and 12-months post-procedure. Patients included in the study were aged 18 years and older, who had been diagnosed with ETD for 12 months or greater, had three or more symptoms, and had failed medical therapy of intranasal steroids or oral steroids. After six weeks, subjects in the control group had the option to undergo the procedure if their symptoms persisted. Comparison between baseline and post treatment was evaluated using an ETDQ-7. The study found that balloon dilation led to a significant reduction in overall ETDQ-7 scores, as well as statistically significant improvement in ETD symptoms and middle ear functional assessments. The authors concluded that BDET is a safe, effective, and durable treatment for ETD.

Huisman et al (2018) performed a meta-analysis to evaluate the success of BDET in reducing symptoms in adult patients with ETD. The search yielded 15 studies that met inclusion criteria for a total of 1,155 patients. Inclusion criteria involved studies that were BDET in adults with ETD. The studies evaluated improvement of ETD symptoms to measure effectiveness of treatments such as the Valsalva maneuver, otoscopy, tympanometry, and the ET score. Revisions due to failure of the first ET balloon dilation procedure were reported in three of the 15 studies, including 714 patients. Overall, the results from the studies included in the analysis found that all types of ETD showed an improvement in short-term follow-up, and the number of complications was relatively low. The authors recommended future research in randomized homogenous populations.

Pediatric Population

Aboueisha et al (2022) published a meta-analysis of BDET in children less than 18 years of age. A database search identified seven studies that examined the safety and efficacy of BDET in pediatric patients (n=408) from the database inception to March 2021. The evidence base included six retrospective cohort studies and one prospective cohort study with a matched retrospective control group. Among these studies, four were designed as single-arm investigations, while three studies compared the outcomes of BDET with ventilation tube insertion (VT). The pooled studies included a total of 408 children, averaging 9.9 years of age, with an average follow-up period of 19.2 months. In all but one study, patients had a history of prior surgeries, including VT plus adenoidectomy or VT alone. Aggregating data from all seven studies, the pooled complications exhibited an incidence rate of 5.1% (95% CI, 3.1 to 8.4), with self-limited epistaxis being the most frequently reported complication. No major adverse events were reported. Type A tympanograms increased from 15.1% to 73.6% (95% CI, 58% to 84.9%) and Type B tympanograms decreased from 64.2% in the pre-operative period to 16.1% (95% CI, 8.5 to 28.4). In the three studies that compared BDET to VT, a significant difference in the rate of failure (need for reoperation, persistent type B tympanogram, or persistence of symptoms) was observed, favoring the BDET group, however, high heterogeneity was observed across the three studies pooled for this estimate.

Although Aboueisha and colleagues noted several limitations (e.g., RCTs, small number of studies, that the BDET technique is not yet standardized, and different types of balloons were used during studies), they concluded that BDET with or without tympanostomy tube placement may produce outcomes that are comparable, if not superior to, tympanostomy tube placement alone in treating chronic otitis medica with effusion. The authors concluded the procedure was safe with no major adverse events, and future prospective RCTs may help better determine the best candidate in the pediatric population.

Saniasiaya et al (2022) performed a literature review to cover the current literature available on the outcomes of BDET in children. A literature search, conducted from 1990 to 2020, identified only seven articles which included six retrospective cohort case series and one cohort of matched controls. Of the 284 patients included in the review, a total of 463 balloon dilations were performed either bilaterally or unilaterally. The total number of patients for each study ranged from 1 to 66, with a mean age of 7.8 years. BDET was performed as a second-line treatment in six studies, whereas in one study, BDET was the first-line treatment for ETD. The most common finding of ETD was middle ear effusion, as demonstrated in five studies. No major complications were reported in all seven studies included. Minor complications were noted in four studies, with the most common minor complication includes serous otitis media in 13 patients and epistaxis in five patients. The authors concluded that BDET may be considered as an alternative procedure following failed standard treatment. However, the authors noted that the quality of evidence is inadequate to recommend widespread use of the technique until better quality studies are completed.

Gurberg et al (2024) conducted a retrospective matched cohort study of 20 pediatric patients, each from two centers in the United States, to report the long-term safety and efficacy of BDET compared with tympanostomy tube (TT) placement in the pediatric population. Inclusion criteria were patients aged less than 18 who were indicated for TT placement. All patients were successfully matched for number of prior TT, prior adenoidectomy, and gender. Of the 20 patients, 17 were matched exactly for age. Charts were retrospectively reviewed for demographics, tympanometry data, adjunctive procedures, and need for additional interventions. A total of 33 Eustachian tubes were dilated in 20 patients with a mean age of 7 years (range 1.2-14). The mean duration of follow-up was 6.7 years (SD 2.6; range 1.4 to 10.8 years). Over the follow-up time period, two patients failed in the BDET group vs. eight patients in the TT insertion group. Patients who underwent BDET had a lower risk of failure than patients who underwent TT insertion (adjusted HR: 0.18; 95=CI: 0.04, 0.81; p=0.03). The probability of being failure free at six years was 88% (95CI, 71- 95%) in the BDET cohort and 53% (95% CI, 33-70%) in the TT insertions cohort. There were no serious injuries reported in either group. Given that these results occurred in the absence of other interventions in the tympanic membrane, authors suggest the possibility that BDET could serve as a standalone procedure for the treatment of chronic otitis media with effusion. The limitations of the study include the small sample size, its retrospective nature, and the differences in location of the cohorts matched. Authors concluded that while the present study bolsters literature support for the use of BDET in patients with ETD refractory to standard surgical treatment, large randomized clinical trials with long term follow up are indicated.

Transtympanic BDET

There is insufficient peer-reviewed evidence to support the safety and efficacy of the transtympanic approach to BDET. The evidence includes a systematic review of studies, which included two case series on human subjects and one case series on human cadavers (Jufas and Patel, 2016). In 2018, Kapadia and colleagues evaluated the safety of transtympanic BDET of the cartilaginous proximal ET on 8 cadavers (15 ears). Kapadia and Tarabichi (2018) conducted a case series study to assess the safety and feasibility of transtympanic dilation of proximal (tympanic-end) of the cartilaginous segment of the Eustachian tube in patients (n=40) undergoing surgery for chronic ear disease. All

conclude that further study of the technique is warranted.

PROFESSIONAL GUIDELINE(S)

In 2019, the American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS) developed clinical consensus statements on BDET (Tucci et al 2019). The target population was defined as adults ≥ 18 years who are candidates for BDET because of obstructive ETD in one or both ears for 3 months or longer that significantly affects quality of life or functional health status. The expert panel concluded that BDET is an option for treatment of obstructive ETD and reached consensus of 28 statements related to patient criteria, perioperative considerations, and outcomes. There were 28 other statements that the expert panel did not reach consensus, likely reflecting knowledge gaps regarding the role of BDET in managing OETD. This includes the role for repeat BDET, which was found to lack adequate literature to support the efficacy of repeat BDET if the first BDET has not been successful.

In 2019, the National Institute for Health and Care Excellence (NICE) published updated guidance on BDET. The guidance was based on a rapid review of the evidence and stated, "Evidence on the safety and efficacy of balloon dilation for Eustachian tube dysfunction is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit." The guidance also noted that the procedure was not effective in all patients, there was little evidence on the benefit of repeat procedures, and the procedure is only indicated for chronic ETD refractory to medical treatment.

Although the Food and Drug Administration (FDA) expanded clearance for one dilation system to be used for ages 8-17, there is no clinical practice guideline or consensus statement published for BDET in the pediatric population.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates balloon dilation systems as medical devices. All balloon dilation systems including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 May 29]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 May]

In September 2016, the Acclarent AERA Eustachian Balloon Dilation System (Acclarent, Inc.) was granted de novo classification by the FDA. Initially cleared for patients with persistent ETD aged 22 years and older, the system received FDA approval for ages 18 and older (K171761) in January 2018.

Based on real-world evidence, with data from published literature and data provided by established physicians, the FDA expanded the Acclarent AERA's indications for use to include patients ages 8 – 17 years (K230742) in December 2023. The system is indicated for use alone or in combination with adjunctive procedures, to treat objective signs of persistent obstructive ETD from inflammatory

pathology, resulting in chronic otitis media with effusion and are refractory to at least one surgical intervention for persistent obstructive ETD.

In December 2016, the XprESS ENT Dilation System (Entellus Medical) was also cleared for marketing by the FDA through the 510(k) process for two indications. Specifically related to ETD, the device is cleared for patients 18 years and older using a transnasal approach. The FDA determined that the device was equivalent to existing devices used for ETD.

In August 2021, the NuVent Eustachian Tube Dilation Balloon (Medtronic Xomed, Inc.) was cleared for marketing through the 501(k) process to treat persistent ETD in patients 18 years and older (K210841).

In August 2023, the TubaVent Balloon Dilatation System (Spiggle & Theis Medizintechnik, Germany) received FDA 510(k) premarket notification clearance (K223542) for the indicated use of dilating the cartilaginous portion of the Eustachian tube for treatment of persistent obstructive ETD in patients 18 years and older.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
31231	Nasal endoscopy, diagnostic, unilateral or bilateral (separate procedure)
69705	Nasopharyngoscopy, surgical, with dilation of Eustachian tube (i.e., balloon dilation); unilateral
69706	Nasopharyngoscopy, surgical, with dilation of Eustachian tube (i.e., balloon dilation); bilateral
69799	Unlisted procedure, middle ear
92511	Nasopharyngoscopy with endoscope (separate procedure)

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
H65.00-H65.93	Nonsuppurative otitis media (code range)
H66.001-H66.93	Suppurative and & unspecified otitis media (code range)
H67.1-H67.9	Otitis media in diseases classified elsewhere (code range)
H68.001-H68.029	Eustachian salpingitis and obstruction (code range)
H69.80-H69.93	Other specified and unspecified disorders of Eustachian tube (code range)
H71.00-H71.93	Cholesteatoma of middle ear (code range)
H72.00-H72.93	Perforation of tympanic membrane (code range)
H81.01-H81.09	Meniere's disease (code range)
H81.311-H81.4	Peripheral and Central vertigo (code range)
H91.01-H91.93	Other and unspecified hearing loss (code range)
J30.0-J30.9	Vasomotor and allergic rhinitis (code range)
J31.0-J31.2	Chronic rhinitis, nasopharyngitis and pharyngitis (code range)
J32.0-J32.9	Chronic sinusitis (code range)

REFERENCES

Aboueisha Mohamed A, et al. Efficacy and safety of balloon dilation of Eustachian tube in children: systematic review and meta-analysis. Int J Pediatr Otorhinolaryngol. 2022 Mar;154:111048.

Anand V, et al. Balloon dilation of the Eustachian tube: 12-month follow-up of the randomized controlled trial treatment group. Otolaryngol Head and Neck Surg. 2019 Jan;160(4):687–694.

Chisolm PF, et al. Complications of Eustachian tube balloon dilation: Manufacturer and User Facility Device Experience (MAUDE) database analysis and literature review. Laryngoscope Investig Otolaryngol. 2023 Nov 15;8(6):1507-1515. PMID: 38130257

Choi SW, et al. A multicenter, randomized, active-controlled, clinical trial study to evaluate the efficacy and safety of navigation guided balloon Eustachian tuboplasty. Sci Rep. 2021 Dec 2; 11 (1):23296.

Cutler JL, et al. Long-term outcomes for balloon dilation for persistent Eustachian tube dysfunction. Otol Neurotol. 2019 Dec;40(10):1322-1325.

Froehlich MH, et al. Eustachian tube balloon dilation: a systematic review and meta-analysis of treatment outcomes. Otolaryngol Head Neck Surg. 2020 Nov;163(5):870-882.

Gurberg J, et al. Long-term efficacy of balloon dilation of the pediatric Eustachian tube: a six-year matched cohort study. Am J Otolaryngol. 2024 May-Jun;45(3):104208.

Huisman J, et al. Treatment of Eustachian tube dysfunction with balloon dilation a systemic review. Laryngoscope. 2018; 128:237-247.

Jansen S, et al. Subjective and objective effectiveness of Eustachian tube balloon dilation for patients with Eustachian tube dysfunction – Evaluation in a pressure chamber. Otology & Neurotology. 2020 July;41(6):795-801.

Jufas N and Patel N. Transtympanic balloon dilatation of the Eustachian tube: Systematic review. J Laryngol Otol. 2016;130(5):425-430.

Kapadia M, Tarabichi M. Feasibility and safety of transtympanic balloon dilatation of eustachian tube. Otol Neurotol. 2018 Oct;39(9):e825-e830.

Kjaer Krogshede S, et al. Balloon dilation of the eustachian tube: a randomized controlled trial with 6 months follow-up. J Int Adv Otol. Nov 2022;18(6):501-506. PMID: 36349672.

Liang M, Xiong H, Cai Y, Chen Y, Zhang Z, Chen S, Xu Y, Ou Y, Yang H, Zheng Y. Effect of the combination of balloon Eustachian tuboplasty and tympanic paracentesis on intractable chronic otitis media with effusion. Am J Otolaryngol. 2016 Sep-Oct;37(5):442-6.

Luukkainen V, et al. Balloon Eustachian tuboplasty: systematic review of long-term outcomes and proposed indications. J Int Adv Otol. 2018 Apr;14(1):112-126.

Meyer T, et al. A randomized controlled trial of balloon dilation as a treatment for persistent Eustachian tube dysfunction with 1-year follow-up. Otology & Neurotology. 2018;39:894-902.

National Institute for Health and Care Excellence (NICE)[Internet]. Balloon dilation for chronic Eustachian tube dysfunction. Interventional procedures guidance [IPG665]. 2019 Dec 18 [accessed 2026 May 29]. Available from: https://www.nice.org.uk/guidance/ipg665

Oehlandt H, et al. Balloon dilatation of the Eustachian tube in chronic Eustachian tube dysfunction: A retrospective study of 107 patients. J Int Adv Otol. 2022;18(6):495-500.

Oehlandt H, et al. Efficacy of balloon tuboplasty for baro-challenge-induced eustachian tube dysfunction: a systematic review and a retrospective cohort study of 39 patients. Otol Neurotol. 2022 July 1;43(6):611-618. PMID: 35761452

Poe D, et al. Balloon dilation of the Eustachian tube for dilatory dysfunction: a randomized controlled trial. Laryngoscope. 2018 May;128(5): 1200-1206.

Ramakrishnan N, et al. A systemic literature review of the safety and efficacy of Eustachian balloon tuboplasty in patients with chronic Eustachian tube dysfunction. Indian J Otolaryngol Head Neck Surg. 2019 Sept;71(3):406-412.

Saniasiaya J, et al. Outcome of Eustachian tube balloon dilation in children: A systematic review. Ann Otol Rhinol Laryngol. 2022;131(7):797-804.

Schilder AG, et al. Eustachian tube dysfunction: consensus statement on definition, types, clinical

presentation, and diagnosis. Clin Otolaryngol. 2015 Oct;40(5):407-411. PMID 26347263

Siouw JK and Tan JL. Indications for Eustachian tube dilation. Curr Opin Otolaryngol Head Neck Surg. 2020 Feb;28(1):31-35.

Standring RT, et al. Balloon dilation of the Eustachian tube with a seeker-based device: A registry of 169 patients. Laryngoscope Investig Otolaryngol. 2021 Sep 10;6(5):975-982. PMID: 34667839.

Swords C, et al. Balloon dilatation of the Eustachian tube for obstructive Eustachian tube dysfunction in adults. Cochrane Database of Systematic Reviews. 2019 Sep 29 [updated 2025 Feb 26; accessed 2026 June 5]. Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013429.pub2/full

Toivonen J, et al. Balloon dilation for obstructive Eustachian tube dysfunction in children. Otology & Neurotology. 2021;42(4):566-572.

Tucci DL, et al. Clinical consensus statement: balloon dilation of the Eustachian tube. Otolaryngol Head Neck Surg. 2019 Jul;161(1):6-17.

U.S. Food and Drug Administration (FDA) [Internet]. 501(k) Premarket Notification. Acclarent Aera Eustachian Balloon Dilation System (K171761). 2018 Jan 16. [accessed 2026 May 29]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K171761

U.S. Food and Drug Administration (FDA) [Internet]. 510(k) Premarket Notification. Acclarent Aera Eustachian Balloon Dilation System (K230742). 2023 Dec 13 [accessed 2026 May 29] Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K230742

U.S. Food and Drug Administration (FDA) [Internet]. 510(k) Premarket Notification. TubaVent Balloon Dilatation System (K230742). 2023 Aug 03 [accessed 2025 May 02]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K223542

U.S. Food and Drug Administration (FDA) [Internet]. De Novo Classification 513(f)(2)(De Novo). Acclarent Aera Eustachian Tube Balloon Dilation System (DEN150056). 2016 Sep 16. [accessed 2026 May 29 Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=den150056

U.S. Food and Drug Administration (FDA) [Internet]. Premarket notification 510(k). NuVent Eustachian Tube Dilation Balloon (K210841). 2021 Aug 16. [accessed 2026 May 29] Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K210841

U.S. Food and Drug Administration (FDA) [Internet]. Premarket notification 510(k). XpreESS ENT Dilation System (K163509). 2017 Apr 05. [accessed 2026 May 29] Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K163509

Wang TC, et. al. Comparison of balloon dilation and laser Eustachian tuboplasty in patients with Eustachian tube dysfunction: a meta-analysis. Otolaryngol Head Neck Surg. 2018;158:617-626.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Balloon dilation of the Eustachian tube is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New:7/23

Revised:11/25

Reviewed:7/24, 7/25, 9/26

Date	Summary of Changes
1/1/2026	• Transitioned Balloon Dilation of the Eustachian Tube policy, 1370/20.000513 to Lifetime Healthcare Companies policy template.
11/1/2023	• New policy

MEDICAL POLICY

Medical Policy Title	**Bariatric and Metabolic Surgery**
Policy Number	**7.01.29**
Current Effective Date	**January 1, 2026**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. The surgical treatment of obesity by Roux-en-Y gastric bypass (open or laparoscopic), biliopancreatic diversion with duodenal switch (BPD-DS), single-anastomosis duodenoileal bypass with sleeve gastrectomy (SADI-S), laparoscopic adjustable gastric banding (LAGB), and sleeve gastrectomy is considered **medically appropriate** when **ALL** of the following criteria are met:

A. The individual's body mass index (BMI) meets **one (1)** of the following:

Adult

1. Class 3 obesity (BMI 40 kg/m^2 or greater);
2. Class 2 obesity (BMI 35 to 39.9 kg/m^2) and at least one (1) obesity-related comorbidity (e.g., cardiovascular disease, dyslipidemias, hypercholesterolemia, hypertension, metabolic syndrome, non-alcoholic fatty liver disease, pulmonary hypoventilation, obstructive sleep apnea, or weight-bearing joint arthropathy); **or**
3. Class 1 obesity (BMI 30 to 34.9 kg/m^2) and type 2 diabetes (T2D) with documentation of inadequate glycemic control despite optimized lifestyle and medical management; **or**

Adolescent

4. Class 3 obesity (BMI greater than or equal to 40 kg/m^2, or BMI greater than or equal to 140% of the 95th percentile, whichever is lower based on age and sex); **or**
5. Class 2 obesity (BMI 35 to 39.9 kg/m^2, or BMI between 120% to 139.9% of the 95th percentile, whichever is lower based on age and sex), and at least one (1) obesity-related comorbidity (e.g., cardiovascular disease, dyslipidemias, hypercholesterolemia, hypertension, metabolic syndrome, non-alcoholic fatty liver disease, pulmonary hypoventilation, obstructive sleep apnea, type 2 diabetes, or weight-bearing joint arthropathy);

B. Documentation of the individual's participation efforts to achieve weight loss or metabolic improvements including **all** of the following:

1. Pre-operative lifestyle and medical optimization efforts including the type of the weight-loss/nutritional program(s), applicable medication(s), length of participation, and results

achieved (e.g., weight loss, lowered hemoglobin A1C). Documentation can be provided by the bariatric surgeon, primary care provider, registered dietician, or nutritionist;

2. Pre-operative nutrition evaluation conducted by a registered dietician is mandatory; **and**
3. Planned participation in a post-operative weight management program through the first year after surgery that supports long-term health outcomes through nutritional management (including assessment for malabsorption), physical activity, and behavioral health support;

C. Medical clearance attestation for surgery from the primary care provider or bariatric surgeon;

D. Behavioral health clearance for surgery is documented by **either** of the following:

1. The bariatric surgeon or primary care provider documents the absence of any psychiatric or psychosocial comorbidities; **or**
2. A licensed behavioral health provider familiar with the implications of weight loss surgery is required for **either** of the following:
   a. history of alcohol or substance use disorder with 6 months or less of abstinence; **or**
   b. psychosocial, psychological, or psychiatric concerns identified by any member of the bariatric pre-operative evaluation team.

II. Bariatric and metabolic surgery as a treatment for individuals with a BMI less than or equal to 29.9 kg/m^2 is considered **investigational.**

III. The following procedures for the surgical treatment of obesity are considered **investigational**:

A. Laparoscopic gastric plication (also known as laparoscopic greater curvature plication);

B. One anastomosis gastric bypass (OAGB) (also known as mini-gastric bypass);

C. Vertical banded gastroplasty (VBG);

D. Intragastric space occupying mechanisms (e.g., intragastric balloon or expanding material/capsules);

E. Endoscopic/endoluminal procedures or devices, including but not limited to:

1. Gastric aspiration therapy;
2. Transoral gastroplasty (TOGA, also known as vertical sutured gastroplasty, endoluminal vertical gastroplasty, System);
3. Restorative obesity surgery endoluminal (ROSE);
4. Closure/plication and suturing (e.g., StomaphyX, EndoCinch, Apollo Overstitch)
5. TransPyloric Shuttle;
6. Gastrointestinal liners (e.g., duodenal-jejunal bypass liners such as EndoBarrier); and
7. Endoscopic sleeve gastroplasty (ESG);

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8. Transoral outlet reduction [TORe]).

Revisional and Corrective Surgery

IV. Surgical revision is considered **medically necessary** for documented complications following the primary procedure (e.g., malabsorption or malnutrition, obstruction, or stricture, staple-line disruption, severe gastroesophageal reflux disease that does not respond to medical treatment).

V. LAGB revision or removal is considered **medically appropriate** for documented complication(s) or technical failure(s) (e.g., band slippage, band erosion, infection, esophageal dilation, dysphagia, heartburn/reflux, displaced band, port dislocation band intolerance [e.g., pain or vomiting], and port and/or catheter leakage).

VI. Revision or conversion to another medically appropriate procedure due to inadequate weight loss or metabolic improvement following the primary bariatric procedure is considered **medically appropriate** when **BOTH** of the following are met:

   A. Documented compliance to the prescribed post-operative nutrition and physical activity program for at least 6-months;

   B. **Either** of the following are met:

      1. Non-response to the primary procedure (failure to achieve adequate outcomes); **or**

      2. Weight recurrence following initial successful weight reduction from the primary procedure.

VII. Reoperation or revision surgical treatment of obesity is considered **investigational** for **EITHER** of the following:

   A. Placement of a second adjustable gastric band (AGB);

   B. Endoscopic/endoluminal procedures (e.g., transoral outlet reduction [TORe], endoscopic sleeve gastroplasty [ESG]).

Concomitant Procedures

VIII. Performing a routine liver biopsy at the time of the bariatric surgery is considered **not medically necessary** in the absence of documented signs or symptoms of liver disease (e.g., abnormal liver function tests of unknown etiology, knowledge of a specific diagnosis that will likely alter the treatment plan, known liver disease where prognostic information about fibrosis may guide subsequent treatment, the presence of a mass or lesions, or focal or diffuse abnormalities seen on imaging studies of unknown etiology).

IX. Prophylactic removal of a normal and asymptomatic gallbladder at the time of bariatric surgery is considered **not medically necessary**, unless cholelithiasis is present, or the patient will undergo biliopancreatic diversion with or without duodenal switch based on a higher incidence of biliary complications.

RELATED POLICIES

Corporate Medical Policy

7.01.53 Abdominoplasty and Panniculectomy, and Lipedema Reduction Surgery

7.01.64 Gastric Electrical Stimulation

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Body mass index (BMI) requirements are based on preoperative measurements. BMI is calculated by dividing a person's weight in kilograms (kg) by the square of height in meters (m^2).

II. BMI thresholds may be adjusted for ethnicity (e.g., Asian population) on a case-by-case basis. Obesity definitions using BMI thresholds do not apply similarly to all populations, clinical obesity in the Asian population is recognized in individuals with BMI >25 kg/m^2 (Eisenberg 2022).

III. Individuals considering surgery must participate in a multidisciplinary pre- and post-operative lifestyle modification program that addresses long-term commitment and management of modifiable risk factors (e.g., dietary changes, nutritional monitoring, physical activity, behavioral modification, and psychosocial support). The post-operative plan must include participation in ongoing postoperative follow-up through the first year after surgery.

IV. Revision or conversion surgery may be performed for weight recurrence, non-response, or post-operative symptoms (e.g., gastroesophageal reflux disease) that do not respond to medical management.

   A. Surgery for medical complication(s) or technical failure(s) does not require adherence to post-operative follow-up recommendations.

   B. Surgery for weight recurrence or non-response requires documented adherence to post-operative program recommendations for at least six (6) months.

V. The American Society of Metabolic and Bariatric Surgery (ASMBS) reiterates that a multidisciplinary team should evaluate patients to optimize surgical outcomes including:

   A. Comprehensive preoperative assessment of medical history, physical examination, laboratory testing (e.g., H. pylori, kidney function, liver profile, thyroid stimulating hormone), psychosocial history (e.g., functioning, substance use, maladaptive eating patterns), lifestyle/nutritional evaluation (e.g., sleep hygiene, smoking, healthy eating index) (Carter 2021; Mechanick 2019).

   B. Pre-operative optimization refers to the management of modifiable risk factors prior to elective surgery, with the goal of reducing the risk of perioperative complications and improving outcomes by implementing interventions that can address disordered eating, severe uncontrolled mental illness, or active substance abuse (Carter 2021; Eisenberg 2022).

VI. Adult classification of obesity by BMI (National Heart, Lung, and Blood Institute [NHLBI] 1998):

- Class 1 obesity: BMI 30 to 34.9 kg/m^2

- Class 2 obesity: BMI 35 to 39.9 kg/m^2
- Class 3 extreme obesity: BMI 40 kg/m^2 or greater

VII. Child and adolescent BMI interpretation is age- and sex-specific with weight category and classification of (Hampl 2023):

- Class 2 obesity: BMI 35 to 39.9 kg/m^2 or BMI between 120% to 139.9% of the 95th percentile
- Class 3 obesity: BMI greater than or equal to 40 kg/m^2 or BMI greater than or equal to 140% of the 95th percentile

VIII. The behavioral health evaluation should be performed by a licensed behavioral health provider familiar with the implications of weight reduction surgery. A current licensed behavioral health provider familiar with the implications of weight reduction surgery who provides ongoing care for the patient may also provide this evaluation. For psychological testing criteria, refer to the Related Policies section.

IX. Adolescents should be referred to an accredited pediatric/adolescent bariatric surgery program, such as a Surgical Review Corporation (SRC) or a Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) accredited pediatric program to ensure care in programs that meet established standards for patient safety and quality.

X. Coverage is limited to physicians who have been properly trained in performing a bariatric procedure at facilities with the diagnostic and support services necessary for the care of morbidly obese patients.

XI. Any device used for bariatric surgery must be used in accordance with the approved indications of the United States Food and Drug Administration (FDA).

XII. An expected outcome of successful bariatric surgery is redundant/excessive skin.

XIII. The adjustment of a previously placed laparoscopic adjustable gastric band (LAGB), beyond the global, 90-day limit, controls the rate of weight loss and/or treat symptoms secondary to gastric restriction following the initial medically necessary adjustable gastric banding procedure. Adjustment of LAGB is performed via accessing the subcutaneous port, with or without imaging).

DESCRIPTION

Obesity is a complex multifactorial condition that substantially increases the risk of weight-related complications and comorbidities associated with excess adiposity. Complications may include, but are not limited to asthma, nonalcoholic fatty liver disease, hypertension, dyslipidemia, pre-diabetes, type 2 diabetes, metabolic syndrome, coronary artery disease, stroke, gallbladder disease, osteoarthritis, obstructive sleep apnea, respiratory problems, and a variety of certain types of cancers (e.g., colorectal cancer). BMI is a measure used to screen for excess body adiposity (body fat) and is calculated by dividing a person's weight in kilograms (kg) by the square of height in meters (m2).

Clinically severe obesity includes class III obesity (formerly referred to as morbid obesity) and class II obesity with associated comorbid conditions (NHLBI 1998). The NHLBI outlines the following

relationship between overweight/obesity BMI and disease risk, which is noted to vary among individuals and different populations:

Obesity Classification	BMI (kg/m^2)	Disease Risk*
Overweight	25.0-29.9	Increased
Class 1 obesity	30-34.9	High
Class 2 obesity	35-39.9	Very High
Class 3 extreme obesity	>40	Extremely High

*Disease risk for type 2 diabetes, hypertension, and cardiovascular disease.

The first line of treatment for obesity is dietary and lifestyle modification, including intensive lifestyle intervention (ILI). Under medical supervision ILI programs include comprehensive behavioral management strategies that focus on improving dietary habits, increasing physical activity, and enhancing self-care and psychological well-being. Strong evidence suggests that multidomain ILI reduces cardiovascular risk factors among persons with type 2 diabetes (Huckfeldt 2023). Although this strategy may be effective in some individuals, not all individuals can reduce and control weight through diet and activity/exercise/movement. When conservative measures fail, some individuals consider surgical approaches.

Bariatric surgery, also referred to as metabolic or bariatric surgery (MBS), is an evidence-based option for individuals with class II or III obesity who have not achieved sufficient weight loss through non-surgical interventions. Long-term evidence demonstrates significant and durable clinical improvement, and in some cases remission, of co-morbidities (e.g., type 2 diabetes). Bariatric or metabolic surgery works by changing the anatomy and size of the stomach to reduce/restrict food intake, as well as modifying the digestion process to improve fat metabolism. Some procedures can also affect the production of intestinal hormones, which can influence appetite and metabolic improvements.

Bariatric and metabolic surgery for individuals with class I obesity and T2D is increasingly performed based on evidence showing improvement or remission of diabetes following surgery, sometimes occurring before substantial weight loss. Various surgical procedures have different effects on weight loss. Gastrointestinal rearrangement appears to confer antidiabetic benefits independent of weight loss and caloric restriction, although the precise mechanisms remain under investigation. Proposed mechanisms include changes in gastrointestinal peptides such as glucagon-like peptide-1 (GLP-1), glucose-dependent insulinotropic peptide (GIP), and peptide YY (PYY). GLP-1, secreted by L cells in the distal ileum, enhances glucose-dependent insulin secretion, slows gastric emptying, blunts postprandial glycemia, and promotes satiety. GIP acts on pancreatic beta cells to increase insulin secretion, while PYY contributes to satiety and delayed gastric emptying. These hormonal changes may also improve insulin sensitivity.

Bariatric surgery is generally categorized into two types: gastric restrictive procedures and malabsorptive procedures. Restrictive procedures mechanically limit the volume of food intake before

satiety is achieved, while malabsorptive procedures reduce nutrient absorption by altering the normal digestive pathway. Many operations combine both mechanisms.

Procedures/Interventions

Roux-en-Y gastric bypass (RYGB) combines restrictive and malabsorptive components. The stomach is partitioned horizontally or vertically and connected to the jejunum via a Roux-en-Y configuration, bypassing the duodenum and proximal small bowel. This procedure can be performed via open or laparoscopic techniques. Potential complications include dumping syndrome, anastomotic complications, (e.g., leakage or marginal ulceration), and nutritional deficiencies due to altered absorption (e.g., iron, vitamin B-12, and calcium).

Sleeve gastrectomy (SG) involves resection of the greater curvature of the stomach from the angle of His to the distal antrum, creating a tubular gastric remnant. The pylorus is preserved, allowing more physiological gastric emptying and reducing the risk of dumping syndrome. SG may serve as a standalone procedure or as a first stage before a more extensive malabsorptive operation (e.g., BPD).

Adjustable gastric banding (AGB) uses a laparoscopically placed band around the upper stomach, connected to a subcutaneous reservoir for saline injection. Adjustments alter stoma size to regulate food passage. Complications include band slippage, erosion, and port-related issues.

Biliopancreatic diversion (BPD), also known as the Scopinaro procedure, combines subtotal gastrectomy with diversion of biliopancreatic secretions to the distal ileum via a long Roux-en-Y limb. This procedure carries significant risks, including protein malnutrition, iron deficiency anemia, hypocalcemia, and bone demineralization. BPD with duodenal switch (DS) modifies BPD by replacing distal gastrectomy with sleeve gastrectomy, preserving the pylorus and proximal duodenum. This reduces dumping syndrome and ulcer risk while maintaining selective malabsorption.

Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy (SADI-S), also known as stomach-intestine pylorus-sparing surgery (SIPS), combines SG with a single duodeno-ileal anastomosis, preserving the pylorus and reducing complexity compared to DS. It aims to minimize risks such as short bowel syndrome while maintaining malabsorptive benefits.

Gastric plication is a restrictive laparoscopic procedure that reduces gastric volume by folding and suturing the stomach without tissue resection.

Vertical banded gastroplasty (VBG) creates a small pouch by vertically stapling and horizontally banding the upper stomach. This once common legacy procedure has largely been abandoned due to high revision rates from complications such as staple line disruption and band erosion.

Reversal or Revisional Surgery

Professional society guidance recognizes the role of revisional procedures to address device- or procedure-related complications, technical failures, or inadequate outcomes following prior bariatric interventions. Endoscopic revision, including TORe and repeat gastric remodeling using suturing techniques (e.g., repeat ESG/re-suturing patterns), is described as a stepwise strategy to manage weight regain or anatomic dilation after prior endoscopic or surgical procedures.

Procedures are generally not indicated when failure is attributable to noncompliance with recommended dietary and behavioral protocols, such as gastric pouch dilation resulting from overeating.

Endoscopic and Device-Based Procedures

As revisional metabolic and bariatric surgery (MBS) is associated with a higher complication rate than primary MBS, there is interest in endobariatric revisional procedures to treat weight related issues while potentially minimizing the risk of complications (Docimo 2026). The primary goals vary by intervention type, with gastric endoscopic bariatric and metabolic therapies (EBMTs) primarily targeting weight loss, whereas small-bowel interventions focus on glycemic improvement as the primary efficacy endpoint, with weight loss assessed as a co-primary or secondary outcome (e.g., duodenal–jejunal bypass liner).

Endoscopic suturing is an endoscopic tissue-approximation technique used to place full-thickness sutures or plications within the gastrointestinal tract and is used to perform several EBMTs and revisional procedures, including endoscopic sleeve gastroplasty (ESG) and other gastric remodeling procedures. Specialized devices (e.g., EndoCinch, Apollo OverStitch) place stitches inside the gastrointestinal tract.

Endoscopic gastric remodeling (EGR) refers to a group of endoscopic interventions that use endoscopic tissue-approximation technologies to remodel the stomach, reduce gastric volume, alter motility, and promote early satiety. EGR encompasses ESG and includes multiple devices (e.g., Apollo ESG System/OverStitch, POSE system, and Endomina).

Endoscopic sleeve gastroplasty (ESG) is a minimally invasive endoscopic procedure that reduces gastric volume by creating full-thickness plications along the greater curvature of the stomach using endoscopic suturing to produce a sleeve-like gastric remodeling and clinically meaningful weight loss. ESG mimics the restrictive effect of sleeve gastrectomy without gastric resection. Endoscopic "resleeve" gastroplasty has been described as an endoscopic option for revision following sleeve gastrectomy.

Transoral outlet reduction (TORe) is an endoscopic revisional procedure for weight regain after Roux-en-Y gastric bypass due to dilation of the gastrojejunal anastomosis (GJA). Techniques to reduce anastomotic diameter, to support satiety and weight control, include endoscopic suturing, argon plasma coagulation (APC), or both

Transoral gastroplasty (TG), also known as vertical sutured gastroplasty or endoluminal vertical, is an endoluminal approach intended to create gastric restriction using incisionless or stapling-based (e.g., TOGA) to create a restrictive gastric pouch.

Intragastric balloons (e.g., Orbera, Obalon, Spatz3) are temporary, endoscopically placed balloons that reduce gastric capacity to promote satiety. They are used for short-term weight loss or as a bridge to definitive surgery.

Aspiration therapy (AT) uses a percutaneous gastrostomy tube to aspirate gastric contents post-meal, reducing caloric absorption. Success depends on individual adherence.

TransPyloric shuttle (TPS) is an endoscopically inserted device that intermittently obstructs the pylorus to delay gastric emptying, promoting early and prolonged satiety.

Small-bowel interventions include the duodenal–jejunal bypass liner (DJBL) (e.g., EndoBarrier), which limits nutrient contact with the proximal small intestine and is evaluated primarily for glycemic improvement. Duodenal mucosal resurfacing (DMR) is an endoscopic treatment to ablate the duodenal mucosa in an attempt to improve diabetes mellitus and fatty liver disease in patients with obesity.

SUPPORTIVE LITERATURE

The 1991 National Institute of Health (NIH) Consensus Statement first supported the safety and effectiveness of bariatric surgery. The Swedish Obese Subjects (SOS) trial, the most influential study comparing bariatric surgery to conservative treatment, demonstrated substantial weight loss, improved comorbid conditions, and enhanced quality of life after surgery (Sjostrom 2007).

Class II and III Obesity

There is sufficient published medical literature demonstrating the safety and efficacy of specific bariatric procedures including: open or laparoscopic Roux-en-Y gastric bypass procedures (Himpens 2012; Wadden 2019; Cui 2021; Angrisani 2021), sleeve gastrectomy (Leyba 2011; Himpens 2010; D'Hondt 2011; Chouillard 2011; Wolnerhanssen 2021; Vitiell 2023), adjustable gastric band (Dixon 2008; Himpens 2011), biliopancreatic diversion with duodenal switch (Prachand 2006; Strain 2007; Skogar 2017), and SADI-S (Dijkhorst 2021; Esparham 2023; Axer 2024).

Class III Obesity with BMI ≥45 kg/m^2

Pereira et al (2024) conducted a prospective, interventional, open-label randomized study that assessed weight trajectories and postprandial endocrine/metabolic responses through 12 months in adults with class III obesity (BMI 45–55 kg/m²). Participants were randomized to SADI-S (n=7) or to sleeve gastrectomy (SG) as the first step of a planned two-step SADI-S (n=7). Study visits occurred pre-operatively and at 3, 6, and 12 months. Anthropometric, metabolic, and micronutrient profiles did not differ significantly between groups at baseline or at follow-up. Fasting and postprandial glucose, insulin, C-peptide, ghrelin, insulin secretion rate, and insulin clearance during the mixed-meal tolerance test (MMTT) were not significantly different between SADI-S and SG. No participants were lost to follow-up. At 12 months, the study reports no significant between-group differences in the clinical and metabolic outcomes assessed.

Esparham et al (2025) performed a systematic review and meta-analysis comparing duodenal switch (DS) and Roux-en-Y gastric bypass (RYGB) in patients with BMI ≥ 50 kg/m² (12 studies; n=2,678; 1–15 years follow-up). DS showed significantly greater BMI reduction ($p < .001$) and greater total weight loss ($p < .001$) than RYGB. Complication, reoperation, mortality, and comorbidity remission rates (diabetes, hypertension, dyslipidemia, obstructive sleep apnea) did not differ significantly between groups. However, DS was associated with higher malnutrition rates (8.3% vs. 1.2%; $p = .02$), more revisional surgeries for malnutrition (5.4% vs. 0%; $p = .05$), and increased gallbladder disease requiring cholecystectomy (24.6% vs. 4.5%; $p = .01$). The authors concluded that DS

provides superior weight loss for patients with BMI ≥50 kg/m² but carries a higher risk of major malnutrition and revisional surgery compared to RYGB.

Class I Obesity with Type 2 Diabetes

Bariatric surgery as treatment for class 1 obesity and type 2 diabetes is supported meta-analysis and systematic reviews (e.g., De Luca 2023) which have found significantly greater remission rates of diabetes, decrease in HbA1c levels, and decrease in BMI with bariatric surgery than with nonsurgical treatment. Supporting randomized controlled trials (RCTs) include the STAMPEDE 5-year outcomes, which demonstrated that RYGB and SG were superior to intensive medical therapy for individuals with BMI 27–43 (Schauer 2017). The Alliance of Randomized Trials of Medicine vs Metabolic Surgery in Type 2 Diabetes (ARMMS-T2D) 3-year follow-up showed durable metabolic benefit with bariatric surgery compared with medical/lifestyle interventions across RYGB, SG, and adjustable gastric banding (Kirwan 2022), and 12-year long-term ARMMS-T2D data demonstrating sustained, clinically significant improvements in glycemic control, higher diabetes remission rates, and reduced need for diabetes medications after surgery (Courcoulas 2024).

Class I Obesity without Type 2 Diabetes

Evidence is limited for individuals with a BMI 35 kg/m^2 who do not have type 2 diabetes. A few small randomized controlled trials and case series have reported weight loss and improvements in comorbidities in this population; however, the available evidence does not allow conclusions regarding the long-term risk-benefit profile of bariatric surgery for these individuals.

One-Anastomosis Gastric Bypass (OAGB),

OABG, formerly known as mini-gastric bypass or loop gastric by-pass lacks sufficient published in the medical literature to draw conclusions about the safety and effectiveness of the procedure.

Robert et al (2024) reported the 5-year extension study of the YOMEGA trial, a prospective, open-label, non-inferiority, randomized controlled trial done across nine high-volume bariatric institutions in France, enrolling adults aged 18–65 years with BMI ≥ 40 kg/m² or BMI ≥ 35 kg/m² with ≥1 comorbidity, and excluding those with severe gastro-esophageal reflux disease (GERD), Barrett's esophagus, or prior bariatric surgery (OAGB used a 200-cm biliopancreatic limb). A total of 127 participants were assigned to OAGB and 121 to RYGB, with scheduled assessments at 1, 3, 6, 12, 18, and 24 months and annually thereafter; at 5 years, OAGB was non-inferior to RYGB for percentage excess BMI loss, and there was no significant between-group difference in the frequency of type 2 diabetes remission, while the mean decrease in HbA1c from 2 to 5 years did not differ between procedures. Diarrhea decreased from 2 to 5 years in the OAGB arm while increasing in the RYGB arm; early dumping syndrome at 5 years was more frequent with RYGB than OAGB; and GERD increased over time in both groups but was significantly higher after OAGB, with greater proton-pump inhibitor use; ten OAGB patients were converted to RYGB during follow-up. The investigators noted that malabsorption-related adverse events improved over time in the OAGB group (no hospitalizations for malnutrition from years 2–5 after nine serious malnutrition events within the first 2 years). Although the authors concluded that OAGB was non-inferior to RYGB for weight and metabolic outcomes at 5 years, the higher frequency of GERD after OAGB supports the need for

ongoing surveillance. Study limitations include substantial loss to follow-up at 5 years, reliance on symptom-based GERD assessment rather than standardized reflux testing, and a relatively small diabetes subgroup, all of which may affect the precision and generalizability of adverse-event and metabolic outcome estimates.

Endobariatric Procedures

Mrad et al (2025) conducted a network meta-analysis of randomized trials comparing any of the currently commercially available endoscopic bariatric therapies (EBTs) with controls, either sham procedures or diet plus lifestyle interventions for patients with obesity or overweight. Ten and eight studies were eligible for qualitative and quantitative analysis, respectively. The authors concluded that, considering percentage of total weight loss (%TWL) at the time of IGB removal, all EBTs were associated with statistically higher % TWL than controls. There were no significant differences among EBTs. All currently available EBTs approved by the U.S. Food and Drug Administration (FDA) are more effective than both diet plus lifestyle intervention and sham procedures with an acceptable safety profile. ESG seems the most effective and may be prioritized for patients fit for both ESG and IGBs; however, direct controlled trials between EBTs are warranted to confirm these findings.

Docimo et al (2026) with the American Society for Metabolic and Bariatric Surgery (ASMBS) conducted a systematic review of pertinent endoluminal bariatric therapies for both primary and revisional indications. Available evidence has shown intragastric balloons (IGBs) to be associated with percent total weight loss (%TWL) ranging from 4–13% across most studies, with a serious adverse event rate of less than 2%. The majority of studies do not report outcomes beyond one year; therefore, long-term effects on weight remain unknown and require further investigation in the context of treating a chronic disease. Available evidence for endoscopic sleeve gastroplasty (ESG) shows favorable improvement in weight (excess weight loss [EWL] of 45–60%) and metabolic disease. Although laparoscopic sleeve gastrectomy (LSG) consistently demonstrates greater improvement in weight loss and comorbidities, ESG may be a suitable option for patients who are unable or unwilling to undergo LSG. Based upon current results, endoluminal duodenal-jejunal liners in their present form remain investigational. The literature for transoral outlet reduction (TORe) reports modest weight loss (%TWL 7–8%) up to one year after treatment, with weight regain observed between 6 and 12 months, and no longer-term follow-up available. Techniques including full-thickness endoscopic suturing alone, argon plasma coagulation (APC) alone, and suturing combined with APC have all been described without clear evidence of superiority among methods. The ASMBS concluded that obesity is a chronic disease best treated in a multidisciplinary setting. Therefore, endoluminal bariatric procedures should be performed within a multidisciplinary program that provides longitudinal support for patients with obesity over time and facilitates ongoing data collection on patient outcomes.

Endoscopic Sleeve Gastroplasty (ESG)

Abu Dayyeh et al (2022) conducted a prospective, multi-center, randomized trial (MERIT) with individuals (n=209) aged 21-65 with class I or class II obesity and who agreed to comply with lifelong dietary restrictions. Participants were randomly assigned (1:1) to ESG with lifestyle modifications (ESG group; n=85) or lifestyle modifications alone (control group; n=124), with

potential retightening or crossover to ESG, respectively, at 52 weeks. Participants in the primary ESG group were followed up for 104 weeks. At 52 weeks, the primary endpoint of mean percentage of EWL was 49.2% for the ESG group and 3.2% for the control group ($p<0.0001$). Mean percentage of total bodyweight loss was 13.6% for the ESG group and 0.8% for the control group ($p<0.0001$). At 52 weeks, 41 (80%) of 51 participants in the ESG group had an improvement in one or more metabolic comorbidities, whereas six (12%) worsened, compared with the control group in which 28 (45%) of 62 participants had similar improvement, whereas 31 (50%) worsened. At 104 weeks, 41 (68%) of 60 participants in the ESG group maintained 25% or more of EWL. ESG-related serious adverse events occurred in three (2%) of 131 participants, without mortality or need for intensive care or surgery. Study limitations include the absence of a sham intervention group, inadequate cohort size, and follow-up to detect differences outcomes.

Docimo et al (2023), on behalf of the American Society for Metabolic and Bariatric Surgery Clinical Issues Committee, published a systematic review of the peer-reviewed literature on endoscopic sleeve gastroplasty (ESG) and primary obesity surgery endoluminal procedures (POSE, POSE 2.0), collectively regarded as alternative forms of endoscopic sutured gastroplasty. The panel noted that most published studies used ESG in patients with a BMI of 30–40 kg/m², with limited data available for patients outside this range. Across multiple studies, ESG yielded an average total body weight loss of 13%–20% at 12 months, which was significantly less than the weight loss observed after laparoscopic sleeve gastrectomy in comparative analyses. Among the studies reporting 2- and 3-year outcomes, most demonstrated sustained weight loss. ESG was also associated with improvements in metabolic disease, and postoperative surveys across several studies indicated a <3% incidence of de novo GERD. With similar weight-loss outcomes and complication rates, POSE and POSE 2.0 represent alternative endoluminal plication techniques to ESG. Endoscopy may be performed in advance or as the first step of a single-stage conversion. For practices offering ESG or POSE, these procedures should be integrated within a comprehensive multidisciplinary bariatric program, optimally within a bariatric center of excellence.

Abad et al (2025) conducted a prospective, multicenter, randomized, controlled, and double-blind study to evaluate the effectiveness and safety of ESG (with OverStitch) in patients with metabolic dysfunction-associated steatohepatitis (MASH). A total of 40 patients were randomized 1:1 to ESG plus lifestyle modification vs sham endoscopy plus lifestyle intervention. Inclusion criteria included biopsy-proven MASH with nonalcoholic fatty liver disease activity score (NAS) ≥3 and fibrosis stage F0 to F3. At the 72-week follow-up, 18 participants from the ESG group and 19 in the endoscopic simulated intervention (ESI) group completed the study. From baseline to the end of follow-up, total body weight loss was significantly greater with ESG than ESI ($P < .05$). ESG also resulted in significantly greater reductions in liver stiffness ($P < .05$) and steatosis ($P = .033$). In patients achieving weight loss >10%, there was significant improvement on NAS score ($p < .01$), but not in fibrosis stage. Only two patients in the ESG group had an adverse event, which resolved conservatively. Study limitations may limit generalizability and long-term inference, including a small sample, the single-disease population (MASH), and trial duration. The authors concluded that the results suggest that ESG may be an effective alternative therapy in the treatment of patients with MASH and should be used as part of second-line treatment, with or without other complementary

weight loss therapies, especially in patients who do not respond to lifestyle modification. Further studies are needed to confirm these findings and to better characterize its potential role in the management of patients with MASH.

Duodenal-Jejunal Bypass Liner (DJBL)

There is insufficient published evidence to establish DJBL safety and clinical efficacy.

Glaysher et al (2021) published a sub-study of a multicenter, randomized, controlled trial of patients within two treatment groups (n=70 per group) diagnosed with type-2 diabetes mellitus and BMI 30-50 kg/m^2. The authors reported that one year of DJBL therapy is associated with significantly greater weight loss and greater reduction in cholesterol; however, DJBL depleted essential fatty acids (EFAs).

Ruban et al (2022) conducted an open-label RCT of 170 adults with inadequate controlled T2DM and obesity. The authors reported there was no significant difference in the percentage of patients achieving a glycated hemoglobin reduction of at least 20%, and 16 patients (24%) achieved at least 15% weight loss in the DJBL group compared to 2 patients (4%) in the control group at 12 months.

Hollenbach et al (2024) reported on a RCT of 33 patients (11 DJBL, 15 intragastric balloon, and 7 sham group) which was terminated early after the DJBL device lost its CE mark in Europe. The authors concluded that, despite the lack of power, the data strongly suggest that intragastric balloon and DJBL lead to comparable weight loss while implanted; however, these procedures failed to achieve effective weight loss 12 months after explantation.

Chen et al (2024) conducted a systematic review and meta-analysis of 30 studies (1751 patients), concluding that DJBL offers significant improvement in weight loss, glycemic control, and cardiovascular parameters while in situ; however, recommended that further studies are warranted to better understand the long-term efficacy and safety of DJBL and that the benefits of DJBL need to be carefully weighed against the risks in clinical decision-making.

Gastric Plication

Research preliminarily supported that the procedure has acceptable short-term complication rates and weight loss outcomes (e.g., Fried 2012; Skrekas 2011; Kourkoulos 2012; Talebpour 2012); however, additional well-designed comparative studies with established bariatric procedures are needed, to determine its overall safety, efficacy, and impact on health outcomes.

Intragastric Space Occupying Devices

Published finding are insufficient and further studies are needed to demonstrate the long-term effects of utilizing intragastric balloon as a weight loss strategy (Ponce 2015; Bazerbachi 2018; Hollenback 2024; Silva 2024; Mrad 2025).

Dang et al (2018) performed a propensity-matched analysis between IGB and laparoscopic bariatric surgery (LBS) to compare safety profiles, concluding that IGB was associated with a higher adverse event rate than LBS, more research is needed, and IGB appears less safe than bariatric surgery as a standalone weight loss intervention.

Sullivan et al (2018) conducted a 24-week, double-blinded, randomized, sham-controlled trial of the

Obalon 6-month swallowable gas-filled IGB system (Carlsbad, CA) at 15 academic and private practice centers in the United States. Adults aged 22–60 years with BMI 30-40 kg/m^2 were randomized to receive either treatment (n=198) or control (n=209). Among participants who completed the 24 week treatment mean percent total body weight loss was 7.1% ± 5.0% in the treatment group and 3.6% ± 5.1% in the control group, for a mean difference of 3.5% (p = 0.0085). Although balloons were removed after 24 weeks, 89% of the treatment group maintained weight loss through 48 weeks. Nonserious adverse events occurred in 91.1% of patients, but only 0.4% were severe. Despite several study limitations, the authors concluded Treatment with lifestyle therapy and the 6-month swallowable gas-filled intragastric balloon system was safe and resulted in twice as much weight loss compared with a sham control, with high weight loss maintenance at 48 weeks. Study limitations include the short duration of randomized treatment (24 weeks) and limited long-term comparative data beyond balloon removal, which restricts conclusions regarding the durability of weight loss and longer-term safety outcomes.

Transoral Gastroplasty (TG)

For the treatment of obesity, TG has limited published literature, and the evidence is insufficient to provide conclusions on its safety and efficacy. Well-designed studies with long-term follow-up are needed, to measure the durability of the observed weight loss. In particular, the stability of the gastric sutures' procedure remains unproven, given the lack of long-term data.

Transoral Outlet Reduction (TORe)

Although preliminary results showing promising feasibility, safety, and short-term efficacy being demonstrated in case series (Jirapinyo 2013 [RESTORe trial]; Thompson 2013; Kumar 2014), longer-term durability of the procedure still needs to be proven in larger studies.

Jirapinyo et al (2020) conducted a retrospective review of prospectively collected data on RYGB patients who underwent TORe for weight regain or inadequate weight loss to assess long-term (5 year) efficacy. A total of 331 RYGB patients, with a mean BMI of 40±9 kg/m^2, underwent 342 TORe procedures. On follow-up, patients experienced a %TWL of 8.5 ± 8.5%, 6.9 ± 10.1%, and 8.8 ± 12.5% at 1, 3, and 5 years, respectively. At 5 years after TORe, nearly all patients had cessation of weight gain with the majority experiencing and maintaining clinically significant weight loss. Pre-TORe GJA size was 23.4 ± 6.0 mm, which decreased to 8.4 ± 1.6 mm after TORe. There were no severe or fatal AEs, with moderate AEs occurring in 11 out of 342 cases. The study was limited by a single site, retrospective design without a control group, one third of the patient received adjunctive therapy after the initial TORe, and technique variations over the years. The authors concluded that TORe appears to be safe, effective, and durable at treating weight regain after RYGB.

Valats et al (2024) conducted a prospective, multicenter, simple blind, randomized study evaluating the percentage of excess weight loss (%EWL) at 12 months following TORe in adults with weight recurrence after Roux-en-Y gastric bypass (RYGB). The final analysis included 50 subjects (25 per group), with a mean BMI of 40.6 kg/m². At 12 months, the TORe group demonstrated a significantly higher %EWL compared with the Sham group (p = 0.002), with a large effect size (Cohen's d = 0.91). No significant between-group differences were observed in the improvement of obesity-related comorbidities (diabetes, dyslipidemia) or quality-of-life measures at 12 months. Adverse events

occurred more frequently in the TORe group (20% procedural-related events). Three adverse events were classified as serious, including two gastro-jejunal anastomosis perforations in the TORe group, which led to premature termination of the study.

Routine Liver Biopsy in Conjunction with Bariatric Surgery

The impact on patient health outcomes has not been well-established, and there is insufficient clinical evidence to support routine liver biopsy in patients undergoing bariatric surgery.

Barajas-Gamboa et al (2025) performed a retrospective analysis of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) database from 2020 to 2022 of patients undergoing primary Roux-en-Y gastric bypass or sleeve gastrectomy with or without concomitant liver biopsy. Of the 511,981 patients, 30,819 (6.02%) underwent concomitant liver biopsy. The authors concluded that after adjusting for patient factors, the analysis demonstrates that concomitant liver biopsy during bariatric surgery does not independently increase the risk of major complications (Clavien-Dindo grade III and IV), readmission, or mortality. However, it is associated with statistically significant increases in both postoperative bleeding and transfusion requirements, though not with reoperation rates. When balancing the potential benefits of early liver disease diagnosis against risks, concomitant liver biopsy remains a reasonable option for appropriately selected patients undergoing bariatric surgery, provided clinicians are prepared for increased bleeding-related complications and blood product utilization. Careful patient selection, pre-operative optimization, and availability of blood products are essential considerations when planning concomitant liver biopsy.

Hiatal Hernia Repair in Conjunction with Bariatric Surgery

There is limited evidence regarding whether repair of hiatal hernias at the time of bariatric surgery improves outcomes after surgery; it consists primarily of cohort studies comparing outcomes for patients who had a hiatal hernia and underwent repair during bariatric surgery with patients without a hiatal hernia (Santonicola 2014; Gulkarov 2008).

Chen et al (2021) published a systematic review of 18 studies that evaluated outcomes after hiatal hernia repair plus sleeve gastrectomy (SG) in obese patients (N=937). Results demonstrated that patients who underwent hiatal hernia repair during SG had significant reductions in BMI, and the risk of GERD symptoms and esophagitis. Hiatal hernia repair during SG was superior to SG alone for GERD remission, but not de novo GERD.

PROFESSIONAL GUIDELINE(S)

Adults

The 2022 American Society for Metabolic and Bariatric Surgery (ASMBS) position statement on the impact of metabolic and bariatric surgery on nonalcoholic steatohepatitis concluded that metabolic and bariatric surgery has a positive impact on nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH) either with or without fibrosis (Mazzini 2022). Although RCTs are needed to determine whether MBS should be considered as a frontline therapy for NAFLD and NASH, metabolic and bariatric surgery should be considered for patients with severe obesity.

In 2022, the ASMBS and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) produced a joint statement on the current available scientific information on metabolic and bariatric surgery and its indications (Eisenberg 2022). Long-term data, published in the decades following the 1991 NIH Consensus Statement, consistently demonstrates the safety, efficacy, and durability of MBS in the treatment of clinically severe obesity. With significant improvement of metabolic disease, decreases in overall mortality, and superior weight loss outcomes compared with nonoperative treatment, the joint statement indicates:

- MBS is recommended for individuals with BMI >35 kg/m^2, regardless of presence, absence, or severity of comorbidities.
- MBS is recommended in patients with T2D and BMI >30 kg/m^2.
- MBS should be considered in individuals with BMI of 30 - 34.9 kg/m^2 who do not achieve substantial or durable weight loss or co-morbidity improvement using nonsurgical methods.
- Obesity definitions using BMI thresholds do not apply similarly to all populations. Clinical obesity in the Asian population is recognized in individuals with BMI >25kg/m^2. Access to MBS should not be denied solely based on traditional BMI risk zones.
- There is no upper patient-age limit to MBS. Older individuals who could benefit from MBS should be considered for surgery after careful assessment of co-morbidities and frailty.
- Children and adolescents with BMI >120% of the 95th percentile and a major co-morbidity, or a BMI >140% of the 95th percentile, should be considered for MBS after evaluation by a multidisciplinary team in a specialty center.
- MBS is an effective treatment of clinically severe obesity in patients who need other specialty surgery, such as joint arthroplasty, abdominal wall hernia repair, or organ transplantation.

The 2024 American Diabetes Association Standards of Medical Care in Diabetes sets forth recommendations for the treatment diabetes, including Section 8, which discusses metabolic surgery (ADAPPC 2024). Citing that a substantial body of evidence has demonstrated that metabolic surgery has beneficial effects on type 2 diabetes irrespective of pre-surgical BMI, including achieving superior glycemic management, reduction of cardiovascular risk and obesity, the ADAPPC recommends:

- Consider metabolic surgery as a weight and glycemic management approach in people with diabetes with BMI ≥30.0 kg/m^2 (or ≥27.5 kg/m^2 in Asian American individuals) who are otherwise good surgical candidates (grade A.)
- People being considered for metabolic surgery should be evaluated for comorbid psychological conditions and social and situational circumstances that have the potential to interfere with surgery outcomes (grade B).
- In people who undergo metabolic surgery, routinely screen for psychosocial and behavioral health changes, and refer to a qualified behavioral health professional as needed (grade C).
- Metabolic surgery should be performed in high-volume centers with interprofessional teams knowledgeable about and experienced in managing obesity, diabetes, and gastrointestinal

surgery (grade E).

Single-Anastomosis Duodeno-Ileal Bypass with Sleeve Gastrectomy (SADI-S)

The ASMBS endorses SADI-S as a modification of the classic Roux-en-Y duodenal switch (DS), an already-endorsed metabolic/bariatric procedure (Kallies 2020). The ASMBS states that it is reasonable to consider the SADI-S could be considered for endorsement with less available published peer-reviewed data than would be required for an entirely novel surgical procedure for which no predicate procedure exists. Based on additional publications the ASMBS concludes that SADI-S provides for similar outcomes to those reported after classic DS.

SADI-S was initially endorsed by the IFSO in 2020 (Brown 2021) and re-affirmed in 2023 (Ponce de Leon-Ballesteros 2024). Based on an updated systematic review of current evidence on SADI-S/SADS, the IFSO made the following recommendations:

- SADI-S/SADS is a safe and reproducible procedure with low rates of early and late complications. Also, it seems that primary procedures provide better outcomes in comparison to revisional procedures.
- SADI-S/SADS yields significant and sustained weight loss over a medium- to long-term period (5 years). However, there is a lack of data beyond the 6-year mark.
- SADI-S/SADS shows significant and sustained improvement in controlling type 2 diabetes mellitus (T2DM) in the medium term.
- To enhance the quality of evidence, the IFSO encourages participation in national and international registries, publication of long-term follow-up studies, and randomized controlled trials (RCTs).

In 2016, the National Institute for Health and Care Excellence (NICE) issued an interventional procedures guidance on single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity. Based on six case series and zero randomized trials, the committee commented that there is potential for serious metabolic complication after the procedure and there may be a need for revision procedures. Evidence on efficacy is limited in both quality and quantity. NICE recommends that this procedure should only be used with special arrangements for clinical governance, consent and audit or research; patient selection should be done by a multidisciplinary team experienced in managing morbid obesity; treatment should be done by surgeons with specific training in the procedure, in centers with expertise in the treatment of morbid obesity.

Adults - Endoscopic Bariatric and Metabolic Therapies (EBMTs)

In 2024, the IFSO Bariatric Endoscopy Committee endorsed ESG as an effective and valuable intervention for managing obesity based on a comprehensive systematic review and meta-analysis of 44 articles (n=15,714 patients) (Abu Dayyeh 2024). The committee concluded that ESG is particularly beneficial for patients with class I and II obesity, as well as for those with class III obesity who are not suitable candidates for traditional MBS. This minimally invasive procedure not only achieves significant weight loss outcomes in the short and mid-terms but also maintains a favorable safety profile, as evidenced by a low incidence of serious adverse events.

In 2024, Jirapinyo and colleagues authored a joint guideline from the American Society for Gastrointestinal Endoscopy (ASGE) and the European Society of Gastrointestinal Endoscopy (ESGE) on primary endoscopic bariatric and metabolic therapies (EBMTs). Conditional recommendations (very low to moderate certainty) were made for lifestyle modification plus the use of intra-gastric balloons, aspiration therapy, duodenal-jejunal bypass liner, and endoscopic gastric remodeling (EGR) devices (e.g., Overstitch Endoscopic Suturing System) in adults with a BMI ≥30 kg/m², or a BMI of 27.0–29.9 kg/m² with at least one obesity-related comorbidity. Based on limited evidence, transpyloric shuttle and duodenal mucosal resurfacing (DMR) are recommended only in the context of a clinical trial.

In 2024, NICE recommended endoscopic sleeve gastroplasty as an option to treat obesity in adults. Reporting that evidence supports safety in the short and long term, and efficacy when combined with lifestyle changes for people with a body mass index (BMI) over 30 kg/m^2.

In 2013, NICE recommended that duodenal-jejunal bypass sleeve for managing obesity should only be used in the context of research given the limited quality and quality of evidence on safety and efficacy.

Children and Adolescents

In 2023, the American Academy of Pediatrics (AAP) published their first evidence-based clinical practice guideline for the evaluation and treatment of children and adolescents (ages 2 to 18 years) with obesity (Hampl 2023). The recommendations are based on evidence from RCTs, comparative effectiveness trials, high-quality longitudinal and epidemiologic studies gathered in a systematic review process described in their methodology. The AAP's recommendation related to bariatric surgery is: "Pediatricians and other pediatric health care providers should offer referral for adolescents 13 years and older with severe obesity (BMI ≥ 120% of the 95th percentile for age and sex) for evaluation for metabolic and bariatric surgery to local or regional comprehensive multidisciplinary pediatric metabolic and bariatric surgery center)."

In 2022, the ASMBS and International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) produced a joint statement on the current available scientific information on metabolic and bariatric surgery and its indications, stating MBS is safe and produces durable weight loss and improvement in comorbid conditions (Eisenberg 2022).

In 2019, the AAP published a report outlining the current evidence regarding adolescent bariatric surgery for adolescent metabolic and bariatric surgery that reflected the 2018 American Society for Metabolic and Bariatric Surgery (ASMBS) recommendations (Armstrong 2019). The AAP report noted that generally accepted contraindications to bariatric surgery included: "a medically correctable cause of obesity, untreated or poorly controlled substance abuse, concurrent or planned pregnancy, current eating disorder, or inability to adhere to postoperative recommendations and mandatory lifestyle changes."

In 2018, the American Society for Metabolic and Bariatric Surgery (ASMBS) Pediatric Committee updated its evidence-based guidelines published in 2012 (Pratt 2018). Based on an increased body of evidence the committee stated that metabolic and bariatric surgery (MBS) with vertical sleeve gastrectomy (VSG) and RYGB can be considered both safe and effective treatments for adolescents

with a BMI of 35 kg/m^2 or 120% of the 95th percentile with a co-morbidity or BMI ≥40 kg/m^2 or 140% of the 95th percentile without a comorbidity (whichever is lower). With limited data the committee indicated that adjustable gastric banding and biliopancreatic diversion with or without duodenal switch is less desirable and should be reserved for adults in most cases. Endoscopic bariatric therapies (e.g., intragastric balloons, vagal stimulation, gastric aspiration) are not currently FDA for under 18 years of age. Studies on long-term durability and physiological consequences are needed.

In 2017, the Endocrine Society's clinical practice guideline on pediatric obesity suggested that bariatric surgery be considered only for adolescents who have reached Tanner stage 4 or 5 and near-final adult height, have severe obesity (BMI ≥40 kg/m² or ≥35 kg/m² with serious comorbidities), and continue to have extreme obesity despite compliant lifestyle treatment, provided they also demonstrate psychological stability, the ability to follow healthy habits, and have access to an experienced pediatric bariatric surgery center capable of long-term metabolic and psychosocial follow-up (Styne 2017).

Intragastric Space Occupying Mechanisms

The American Society for Metabolic and Bariatric Surgery (ASMBS) published a position statement on intragastric balloon therapy which was endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons (Ali 2016). Based on current evidence, intragastric balloon (IGB) therapy is FDA approved as an endoscopic, temporary (maximum 6 months) tool for the management of obesity, and further review will evaluate the impact of diet, lifestyle changes, and pharmacotherapy during and after balloon removal. Overall, the data suggests that the intragastric balloon is an effective tool for weight loss. Most of its effect was observed in the first 3 months after insertion, during which patients usually lost greater than 12 kilograms. At removal, or 6 months after insertion, studies, including randomized controlled trials, have suggested that the expected %EWL is about 24%. Early postoperative tolerance challenges can be significant but can be controlled with pharmacotherapy in the majority of patients, thereby minimizing voluntary balloon removals.

Hiatal Hernia Repair in Conjunction with Bariatric Surgery

In 2018, the ASMBS and the American Hernia Society published a consensus guideline on bariatric surgery and hernia surgery concluding that combined hernia repair and metabolic/bariatric surgery may be safe and associated with good short-term outcomes and low risk of infection (Menzo 2018).

Routine Liver Biopsy in Conjunction with Bariatric Surgery

American guidelines do not endorse routine liver biopsies with abdominal surgeries.

In 2023, the American Association for the Study of Liver Diseases (AASLD) published a practice guideline on the clinical assessment and management of nonalcoholic fatty liver disease, citing NAFLD is closely linked to and often precedes the development of metabolic abnormalities such as insulin resistance, dyslipidemia, central obesity, and hypertension (Rinella 2023). Statements within the guidance include:

- Liver biopsy should be considered when there is diagnostic uncertainty, competing or

concomitant possible diagnoses (e.g., autoimmune hepatitis, iron overload); or when there is persistent elevation (>6 month) in liver chemistries.

- General population-based screening for NAFLD is not advised.
- High-risk individuals (e.g., with T2DM, medically complicated obesity, family history of cirrhosis, or more than mild alcohol consumption) should be screened for advanced fibrosis.
- Patients with NAFLD who are overweight or obese should be prescribed a diet that leads to a caloric deficit. When possible, diets with limited carbohydrates and saturated fat and enriched with high fiber and unsaturated fats (e.g., Mediterranean diet) should be encouraged due to their additional cardiovascular benefits.
- Patients with NAFLD should be strongly encouraged to increase their activity level to the extent possible. Individualized prescriptive exercise recommendations may increase sustainability and have benefits independent of weight loss.
- Bariatric surgery should be considered as a therapeutic option in patients who meet criteria for metabolic weight loss surgery, as it effectively resolves NAFLD or NASH in the majority of patients without cirrhosis and reduces mortality from CVD and malignancy.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates bariatric surgery and endoscopic bariatric devices as medical devices. All bariatric surgery and endoscopic bariatric devices require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Apr 27]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls-and-early-alerts [accessed 2026 Apr 27]

Adjustable Gastric Bands

- LAP-BAND (BioEnterics/Allerga/ReShape): Premarket approval (PMA) 2001, with expanded indication in 2011 allowing use in adults with BMI ≥30 with a comorbidity.
- REALIZE Band (Ethicon Endo-Surgery): PMA approved in 2007 for adults with BMI ≥40 or ≥35 with a comorbidity.

Intragastric Balloons/Space-Occupying Devices

- ORBERA (Apollo): PMA approved in 2015 for adults with BMI 30–40 as a temporary implant requiring removal at 6 months.
- ReShape Integrated Dual Balloon (ReShape Medical): PMA approved in 2015 for adults with BMI 30–40 as a temporary (remove at 6 months).

- Obalon Balloon System (Obalon): PMA approved in 2016 for adults with BMI 30–40 as a temporary implant.
- Allurion/ Elipse Swallowable Balloon (Allurion): FDA-approved in February 2026.
- TransPyloric Shuttle (TPS) (BAROnova): PMA approved in 2019 for BMI 35–40 or 30–34.9 with a comorbidity, indicated for up to 12 months of treatment.

Endoluminal Suturing/Tissue Approximation

- OverStitch (Apollo Endosurgery): 510(k)-cleared endoscopic suturing system for tissue approximation/ligation in the GI tract.
- StomaphyX (EndoGastric Solutions): 510(k)-cleared device in 2008 for trans-oral tissue approximation/ligation in the GI tract.

Not Approved for U.S. Marketing

- EndoBarrier (GI Dynamics): Not FDA-approved for commercial use in the U.S.
- TOGA System (Satiety): Not FDA-approved for U.S. marketing.
- AspireAssist (Aspire Bariatrics): PMA approved in 2016, but withdrawn from the U.S. market effective April 8, 2022, for business, not safety/effectiveness, reasons.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0813T (E/I)	Esophagogastroduodenoscopy, flexible, transoral, with volume adjustment of intragastric bariatric balloon
43290 (E/I)	Esophagogastroduodenoscopy, flexible, transoral; with deployment of intragastric bariatric balloon
43291 (E/I)	Esophagogastroduodenoscopy, flexible, transoral; with removal of intragastric bariatric balloon(s)
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
43645	with gastric bypass and small intestine reconstruction to limit absorption
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (e.g., gastric band and subcutaneous port components)

Code	Description
43771	revision of adjustable gastric restrictive device component only
43772	removal of adjustable gastric restrictive device component only
43773	removal and replacement of adjustable gastric restrictive device component only
43774	removal of adjustable gastric restrictive device and subcutaneous port components
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (i.e., sleeve gastrectomy)
43842	Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical-banded gastroplasty
43843	other than vertical-banded gastroplasty
43845	Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoileostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch)
43846	Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less) Roux-en-Y gastroenterostomy
43847	with small intestine reconstruction to limit absorption
43848	Revision, open, of gastric restrictive procedure for morbid obesity, other than adjustable gastric restrictive device (separate procedure)
43860	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; without vagotomy
43865	Revision of gastrojejunal anastomosis (gastrojejunostomy) with reconstruction, with or without partial gastrectomy or intestine resection; with vagotomy
43886	Gastric restrictive procedure, open; revision of subcutaneous port component only
43887	removal of subcutaneous port component only
43888	removal and replacement of subcutaneous port component only
43889 (E/I)	Gastric restrictive procedure, transoral, endoscopic sleeve gastroplasty (ESG), including argon plasma coagulation, when performed (Effective date 01/01/26)
47000 (*NMN)	Biopsy of liver, needle; percutaneous (*NMN when billed with an ICD-10 code listed below unless criteria under concomitant procedures is met.)
47001 (*NMN)	Biopsy of liver, needle; when done for indicated purpose at time of other major procedure (List separately in addition to code for primary procedure) (*NMN when billed with an ICD-10 code listed below unless criteria under

Code	Description
	concomitant procedures is met.)
47100 (*NMN)	Biopsy of liver, wedge (*NMN when billed with an ICD-10 code listed below unless criteria under concomitant procedures is met.)
47379 (*NMN)	Unlisted laparoscopic procedure, liver (*NMN when billed with an ICD-10 code listed below.)

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HCPCS Codes

Code	Description
C9785 (E/I)	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
S2083	Adjustment of gastric band diameter via subcutaneous port by injection or aspiration of saline

ICD10 Codes

Code	Description
E66.0	Obesity due to excess calories
E66.01	Morbid (severe) obesity due to excess calories
E66.09	Other obesity due to excess calories
E66.2	Morbid (severe) obesity with alveolar hypoventilation
E66.3	Overweight
E66.811	Obesity, class 1
E66.812	Obesity, class 2
E66.813	Obesity, class 3
E66.89	Other obesity not elsewhere classified
E66.9	Obesity, unspecified
K91.0 - K91.32	Postprocedural complications and disorders of digestive system (code range)
K95.01- K95.09	Complications of gastric band procedure (code range)
K95.81- K95.89	Complications of other bariatric procedure (code range)
Z68.35-	Body mass index (BMI), 35.0-70 or greater, adult (code range)

Code	Description
Z68.45	

REFERENCES

Abad J, et al. Endoscopic sleeve gastroplasty plus lifestyle intervention in patients with metabolic dysfunction-associated steatohepatitis: a multicenter, sham-controlled, randomized trial. Clin Gastroenterol Hepatol. 2025 Aug;23(9):1556-1566.e3. Epub 2024 Dec 16.

Abu Dayyeh BK, et al. IFSO bariatric endoscopy committee evidence-based review and position statement on endoscopic sleeve gastroplasty for obesity management. Obes Surg. 2024 Dec;34(12):4318-4348.

Abu Dayyeh BK, et al.; MERIT study group. Endoscopic sleeve gastroplasty for treatment of class 1 and 2 obesity (MERIT): a prospective, multicentre, randomised trial. Lancet. 2022 Aug 6;400(10350):441-451.

Agarwal L, et al. Bariatric surgery in non-alcoholic fatty liver disease (NAFLD): Impact assessment using paired liver biopsy and fibroscan. Obesity Surgery. 2021;(31):617-626.

Ali M, et al. American Society for Metabolic and Bariatric Surgery position statement on intragastric balloon therapy endorsed by the Society of American Gastrointestinal and Endoscopic Surgeons. Surg Obes Relat Dis. 2016 Mar;12(3):462-467.

American Diabetes Association [Internet]. Standards of care in diabetes 2025. 8. Obesity and weight management for the prevention and treatment of type 2 Diabetes [accessed 2026 Apr 29]. Available from: https://professional.diabetes.org/standards-of-care

Angrisani L, et al. Long-term results of laparoscopic Roux-en-Y gastric bypass for morbid obesity: 105 patients with minimum follow-up of 15 years. Surg Obes Relat Dis. 2021 Apr;17(4):727-739. Epub 2020 Dec 01.

Armstrong SC, et al. AAP section on obesity, section on surgery. Pediatric metabolic and bariatric surgery: evidence, barriers, and best practices. Pediatrics. 2019;144(6):E20193223.

Ataya K, et al. Roux-en-Y gastric bypass versus one anastomosis gastric bypass as revisional surgery after failed sleeve gastrectomy: a systematic review and meta-analysis. J Metab Bariatr Surg. Dec 2023;12(2):57-66.

Axer S, et al. Perioperative safety and 1-year outcomes of single-anastomosis duodeno-ileal bypass (SADI) vs. biliopancreatic diversion with duodenal switch (BDP/DS): a randomized clinical trial. Obes Surg. Sep 2024;34(9):3382-3389.

Barajas-Gamboa JS, et al. Concomitant liver biopsy during bariatric surgery: no increase in major complications or readmissions but associated with higher transfusion requirements - an analysis of the MBSAQIP database. Obes Surg. 2025 Nov;35(11):4752-4765.

Batista Dantas AC, et al. One-anastomosis gastric bypass versus Roux-en-Y gastric bypass as

revisional surgery after sleeve gastrectomy: a systematic review and meta-analysis. Obesity Surgery. 2022 Dec;32(12):4082-4088.

Bazerbacki F, et al. Endoscopic revision of gastrojejunal anastomosis for the treatment of dumping syndrome in patients with Roux-en-Y gastric bypass: a systematic review and meta-analysis. Surg Endos. 2022 Jun;36(6):4099-4107.

Bazerbachi F, et al. Fluid-filled versus gas-filled intragastric balloons as obesity interventions: a network meta-analysis of randomized trials. Obes Surg. 2018 Sep;28(9):2617-2625.

Benson-Davies S, et al. American Society of Metabolic and Bariatric Surgery consensus statement on laparoscopic adjustable gastric band management. Surg Obes Relat Dis. 2022 Sept;18(9):1120-1133.

Brown WA, et al; IFSO appointed task force reviewing the literature on SADI-S/OADS. Single anastomosis duodenal-ileal bypass with sleeve gastrectomy/one anastomosis duodenal switch (SADI-S/OADS) IFSO position statement-update 2020. Obes Surg. 2021 Jan;31(1):3-25. Epub 2021 Jan 6.

Carter J, et al. ASMBS position statement on preoperative patient optimization before metabolic and bariatric surgery. Surg Obes Relat Dis. 2021 Dec;17(12):1956-1976.

Chen W, et al. Effect of concomitant laparoscopic sleeve gastrectomy and hiatal hernia repair on gastroesophageal reflux disease in patients with obesity: a systematic review and meta-analysis. Obes Surg. 2021 Sep;31(9):3905-3918.

Chen W, et al. Efficacy and safety of duodenal-jejunal bypass liner for obesity and type 2 diabetes: A systematic review and meta-analysis. Obes Rev. 2024 Nov;25(11):e13812.

Chouillard EK, et al. Laparoscopic Roux-en-Y gastric bypass versus laparoscopic sleeve gastrectomy for morbid obesity: case-control study. Surg Obes Relat Dis. 2011 Jul-Aug;7(4):500-5.

Clapp B, et al. Safety of liver biopsy at the time of bariatric surgery: an analysis of the MBSAQIP database. Surg Endosc. 2022 Jan;36(1):413-421.

Courcoulas AP, et al. Bariatric surgery vs lifestyle intervention for diabetes treatment: 5-year outcomes from a randomized trial. J Clin Endocrinol Metab. 2020 Mar 01;105(3):866-76.

Courcoulas AP, et al. Long-term outcomes of medical management vs bariatric surgery in type 2 diabetes. JAMA. 2024;331(8):654–664

Cui BB, et al. Long-term outcomes of Roux-en-Y gastric bypass versus medical therapy for patients with type 2 diabetes: a meta-analysis of randomized controlled trials. Surg Obes Relat. Dis. 2021 Jul; 17(7):1334-1343.

Dang JT, et al. Evaluating the safety of intragastric balloon: An analysis of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program. Surg Obes Relat Dis. 2018 Sep;14(9):1340-1347.

De Luca M, et al. Metabolic bariatric surgery as a therapeutic option for patients with type 2 diabetes: a meta-analysis and network meta-analysis of randomized controlled trials. Diabetes Obes Metab. 2023;25(8):362-2373.

D'Hondt M, et al. Laparoscopic sleeve gastrectomy as a single-stage procedure for the treatment of morbid obesity and the resulting quality of life, resolution of comorbidities, food tolerance, and 6-year weight loss. Surg Endosc. 2011 Aug;25(8):2498-504.

Di Lorenzo N, et al. Clinical practice guidelines of the European Association for Endoscopic Surgery (EAES) on bariatric surgery: update 2020 endorsed by IFSO-EC, EASO and ESPCOP. Surg Endosc. 2020 Jun;34(6):2332-2358.

Dijkhorst PJ, et al. Single anastomosis duodenoileal bypass or Roux-en-Y gastric bypass after failed sleeve gastrectomy: medium-term outcomes. Obes Surg. 2021 Nov;31(11):4708-4716.

Dixon JB, et al. Adjustable gastric banding, and conventional therapy for type 2 diabetes: a randomized controlled trial. JAMA. 2008 Jan 23;299(3):316-323.

Docimo S Jr, et al.; American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. Endoscopic sleeve gastroplasty and its role in the treatment of obesity: a systematic review. Surg Obes Relat Dis. 2023 Nov;19(11):1205-1218.

Docimo S Jr, et al.; Clinical issues committee of the American Society for Metabolic and Bariatric Surgery. American Society for Metabolic and Bariatric Surgery review of endobariatric procedures. Surg Obes Relat Dis. 2026 Jan;22(1):1-17. Epub 2025 Oct 10.

Eisenberg D, et al. American Society of Metabolic and Bariatric Surgery (ASMBS) and International Federation for the Surgery Of Obesity and Metabolic Disorders (IFSO) indications for metabolic and bariatric surgery. Obesity Surgery. 2022 Oct 20;18(12):1345-1356.

Esparham A, et al. Roux-en-Y gastric bypass versus duodenal switch in patients with body mass index ≥50 kg/m^2: a systematic review and meta-analysis. Surg Obes Relat Dis. 2025 Feb;21(2):184-193.

Esparham A, et al. The efficacy and safety of laparoscopic single-anastomosis duodeno-ileostomy with sleeve gastrectomy (SADI-S) in mid- and long-term follow-up: a systematic review. Obes Surg. 2023 Dec;33(12):4070-4079. Epub 2023 Oct 25.

Fayad L, et al. A real-world, insurance-based algorithm using the two-fold running suture technique for transoral outlet reduction for weight regain and dumping syndrome after Roux-En-Y gastric bypass. Obes Surg. 2019;29(7):2225-2232.

Fried M, et al. Laparoscopic greater curvature plication (LGCP) for treatment of morbid obesity in a series of 244 patients. Obes Surg. 2012 Aug;22(8):1298-307.

Ghiassi S, et al. American Society for Metabolic and Bariatric Surgery position statement on one-anastomosis gastric bypass. Surg Obes Relat Dis. 2024;20(4):319-335.

Glaysher MA, et al. The effect of a duodenal-jejunal bypass liner on lipid profile and blood concentrations of long chain polyunsaturated fatty acids. Clin Nutr. 2021 Apr;40(4):2343-2354. Epub 2020 Oct 22.

Goyal H, et al. Endobariatric procedures for obesity: clinical indications and available options. Ther Adv Gastrointest Endosc. 2021 Jan-Dec;14:1-17.

Gulkarov I et al. Hiatal hernia repair at the initial laparoscopic adjustable gastric band operation reduces the need for reoperation. Surg Endosc. 2008 Apr;22(4):1035-1041.

Hampl SE, et al. From the American Academy of Pediatrics. Clinical practice guideline for the evaluation and treatment of children and adolescents with obesity. Pediatrics. 2023 Jan;151(2):e2022060640.

Himpens J, et al. Long-term outcomes of laparoscopic adjustable gastric banding. Arch Surg. 2011;146(7):802-807.

Himpens J, et al. Long-term results of laparoscopic Roux-en-Y gastric bypass: evaluation after 9 years. Obes Surg. 2012 Oct;22(10):1586-93.

Himpens J, et al. Long-term results of laparoscopic sleeve gastrectomy for obesity. Ann Surg. 2010 Aug;252(2):319-24.

Hollenbach M, et al. Weight-loss endoscopy trial: a multicenter, randomized, controlled trial comparing weight loss in endoscopically implanted duodenal-jejunal bypass liners versus intragastric balloons versus a sham procedure. Digestion. 2024;105(6):468-479.

Huckfeldt PJ, et al. Association of intensive lifestyle intervention for type 2 diabetes with labor market outcomes. JAMA Inter Med. 2023;183(10):1071-1079.

Jirapinyo P, et al. American Society for Gastrointestinal Endoscopy - European Society of Gastrointestinal Endoscopy guideline on primary endoscopic bariatric and metabolic therapies for adults with obesity. Endoscopy. 2024 Jun;56(6):437-456. Erratum in: Endoscopy. 2025 Sep;57(9):C12.

Jirapinyo P, et al. Effect of endoscopic bariatric and metabolic therapies on nonalcoholic fatty liver disease: a systematic review and meta-analysis. Clin Gastroenterol Hepatol. 2022 Mar;20(3):511-524.e1.

Jirapinyo P, et al. Evaluation of an endoscopic suturing device for transoral outlet reduction in patients with weight regain following Roux-en-Y gastric bypass. Endoscopy. 2013 Jul;45(7):532-536.

Jirapinyo P, et al. Five-year outcomes of transoral outlet reduction for the treatment of weight regain after Roux-en-Y gastric bypass. Gastrointest Endosc. 2020 May;91(5):1067-1073.

Kallies K, et al.; American Society for Metabolic and Bariatric Surgery Clinical Issues Committee. American Society for Metabolic and Bariatric Surgery updated statement on single-anastomosis duodenal switch. Surg Obes Relat Dis. 2020 Jul;16(7):825-830.

Kiesswetter E, et al., Bariatric surgery in adults with obesity and diabetes mellitus: a network meta-analysis (Protocol). Cochrane Database of Systematic Reviews. 2024, Issue 1. Art.No.:CD015622.

Kim JY and Chung H. Endoscopic intervention for anastomotic leakage after gastrectomy. J Gastric Cancer. 2024;24(1):108-121.

Kiser HM, et al. Associations between psychological evaluation outcomes, psychiatric diagnoses, and outcomes through 12 months after bariatric surgery. Surg Obes Relat Dis. 2023 Jun;19(6):594-603.

Epub 2022 Dec 10.

Kourkoulos M, et al. Laparoscopic gastric plication for the treatment of morbid obesity: a review. Minim Invasive Surg. 2012;2012:696348.

Kumar N, et al. Comparison of a superficial suturing device with a full thickness suturing device for transoral outlet reduction. Gastrointest Endoscopy. 2014 Jun;79(6):984-9.

Leyba JL, et al. Laparoscopic Roux-en-Y gastric bypass versus laparoscopic sleeve gastrectomy for the treatment of morbid obesity. A prospective study of 117 patients. Obes Surg. 2011 Feb;21(2):212-6.

Leyva-Alvizo A, et al.; ASMBS foregut committee. Systematic review of management of gallbladder disease in patients undergoing minimally invasive bariatric surgery. Surg Obes Relat Dis. 2020 Jan;16(1):159-164. Epub 2019 Oct 31.

Mazzini GS, et al. ASMBS position statement on the impact of metabolic and bariatric surgery on nonalcoholic steatohepatitis. Surg Obes Relat Dis. 2022 Mar;18(3):314-325.

Mechanick JI, et al. Clinical practice guidelines for the perioperative nutrition, metabolic, and nonsurgical support of patients undergoing bariatric procedures - 2019 update: cosponsored by American Association of Clinical Endocrinologists/American College of Endocrinology, The Obesity Society, American Society for Metabolic & Bariatric Surgery, Obesity Medicine Association, and American Society of Anesthesiologists. Surg Obes Relat Dis. 2020 Feb;16(2):175-247.

Menzo EL, et al. American Society for Metabolic and Bariatric Surgery and American Hernia Society consensus guideline on bariatric surgery and hernia surgery. Surg Obes Relat Dis. 2018 Sep;14(9):1221-1323.

Mrad R, et al. Comparative effectiveness of balloons, adjustable balloons, and endoscopic sleeve gastroplasty: a network meta-analysis of randomized trials. Gastrointest Endosc. 2025 Mar;101(3):527.e1-527.e19. Epub 2024 Oct 28.

National Heart, Lung, and Blood Institute (NHLBI) [Internet]. Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults. The Evidence Report. NIH Pub. No. 98-4083. 1998 Sep [accessed 2026 Apr 29]. Available from: https://www.nhlbi.nih.gov/files/docs/guidelines/ob_gdlns.pdf

National Institute for Health Care Excellence (NICE) [Internet]. Endoscopic sleeve gastroplasty for obesity. HealthTech guidance (HTG711). 2024 Feb 22 [accessed 2026 Mar 3]. Available from: https://www.nice.org.uk/guidance/htg711.

National Institute for Health and Care Excellence (NICE) [Internet]. Implantation of a duodenal-jejunal bypass sleeve for managing obesity. HealthTech guidance (HTG323). 2013 Nov 27 [accessed 2026 Mar 3]. Available from: https://www.nice.org.uk/guidance/htg323.

National Institute for Health and Care Excellence (NICE) [Internet]. Laparoscopic gastric plication for the treatment of severe obesity. HealthTech guidance (HTG293). 2012 Feb 27 [accessed 2026 Mar 6]. Available from: https://www.nice.org.uk/guidance/htg293.

National Institute for Health and Care Excellence (NICE) [Internet]. Overweight and obesity management. NICE guideline (NG246). 2025 Jan 14 [last updated 2026 Jan 8; accessed 2025 Mar 6]. Available from: https://www.nice.org.uk/guidance/ng246

National Institute for Health and Care Excellence (NICE) [Internet]. Single-anastomosis duodeno-ileal bypass with sleeve gastrectomy for treating morbid obesity. HealthTech guidance (HTG426). 2016 Nov [accessed 2026 Mar 6]. Available from: https://www.nice.org.uk/guidance/htg423

Parikh M, et al. American Society for Metabolic and Bariatric Surgery review of the literature on one-anastomosis gastric bypass. Surg Obes Relat Dis. 2018 Aug;14(8):1088-1092.

Pereira AM, et al. Beyond restrictive: sleeve gastrectomy to single anastomosis duodeno-ileal bypass with sleeve gastrectomy as a spectrum of one single procedure. Obes Facts. 2024;17(4):364-371.

Ponce J, et al. The REDUCE pivotal trial: a prospective, randomized controlled pivotal trial of a dual intragastric balloon for the treatment of obesity. Surg Obes Relat Dis. 2015 Jul-Aug;11(4):874-81. Epub 2014 Dec 16.

Ponce de Leon-Ballesteros G, et al. Single anastomosis duodeno-ileostomy with sleeve gastrectomy/single anastomosis duodenal switch (SADI-S/SADS) IFSO position statement-update 2023. Obes Surg. 2024 Oct;34(10):3639-3685. Epub 2024 Sep 12.

Prachand VN, et al. Duodenal switch provides superior weight loss in the super-obese (BMI > or =50kg/m^2) compared with gastric bypass. Ann Surg. 2006 Oct;244(4):611-619.

Pratt JSA, et al. ASMBS pediatric metabolic and bariatric surgery guidelines, 2018. Surg Obes Relat Dis. 2018;14(7):882–901.

Rinella ME, et al. AASLD practice guidance on the clinical assessment and management of nonalcoholic fatty liver disease. Hepatology. 2023 May 01;77(5):1797-1835.

Robert M, et al. Efficacy and safety of one anastomosis gastric bypass versus Roux-en-Y gastric bypass at 5 years (YOMEGA): a prospective, open-label, non-inferiority, randomised extension study. Lancet Diabetes Endocrinol. 2024 Apr;12(4):267-276

Rothstein RI, et al. Randomized double-blind sham-controlled trial of a novel silicone-filled endoscopically placed device for weight loss. Tech Innov Gastrointest Endos. 2024;26(1):21-29.

Ruban A, et al. Duodenal-jejunal bypass liner for the management of type 2 diabetes mellitus and obesity: a multicenter randomized controlled trial. Ann Surg. 2022 Mar 1;275(3):440-447.

Santonicola A, et al. The effect of laparoscopic sleeve gastrectomy with or without hiatal hernia repair on gastroesophageal reflux disease in obese patients. Surg Obes Relat Dis. 2014 Mar-Apr;10(2):250-255.

Sarma S and Palcu P. Weight loss between glucagon-like peptide-1 receptor agonists and bariatric surgery in adults with obesity: a systematic review and meta-analysis. Obesity (Silver Spring). 2022;30(11):2111-2121.

Schauer PR, et al. STAMPEDE investigators bariatric surgery versus intensive medical therapy for

diabetes – 5-year outcomes. N Engl J Med. 2017;376(7):641–651.

Silva AF, et al. Effectiveness and safety of the Allurion swallowable intragastric balloon for short-term weight loss: a systematic review and meta-analysis. Obes Surg. 2024 Oct;34(10):3735-3747.

Simonson DC, et al. Alliance of randomized trials of medicine vs metabolic surgery in type 2 diabetes (ARMMS-T2D): study rationale, design, and methods. Diabetes Obes Metab. 2022;24(7):1206-1215.

Sjostrom L, et al. Effects of bariatric surgery on mortality in Swedish obese subjects. N Engl J Med. 2007 Aug 23;357(8):741-52.

Skogar ML et al. Duodenal switch is superior to gastric bypass in patients with super obesity when evaluated with the bariatric analysis and reporting outcome system (BAROS). Obes Surg. 2017 Sep; 27(9):2308-2316.

Skrekas G, et al. Laparoscopic gastric greater curvature plication: results and complications in a series of 135 patients. Obes Surg. 2011 Nov;21(11):1657-63.

Sogg S, et al. ASMBS guidelines/statements. Recommendations for the presurgical psychosocial evaluation of bariatric surgery patients. Surg Obes Relat Dis. 2016 May;12(4):731-749.

Strain GW, et al. Comparison of effects of gastric bypass and biliopancreatic diversion with duodenal switch on weight loss and body composition 1-2 years after surgery. Surg Obes Relat Dis. 2007 Jan-Feb 2007;3(1):31-36.

Styne DM, et al. Pediatric obesity – assessment, treatment, and prevention: an Endocrine Society clinical practice guideline. J Clin Endocrinol & Metab. 2017 Mar:102(3):709-757.

Sucandy I, et al. Risk of biliary events after selective cholecystectomy during biliopancreatic diversion with duodenal switch. Obes Surg. 2016 Mar;26(3):531-7.

Sullivan S, et al. Randomized sham-controlled trial of the 6-month swallowable gas-filled intragastric balloon system for weight loss. Surg Obes Relat Dis. 2018 Dec;14(12):1876-1889.

Talebpour M, et al. Twelve-year experience of laparoscopic gastric plication in morbid obesity: development of the technique and patient outcomes. Ann Surg Innov Res. 2012;Aug 22;6(1):7.

Tan YZ, et al. Impact of pre-bariatric surgery weight loss on post-bariatric surgery weight loss and can it predict post-surgical weight loss. Surgery for Obesity and Related Disease. 2019 Oct;15(4):S180.

Telem DA, et al. Updated panel report: best practices for the surgical treatment of obesity. Practice guideline. 2018 Oct;32(10):4158-4164.

Thompson CC, et al. Endoscopic suturing for transoral outlet reduction increases weight loss after Roux-en-Y gastric bypass surgery. Gastroenterology. 2013 Jul;145(1):129-37.

Valats JC, et al. Prospective evaluation of transoral outlet reduction (TORe) after Roux-en-Y gastric bypass (RYGB) failure. Surg Endosc. 2024 Mar;38(3):1454-1464.

Verrastro O, et al. Bariatric–metabolic surgery versus lifestyle intervention plus best medical care in non-alcoholic steatohepatitis (BRAVES): a multicentre, open-label, randomised trial. Lancet.

2023;401:1786-1797.

Vitiello A, et al. Long-term results of laparoscopic sleeve gastrectomy: a review of studies reporting 10+ years outcomes. Obes Surg. 2023 Sep 25;33:3565-3570.

Wadden TA, Chao AM, Bahnson JL, et al. End-of-Trial Health Outcomes in Look AHEAD Participants who Elected to have Bariatric Surgery. Obesity (Silver Spring). Apr 2019; 27(4): 581-590. PMID 30900413

Wattacheril JJ, et al. AGA clinical practice update on the role of noninvasive biomarkers in the evaluation and management of nonalcoholic fatty liver disease: expert review. Gastroenterol. 2023;165:1080-1088.

Wolnerhanssen BK, et al, Laparoscopic Roux-en-Y gastric bypass versus laparoscopic sleeve gastrectomy: 5-year outcomes of merged data from two randomized clinical trials (SLEEVEPASS and SM-BOSS). Br J Surg. 2021 Jan 27;108(1):49-57.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Bariatric Surgery for Treatment of Co-Morbid Conditions Related to Morbid Obesity (NCD 100.1). [accessed 2026 Apr 21]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.

  https://www.health.ny.gov/health_care/medicaid/program/update/2025/no11_2025-11.htm
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New:08/90

Revised:12/94, 11/98, 09/99, 06/00, 10/03, 07/04, 02/05, 02/06, 04/07, 08/07, 03/08, 03/09, 01/10, 03/10, 03/11, 03/12, 03/13, 11/13 (regulatory requirement effective 9/25/13), 03/14,

07/14, 03/15, 03/16, 09/16, 03/18, 03/19, 5/21, 1/23, 3/23, 7/23. 3/24, 7/24, 3/25, 11/25 **Reviewed**:12/92, 10/95, 10/96, 11/97, 09/00, 01/03, 01/07, 03/17, 3/20, 3/21, 3/22, 7/26	
Date	**Summary of Changes**
06/16/26	• Code edit to add CPT 43889 to the policy after its erroneous removal.
1/1/2026	• Transitioned Bariatric Surgery policy, 1370/20.000061 to Lifetime Healthcare Companies policy template.
7/1/2023 *No change to effective date of policy	• Under Bariatric Surgical Procedures section removed statement about CDPHP network facilities as CMS no longer manages Centers of Excellence for bariatric surgeries:
7/1/2023 *No change to effective date of policy	Under Exclusions section: • Clarified code C9785 • Added misc. codes 43659 and 43999
7/1/2023 *No change to effective date of policy	• Under Medicare section added "or Gastric Reduction Duodenal Switch (BPD/GRDS)" as covered to be consistent with the Bariatric Surgery NCD. • Under Exclusions added Endoscopic sleeve gastroplasty and updated Gastric balloon device misc. code 43999 to codes 43290 and 43291. • Under Exclusions, added Apollo ESG and Natural Orifice Transluminal Endoscopic Surgery (NOTES) to the list of examples for Endoscopic oral-assisted bariatric surgery.
7/1/2023	• Added new code C9784 and C9785 to Procedure Codes section.
4/1/2023	• Removed termed vagus nerve blocking therapy codes (0312T-0317T) from Exclusions and replaced with existing code 64999. • Added Apollo Overstitch Device to Exclusions section.
1/1/23 *No change to effective date of policy	Under the Exclusions section, removed: • Gastric electrical stimulation (GES) or gastric pacing (43647, 43648, 43659, 43881, 43882, 43999, 64590, 64595, 95980, 95981, 95982) as this is listed in the Non-Covered Technologies policy.
9/1/2021	• Removed herniorrhaphy for an asymptomatic hiatal hernia from the exclusions section as it is considered incidental to the bariatric procedure

	whether it is symptomatic or asymptomatic. To reflect this change, this will be added to the Adjunct and Non-Standard Technology payment policy.

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: BEHAVIORAL HEALTH ASSESSMENT & TRIAGE

POLICY EFFECTIVE DATE:	8/1/2023
Policy Control #:	**1370/20.000462**
Next Annual Review:	11/2026

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice

DESCRIPTION

The CDPHP behavioral health department directly provides member triage and referral for behavioral health care services, including substance use, through a 24-hours-per-day/seven-days-per-week Behavioral Health Access Center (with normal business hours Monday through Friday, 8 a.m. to 6 p.m.). The access center is staffed by behavioral health professionals. Appropriately licensed, master's-prepared behavioral and social workers assist members with clinical determinations, urgent and emergent care, crisis calls, and referrals to facilities. Clinical intake specialists verify eligibility, confirm benefit information, elicit relevant clinical and psychosocial information, conduct clinical assessment (which includes evaluating for safety), and provide referrals for mental health and substance use treatment. Clinical intake specialists can also offer referrals to a broad range of community resources, including Legal Aid, National Alliance on Mental Illness, and Center for Independent Living. While adhering to HIPAA, family members may also receive outreach from the CDPHP behavioral health case manager to coordinate care for the member concerned. Industry-accepted protocols based on sound clinical evidence are used as the basis for all triage and referral decisions.

RELATED POLICIES/DOCUMENTS

N/A

POLICY NAME: BEHAVIORAL HEALTH ASSESSMENT & TRIAGE

POSITION STATEMENT

Process utilized by the behavioral health department to systematically provide direction and assistance to the plan's members and providers in accessing behavioral health care services.

PROCEDURE	KEY POINTS
Calls managed by a clinical intake specialist	
1. A call is received on the toll-free *Behavioral Health Access Center* line (1-888-320-9584) where preliminary information is collected by the clinical intake specialist.	1. Information obtained includes: • The name of the caller and their relationship to the member for whom services are being requested. • The member's identification number, name, address, telephone number, and date of birth. • A brief description of the service(s) or information being requested.
2. The clinical intake specialist verifies eligibility.	2. If the member is not eligible, the clinical intake specialist informs the caller that eligibility is not in effect. *Note: clinical intake specialists can assist members who do not have active eligibility, including prospective members looking to join CDPHP or previous members with questions on past claims, authorizations, etc*. If eligibility is verified, the clinical intake specialist gives the caller a basic explanation of the benefit, including the following: • Member cost responsibility • Benefit limitations • If it requires authorization
3. If clinically appropriate based on caller's presentation and reported concerns, the clinical intake specialist conducts a clinical assessment to obtain necessary information to determine if additional steps are necessary to ensure safety and/or make a clinical recommendation on most appropriate level of care.	3. The purpose of the assessment is to collect a brief clinical picture of the member/caller's immediate need(s): • Suicidal or homicidal risk • Description of the problem • Description of any unusual symptoms • Description of prior treatment(s) • Perception of the current situation • Determination if there's substance use related crisis: • Triggers for potential SUD crisis: o Member says they "used too much" or used a large amount of a substance and they are scared for their acute

POLICY NAME: BEHAVIORAL HEALTH ASSESSMENT & TRIAGE

health/safety
- Member reports having trouble breathing or having breathing problems after using a substance or multiple substances
- Member with significantly slurred speech
- Member with significant difficulty maintaining train of thought during call
- Member is speaking incoherently or not making sense during the call
- Member indicates they are experiencing current withdrawal symptoms (have member elaborate on what symptoms they are experiencing e.g. nausea/vomiting/diarrhea, sweating, shaking, fast or irregular heart beat)
- Member makes any statement related to no longer wanting to live and/or wanting to overdose

If the member's responses to the assessment indicate imminent risk to harm self or others, the intake specialist keeps the member on the phone while another staff member calls a mobile crisis team and/or the police. The intake specialist remains on the line with the member until emergency services arrive and assure that the member is safe and receiving treatment.

If the member's response to the assessment indicate a substance use disorder diagnosis, the intake specialist can assist the member with referrals to OASAS for services both within and beyond their benefit (i.e. halfway houses). The intake specialist will also encourage self-referral and early entry into treatment.

If the member's responses to the assessment require advanced clinical judgment, the clinical intake specialist consults with behavioral health/HARP outpatient care manager. If the caller can contract for safety, the intake specialist transfers the caller to the behavioral health case manager. The care manager then follows below procedure, titled "Calls managed by a behavioral health/HARP outpatient care manager."

4. The caller gives information indicating no clinical judgment is necessary in making the triage and referral decision.	4. The clinical intake specialist facilitates a routine referral.
5. Members are given the opportunity to choose from several providers, including those OASAS providers for substance use disorder, within the CDPHP network, whenever possible.	5. Members are given the opportunity to make their own appointments for all behavioral health specialties, including substance use disorder, with providers once they are given the appropriate referral and identifying information.
6. For referrals to outpatient providers, the clinical intake specialist asks if the caller has any specific requests or preferences.	6. The clinical intake specialist will utilize Find-A-Doc, as well as internal knowledge and resources, to locate a provider(s) that matches the caller's preferences. If the caller is a new subscriber with CDPHP who is requesting authorization for their current out-of-network provider, the clinical intake specialist will provide caller with information regarding transition of care, based on CDPHP policy, and authorize if appropriate. If caller is requesting an out of network provider without applicable transition of care or out-of-network benefits, clinical intake specialist educates caller on their benefits and explains the member's right to request out-of-network coverage.
7. The clinical intake specialist gives the caller the names of providers depending on availability.	7. The intake specialist suggests to the caller to sign a *Permission to Exchange Information* for their primary care physician during their first session with their chosen provider. It is explained that the purpose of this disclosure is to coordinate treatment with their primary care physician.
8. Member needs directions to a provider's office.	8. The clinical intake specialist can assist by using a map application on the Internet: • Mapquest <www.mapquest.com> • Google Maps <https://maps.google.com/>
9. The clinical intake specialist completes the documentation in Facets before taking the next call.	
Calls managed by a behavioral health/HARP Outpatient care manager	
1. A member's incoming call is immediately transferred to the behavioral health/HARP outpatient care manager.	1. The following information is collected unless the urgency of the situation necessitates an abbreviated assessment:

	• Presenting problem/precipitating event. • Other relevant medical, behavioral health, or social/environmental history. • An informal assessment of mental status of the identified patient. (If the identified patient is not the caller, relevant questions can be asked of the caller.) • Further risk assessment including danger to self or others. This assessment is not intended to substitute for a face-to-face diagnostic evaluation. • The behavioral health/HARP outpatient care manager does not assign a diagnosis. • The behavioral health/HARP outpatient care manager collects only the information necessary to apply the medical necessity criteria and make a referral to an appropriate provider or facility-based outpatient program.
2. Referrals may be made to an outpatient practitioner or facility-based program, when appropriate.	2. The behavioral health/HARP outpatient care manager gives the caller the name of the nearest and/or most appropriate outpatient practitioner or facility-based program. An alternate can be offered, if available, when the member does not wish to use the nearest program.
3. Member needs directions to the facility-based outpatient program.	3. The behavioral health/HARP outpatient care manager assist by using a map application on the Internet through Mapquest <www.mapquest.com> or Google Maps <https://maps.google.com/>.
4. The behavioral health/HARP outpatient care manager documents his/her assessment and disposition in Salesforce	
5. The behavioral health manager, in coordination with the behavioral health medical director, is responsible for the clinical oversight of all triage and referral decisions	

POLICY CONSIDERATIONS

The appropriate level of care is determined by applying the medical necessity criteria as stated below.

Mental Health

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: BEHAVIORAL HEALTH ASSESSMENT & TRIAGE

InterQual provides nationally recognized, evidence-based criteria for various levels of mental health care, specific to member age. InterQual also provides an evidence base on common psychiatric treatment modalities including electro-convulsive therapy (ECT), transcranial magnetic stimulation (TMS) and further, new and existing technologies being used in the treatment of mental health conditions have coverage criteria outlined in CDPHP policy. See policy, *Experimental, Investigation and Non-Standard Treatment/Clinical Trials, 1370/20.000152.*

When the recommended level of care or service is not a covered benefit/not available through CDPHP (i.e., residential mental health treatment accessed through agencies licensed by the New York State Office of Mental Health or the New York State Office for People with Developmental Disabilities), the clinical intake specialist will educate and refer the member to the appropriate state agency.

In order to release any personal health information to anyone aside from the member, written authorization is required after they turn 14 years old.

Substance Use Disorders and Substance Use

The New York State Office of Addiction Services and Supports (OASAS), in partnership with The National Center on Addiction and Substance Abuse (CASA Columbia), has designed, built, and tested a web-based tool that aids health plans and substance-use treatment providers in determining the best level of care for a client with a substance use disorder. This tool is named the LOCADTR 3.0, which stands for Level of Care for Alcohol and Drug Treatment Referral.

CDPHP utilizes LOCADTR 3.0 for guiding decision making regarding the appropriate level of care for a member.

- The LOCADTR 3.0 is meant to ensure that all individuals in need of treatment for a substance use disorder have access to care and are placed in the setting closest to the client's community that provides a safe and effective setting for treatment.
- The data collected through the LOCADTR 3.0 is analyzed by NYS OASAS to assess provider and system level performance, inform needs assessments, and inform the relationship between level-of-care determinations and client outcomes. All personal health information collected will be protected and never redisclosed.
- Level of care (e.g., outpatient clinic, inpatient rehabilitation, residential care, etc.) is determined by a variety of factors, including:
    - Assessment of the client's need for crisis or detoxification services (for instance, determining possible medical complications from withdrawal);
    - Risk factors (such as the presence of severe medical and psychiatric conditions); and
    - Resources available to the client (for example, a social or family network supportive of recovery goals).

In order to release any personal health information to anyone aside from the member, written authorization is required after they turn 14 years old.

Adoption of the Protocols and Yearly Updates

The ***Behavioral Health Committee*** reviews all behavioral-health medical necessity and placement criteria protocols annually. This committee includes both community mental health/alcoholism/substance use providers and internal CDPHP mental health/alcoholism/substance use professionals. Suggestions from behavioral health are brought to the CDPHP Quality Management Committee (QMC), and approval

to continue the criteria is sought.

The protocol review focuses on two dimensions: intensity of service and severity of illness. CDPHP always uses the most current version of all protocols. The InterQual behavioral health criteria is updated on a yearly basis. The LOCADTR 3.0 has a "periodic" revision schedule.

Staff Qualifications

The ***clinical intake specialist*** conducts psychosocial and crisis assessment; intervention and stabilization services; triage to case management; evaluation of symptom acuity; and appropriate referral to network behavioral-health providers for next-day appointments and, when appropriate, to emergency services. The qualifications of the clinical intake specialist are an LPN degree or a bachelor's degree, strongly preferred in psychology or a related field, with at least two years of experience in a behavioral health-care environment required. Clinical intake specialists must also demonstrate clinical understanding of DSM 5 diagnoses, including mental health and substance use disorders, and have the ability to effectively manage members in crisis.

The ***Manager, Behavioral Health***oversees, monitors, and supports all activities of the clinical intake specialists, including call management, utilization management, and quality oversight of outpatient requests and authorizations; and serves as a bridge between the clinical intake unit, case managers, and care coordinators.

The ***behavioral health/HARP outpatient care manager*** makes triage and referral decisions requiring clinical judgment. The behavioral health case manager/social worker is a licensed professional who talks to members, assesses their clinical needs and urgency, and makes appropriate referrals. Based on the clinical and treatment needs of the member, the behavioral health case manager may maintain ongoing engagement with a member with identified goals related to their health care needs. The qualifications of the behavioral health case manager/social worker are as follows:

- RN, LMSW, LMHC, or LCSW with previous mental health or substance use experience.
- Knowledgeable with diagnosis and procedural coding, InterQual and LOCADTR 3.0 guidelines, psychiatric medication management, hospital case management, and related mental health and substance abuse treatment.

The ***Manager of behavioral health*** reports to the VP Integrated Care Management, who is a licensed professional, and oversees the behavioral health access center and provides supervision to the clinical intake staff. The behavioral health clinical intake unit manager monitors the consistent application of protocol and adequacy of documentation. For routine calls, the manager ensures utilization of established guidelines to conduct telephonic assessments and information collection. The manager holds daily clinical review with staff to review requests for treatment, and guides all utilization management decisions as they relate to authorization and quality oversight of outpatient services, such as PROS, Home and Community Based Services, and out-of-network requests for care. The manager oversees and provides crisis-management-related training and education to clinical intake specialists, as well as to other departments in CDPHP when necessary and/or appropriate.

The care management/HARP care management managers and supervisor are licensed professionals who oversee the behavioral health case managers to ensure consistent application of protocol, delivery of clinical assessment, adequate engagement with members, and consistency and completeness of documentation.

POLICY NAME: BEHAVIORAL HEALTH ASSESSMENT & TRIAGE

The ***Supervisor of behavioral health utilization review*** is a licensed master's-level practitioner who oversees staff responsible for making medical-necessity determinations for inpatient, residential services, and partial hospitalization and intensive outpatient program services. This includes daily oversight via chart review to monitor adequacy of documentation, and assessment of inter-rater reliability on a quarterly basis. The manager reviews a random sampling of authorization requests, and triages cases to staff based on clinical background. Supervisor is also responsible for the triage of cases to a medical director for review and final determination. The supervisor facilitates clinical rounds where cases are presented by utilization review staff to the medical director for utilization management determination. The supervisor provides daily oversight to the staff in the selection process for these cases. The supervisor educates and trains staff on utilization management tools to ensure consistent application of protocol, including InterQual, LOCADTR, and company policies.

A licensed ***psychiatrist*** experienced in clinical risk management oversees triage and referral decisions and makes all clinical denial decisions. The qualifications of the psychiatrist is licensure to practice medicine in New York State, with board certification in psychiatry. A minimum of seven years post-residency practice experience is required, including significant exposure to practicing in a managed care environment and experience with critical review in clinical scenarios.

EXCLUSIONS

N/A

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP:	Subject to all terms and conditions noted above in the policy.

SOURCES

1. ASAM Patient Placement Criteria for the Treatment of Substance Related Disorders (2nd edition; revised PPC-2r).
2. Level of Care for Alcohol and Drug Treatment Referral (LOCADTR) Manual.
3. National Committee for Quality Assurance (NCQA), MCO Standards and Guidelines, UM 14: Triage and Referral for Behavioral Healthcare.
4. Transition of Behavioral Health Benefit into Medicaid Managed Care and Health and Recovery Program Implementation, October 2015, NYS DOH OMH OASAS.
5. Guiding Principles for the Review and Approval of Clinical Review Criteria for Mental Health Services, NYS OMH; October 2019

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POLICY APPROVAL DATES

New: 11/09

Revised: 01/11, 11/11, 11/13, 05/16, 05/17, 09/18,11/19, 11/20, 10/21, 8/23, 10/24, 10,25

Reviewed: 11/12, 11/14, 11/15, 11/16, 11/17, 11/22, 11/23

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
10/24	Update job titles/descriptions to in line with current structure.
8/1/23	Updated OASAS acronym Added triggers to identify a SUD crisis
1/1/2023	Removed LOCUS & CALOCUS as InterQual and LOCATDR are the only review tools utilized outside of company policies
1/1/2022	Updating policy from MCG criteria to InterQual Added OASAS and SUD referral information to Step 3 (Key Points), Step 5 (Procedure & Key Points)
12/1/2020	Updated title of behavioral health outpatient case manager/social worker to "behavioral health/HARP outpatient care manager" Removed ASAM criteria and added LOCUS/CALOCUS to the manager of inpatient care coordination Added reference for LOCUS/CALOCUS "6. Guiding Principles for the Review and Approval of Clinical Review Criteria for Mental Health Services, NYS OMH; October 2019"

POLICY NAME: BEHAVIORAL HEALTH ASSESSMENT & TRIAGE

	Updated level of care description for mental health
3/1/2020	Updated Description section. Updated verbiage for Steps # 3 & # 6 for calls managed by a clinical intake specialist. Updated all Staff Qualifications in the Policy Considerations section.

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BEHAVIORAL HEALTH RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: Behavioral Health Home and Community Based Services for Adults

POLICY EFFECTIVE DATE:	3/1/2026
Policy Control #:	1370/20.000489
Next Annual Review:	5/2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

H0036, H0038, H2014, H2015, H2017, H2018, H2023, H2025, T2013, T2017, T2019

DESCRIPTION

Behavioral health home and community-based services (BH HCBS) provide opportunities for an individual with mental illness and/or substance-use disorder (SUD) to receive services in his/her own home or community through a person-centered plan of care that meets the individual's needs.

BH HCBS includes the following services:

Habilitation Services
These services are typically provided on a 1:1 basis and designed to assist an individual with a behavioral health diagnosis (i.e., SUD or mental health) in acquiring, retaining, and improving skills such as communication, self-help, domestic, self-care, socialization, fine and gross motor skills, mobility, personal adjustment, relationship development, use of community resources, and adaptive skills necessary to reside successfully in home and community-based settings. These services assist an individual with developing skills necessary for community living and, if applicable, to continue the process of recovery from an SUD disorder. Services include things such as: instruction in accessing transportation, shopping and performing other necessary activities of community and civic life including self-advocacy, locating housing, working with

landlords and roommates, and budgeting. Services are designed to enable individuals to fully integrate into the community and endure recovery, health, welfare, safety, and maximum independence of the individual.

Educational Support Services

These services are provided to assist an individual with a mental health or substance use disorder who wants to start or return to school or formal training with a goal of achieving skills necessary to obtain employment. Educational support services consist of special education and related services as defined in Sections (22) and (25) of the Individuals with Disabilities Education Improvement Act of 2004 (IDEA) (20 U.S.C. 1401 et seq.), to the extent to which they are not available under a program funded by IDEA or available for funding by the NYS Adult Career & Continuing Education Services Office of Vocational Rehabilitation (ACCES-VR).

Education support services may consist of general adult educational services such as applying for and attending community college, university, or other college level courses. Services may also include classes, vocational training, and tutoring to receive a Test Assessing Secondary Completion (TASC) diploma, as well as support to the individual to participate in an apprenticeship program. An individual authorized for educational support services must relate to an employment goal or skill development documented in the service plan. Education support services must be specific in the service plan as necessary to enable an individual to integrate more fully into the community and to ensure the health, welfare, and safety of the individual. Examples of these goals would include but are not limited to: tutoring or formal classes to obtain a TASC diploma, vocational training, apprenticeship program or formal classes to improve skills or knowledge in a chosen career, community college, university, or any college-level courses or classes.

Ongoing supported education is conducted after an individual is successfully admitted to an educational program. Ongoing follow-along support is available for an indefinite period as needed by an individual to maintain his/her status as a registered student.

Individual Employment Support Services

Pre-Vocational Services

These are time-limited, face-to-face services that prepare an individual for paid or unpaid employment. This service specifically provides learning and work experiences where the individual with mental health and/or disabling substance use disorder can develop general, non-job-task-specific strengths and soft skills that contribute to employability in competitive work environments as well as in the integrated community settings. Pre-vocational services occur over a defined period of time and with specific person-centered goals to be developed and achieved, as determined by the individual and his/her employment specialist and support team and ongoing person-centered planning process as identified in the individual's person-centered plan of care. Pre-vocational services provide supports to an individual who needs ongoing support to learn a new job and/or maintain a job in a competitive work environment or a self-employment arrangement. The outcome of this pre-vocational activity is documentation of the

individual's stated career objective and a career plan used to guide individual employment support.

Transitional Employment
This service is designed to strengthen an individual's work record and work skills toward the goal of achieving assisted or unassisted competitive employment at or above the minimum wage paid by the competitive sector employer. This service is provided, instead of individual supported employment, only when the individual specifically chooses this service and may only be provided by clubhouse, psychosocial club program certified provider, or recovery center. This service specifically provides learning and work experiences where the individual with behavioral health and/or substance use disorder can develop general, non-job, task-specific strengths and soft skills that contribute to employability in the competitive work environment in integrated community settings paying at or above minimum wage. The outcome of this activity is documentation of an individual's stated career objective and a career plan used to guide individual employment support.

Intensive Supported Employment (ISE)
These are services that assist an individual with mental health/substance use disorder to obtain and keep competitive employment. This service is based on the individual placement and support (IPS) model which is an evidence-based practice of supported employment. It consists of intensive supports that enable individuals for whom competitive employment at or above the minimum wage is unlikely, absent the provision of supports, and who, because of their clinical and functional needs, require supports to perform in a regular work setting. Individual employment support services are individualized, person-centered services providing supports to an individual who needs ongoing support to learn a new job and maintain a job in a competitive employment or self-employment arrangement. An individual in a competitive employment arrangement receiving individual employment support services is compensated at or above the minimum wage and receives not less than the customary wage and level of benefits paid by the employer for the same or similar work performed by individuals without disabilities. The outcome of this activity is documentation of an individual's stated career objective and a career plan used to guide individual employment support.

Ongoing Supported Employment
This service is provided after an individual successfully obtains and becomes oriented to competitive and integrated employment. Ongoing follow-along support is available for an indefinite period as needed by an individual to maintain his/her paid employment position. Individual employment support services are individualized, person-centered services providing supports to an individual who needs ongoing support to learn a new job and maintain a job in a competitive employment or self-employment arrangement. An individual in a competitive employment arrangement receiving individual employment support services is compensated at or above the minimum wage and receives no less than the customary wage and level of benefits paid by the employer for the same or similar work performed by individuals without disabilities. The outcome of this service is documentation of an individual's stated career

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POLICY NAME: Behavioral Health Home and Community Based Services for Adults

objective and a career plan used to guide individual employment support.

RELATED POLICIES/DOCUMENTS

Behavioral Health Community Oriented Recovery and Empowerment (CORE) Services 1370/20.000510

Home And Community Based Services For Children 1370/20.000503

POSITION STATEMENT

CDPHP does not provide coverage for behavioral health home and community-based services identified above except for HARP as outlined below.

POLICY CONSIDERATIONS

FOR HARP ONLY

HCBS services defined in this policy are available for a HARP enrollee 21 years of age or older when the eligibility assessment completed by the Health Home identifies eligibility for HCBS services. An enrollee may be eligible for Tier 1 (employment services, education support services, peer support services) or Tier 2 (the full array). If the enrollee is not enrolled in a Health Home, the enrollee will be referred to a Recovery Care Agency (RCA) for assessments and plan of care development only. After completion of the brief assessment for eligibility, the Health Home Care Manager (HHCM) or RCA meets with the enrollee, at a location, date, and time convenient to the enrollee and the enrollee's chosen participants for a person-centered discussion about individual goal(s), engagement in current services, goal achievement, and additional needs. The HHCM or RCA utilizes this information to work with the enrollee to create a plan of care (POC) that includes both a behavioral health and primary care contact, and uses a whole person oriented, person-centered planning approach with health education/health promotion services. The HCBS POC includes preventative services (e.g., annual physicals) and health education/promotion services, including nicotine replacement services. Regular medical necessity criteria does not apply. Enrollee does not require active symptoms to be eligible for services. Enrollee's preferences (enrollee is not required to identify specific procedure code or provider to request service) and the presence of functional impairment is enough to support need.

The HHCM or RCA submits the following documentation to CDPHP, requesting level of service determination:

- Completed eligibility assessment, including Tier eligibility determination
- All services enrollee is currently receiving
- Enrollee's recovery goals

- Specific HCBS recommendations

CDPHP reviews the submitted documentation for support of requested service(s). The enrollee's CDPHP file is reviewed to identify eligibility, duplication of services (i.e. ACT, PROS), member suitability for service(s) based on information that may not have been available to Health Home or RCA, evidence of member readiness, and regulatory requirements identified for the requested HCBS. CDPHP works with the Health Home or RCA to resolve any issues impeding approval of the Level of Service request. CDPHP provides a level of service determination identifying providers taking referrals for the approved service(s).

Upon receipt of the level of service determination, the HHCM or RCA assists the enrollee in selecting provider participating in the CDPHP HARP provider network for each approved HCBS service and submitting referrals.

The HCBS provider(s) contacts CDPHP and is given approval for up to three (3) visits over a 14 calendar day period for assessment, and to complete and submit the *Adult Behavioral Health Home and Community Based Services Prior Authorization/Concurrent Review* form, identifying the frequency, scope, and duration for each requested service, as well as defining goals that accurately reflect the enrollee's HCBS POC, with objectives that are result-oriented, measurable steps toward the overall goal that can be achieved within the requested period of services.

CDPHP reviews the submitted *Adult Behavioral Health Home and Community Based Services Prior Authorization/Concurrent Review* form for support of the requested service(s). The enrollee's CDPHP file is reviewed to identify eligibility, duplication of services (i.e. ACT, PROS), member suitability for service(s) based on information that may not have been available to HCBS provider, evidence of member readiness, and regulatory requirements identified for HCBS, working with the enrollee and HCBS provider to finalize the POC. When finalized, CDPHP enters an authorization to approve or deny requested service. Written notification, including frequency, scope, and duration for approvals is provided to the enrollee, HCBS provider, and Health Home or RCA.

Throughout the HCBS review process, the HHCM or RCA continues to update the POC, as appropriate. If additional HCBS needs are identified during the process, a new request for HCBS Level of Service Determination is submitted to CDPHP. The completed POC is submitted to CDPHP for approval within 90 days of completing the eligibility assessment. The POC is reviewed for compliance with CMS requirements. Final POC is shared with a case manager who works collaboratively with the CDPHP utilization review team and the Health Home CM, or RCA, to monitor approved services, verifying approved services are rendered appropriately regarding the frequency, scope, and duration.

The HHCM or RCA conducts a re-assessment of HCBS needs on an annual basis, or after a significant change in condition, such as an inpatient admission or loss of housing.

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Continued stay is provided when the enrollee makes measurable progress toward goals, or there is evidence that the service plan has been modified to address the barriers in treatment progression, or continuation of services is necessary to maintain progress already achieved and/or prevent deterioration. Continued stay can be requested by telephone, or by submitting an updated *Adult Behavioral Health Home and Community Based Services Prior Authorization/Concurrent Review* form.

Plan of care meetings involving the enrollee, Health Home or RCA, and HCBS provider(s) are conducted, at a location, date, and time convenient to the enrollee and the enrollee's chosen participants, to evaluate the plan of care and identify possible updates to the current plan of care. Enrollee specific requests made during these meetings, as well as requests agreed to by the team, are submitted to CDPHP for review. The enrollee is not required to provide a procedure code or request a specific provider for the requested service. CDPHP will identify procedure code corresponding to the requested service and provide the enrollee with names of providers available to provide the service.

Service specific criteria is identified below:

Rehabilitation Services

Habilitation Services
Admission/Eligibility

- Enrollee requires habilitation and onsite services that may include, but are not limited to: cognition (cognitive skills), functional status (ADLs), and recovery-oriented community support
- Providers who do not apply for both PSR and Habilitation are encouraged to apply for both services. Programs without a joint designation will not be allowed to serve individuals having both a PSR and Habilitation goal on their Plan of Care

Limitations/Exclusions

- The total number of Habilitation hours cannot exceed 500 in a calendar year. Time limited exception to this limit for enrollee transitioning from institution is permitted if prior authorized and found to be part of the cost-effective package of services provided to the enrollee compared to institutional care
- Benefit excluded if enrolled in: ACT

Education Support Services
Admission/Eligibility

- Enrollee who has been assessed to need education support services and clearly states interest in obtaining employment with the skills obtained

Limitations/Exclusions

- Hours for supported education are limited to no more than a total of 250 hours per year
- Documentation is maintained in the file of each individual receiving this service that the

service is not otherwise available under section 110 of the Rehabilitation Act of 1973 or the IDEA
- This service is accessible only if other appropriate state plan services are not available or appropriate
- Benefit excluded for enrollee enrolled in: ACT program

Individual Employment Support Services

Pre-Vocational Services
Admission/Eligibility
- Enrollee must have a clear desire to work in competitive employment

Limitations/Exclusions
- Total combined hours (for pre-vocational services and transitional supported employment) are limited to no more than a total of 250 hours and a duration of nine months of service in a calendar year
- For all employment supports services, documentation is maintained in the file of each enrollee receiving this service that the service is not available under a program funded under section 110 of the Rehabilitation Act of 1973 or the IDEA (20 U.S.C. 1401 et seq.). Federal financial participation is not claimed for incentive payments, subsidies, or unrelated vocational training expenses, such as the following:
  - Incentive payments made to an employer to encourage or subsidize the employer's participation in a supported employment program
  - Payments that are passed through to users of supported employment programs, **and**
  - Payments for training that is not directly related to an enrollee's supported employment program.
- When pre-vocational services are provided at a work site where persons are competitively employed, payment is made only for the adaptations, supervision, and training required by enrollee receiving services as a result of their disabilities but does not include payment for the supervisory activities rendered as a normal part of the business setting or work environment.
- Benefit excluded if enrolled in ACT or PROS program

Transitional Employment
Admission/Eligibility
- Enrollee must have made a clear decision to work in competitive employment in the community regardless of limited or unsuccessful work history, or present status of sobriety and/or abstinence
- The basic tenet of transitional employment is that enrollee is capable of working in competitive employment in the community even without prior training and enrollee interested in employment should be given the opportunity

Limitations/Exclusions

- Total combined hours for pre-vocational and transitional supported employment are limited to no more than a total of 250 hours and a duration of nine months of service in a calendar year
- Transitional Employment placements are part-time and time-limited, usually 15-20 hours/week from 6-9 months in duration
- Documentation is maintained in the file of each enrollee receiving this service that the service is not available under a program funded under section 110 of the Rehabilitation Act of 1973 or the IDEA (20 U.S.C. 1401 et seq.). Federal financial participation is not claimed for incentive payments, subsidies, or unrelated vocational training expenses, such as the following:
    - Incentive payments made to an employer to encourage or subsidize the employer's participation in a supported employment program
    - Payments that are passed through to users of the state VR supported employment programs, **and**
    - Payments for training that is not directly related to an individual's supported employment program
- When employment support services are provided in a competitive and integrated work site where persons without disabilities are employed, payment is made only for the adaptations, supervision, and training required by enrollee receiving services as a result of their disabilities and does not include payment for the supervisory activities rendered as a normal part of the business setting.
- Benefit excluded if enrolled in: ACT or PROS program

Intensive Supported Employment (ISE)
Admission/Eligibility

- Enrollee must make a clear decision to work in competitive employment in the community
- The basic tenet of ISE is that enrollee is capable of working in competitive employment in the community even without prior training and enrollee interested in employment should be given the opportunity.
- Ongoing level of care criteria including service duration, intensity and effectiveness will be reviewed by the HCBS care manager and/or CDPHP at least quarterly

Limitations/Exclusions

- 250 hours per calendar year
- For all employment supports services, documentation is maintained in the file of each individual receiving this service that the service is not available under a program funded under section 110 of the Rehabilitation Act of 1973 or the IDEA (20 U.S.C. 1401 et seq.). Federal financial participation is not claimed for incentive payments, subsidies, or unrelated vocational training expenses, such as the following:
    - Incentive payments made to an employer to encourage or subsidize the employer's participation in a supported employment program
    - Payments that are passed through to users of supported employment programs,

and

- Payments for training that is not directly related to an enrollee's supported employment program

- When employment support services are provided at a work site where persons without disabilities are employed, payment is made only for the adaptations, supervision, and training required by an enrollee receiving waiver services as a result of their disabilities but does not include payment for the supervisory activities rendered as a normal part of the business setting.
- Benefit excluded if enrolled in: ACT or PROS program

Ongoing Supported Employment

Admission/Eligibility

- Enrollee must make a clear goal to maintain employment in a competitive work environment in the community

Limitations/Exclusions

- 250 hours per calendar year
- For all employment supports services, documentation is maintained in the file of each individual receiving this service that the service is not available under a program funded under section 110 of the Rehabilitation Act of 1973 or the IDEA (20 U.S.C. 1401 et seq.). Federal financial participation is not claimed for incentive payments, subsidies, or unrelated vocational training expenses, such as the following:
  - Incentive payments made to an employer to encourage or subsidize the employer's participation in a supported employment program
  - Payments that are passed through to users of supported employment programs, **and**
  - Payments for training that is not directly related to an individual's supported employment program.
- When employment support services are provided at a work site where persons without disabilities are employed, payment is made only for the adaptations, supervision, and training required by an enrollee receiving services as a result of their disabilities but does not include payment for the supervisory activities rendered as a normal part of the business setting.
- Benefit excluded if enrolled in ACT or PROS program

EXCLUSIONS

See exclusions listed under each specific area of coverage.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	Child Health plus does not provide coverage for behavioral health

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POLICY NAME: Behavioral Health Home and Community Based Services for Adults

	home and community-based services.
MEDICARE ADVANTAGE:	Medicare Choices does not provide coverage for behavioral health home and community-based services.
SELECT PLAN/HARP:	Select Plan does not provided coverage for behavioral health home and community-based services. Benefits listed are for HARP enrolled members only.

SOURCES

1. New York State: Health and Recovery Plan (HARP) Home and Community Based Services (HCBS) Provider Manual, September 2022, NYS OMH

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POLICY APPROVAL DATES

New: 05/16

Revised: 07/16, 05/17, 05/18, 05/19; 04/21, 1/22, 5/23

Reviewed: 05/20, 5/22, 3/25, 4/26

BEHAVIORAL HEALTH
RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: Behavioral Health Home and Community Based Services for Adults

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
2/1/2022	NYS transition to CORE services to HARP plan benefits – those benefits are now within policy: *Behavioral Health Community Oriented Recovery and Empowerment (CORE) Services 1370/20.000510*
5/1/2023	Updated limits for CPST & PSR
4/5/26	Removed enrollment in PROS, CDT and OASAS outpatient programs as an exclusion for Habilitation Services.

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BEHAVIORAL HEALTH RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: Behavioral Health Community Oriented Recovery and Empowerment (CORE) Services

POLICY EFFECTIVE DATE:	3/1/2026
Policy Control #:	1370/20.000510
Next Annual Review:	12/2026

DISCLAIMER

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PROCEDURE CODES

H2017, H0036, H0038, H2014

DESCRIPTION

Behavioral Health Community Oriented Recovery and Empowerment (CORE) services provide opportunities for an individual with mental illness and/or substance-use disorder (SUD) to receive person-centered, recovery oriented, mobile behavioral health supports that are intended to build skills and self-efficacy along with facilitating community participation and independence. CORE services must be offered in the setting and modality best suited to support an enrollee's goal acquisition including in the enrollee's home and other community-based locations during times and locations that are convenient for the individual. The scope and intensity of CORE services are based on the level of support needed to assist the individual in achieving their recovery goal(s) and sustaining recovery.

Psychosocial Rehabilitation (PSR)

Psychosocial Rehabilitation (PSR) is designed to assist an individual in improving their functional abilities to the greatest degree possible in settings where they live, work, learn, and socialize. Rehabilitation counseling, skill building, and psychoeducational interventions provided through PSR are used to support attainment of person-centered recovery goals and valued life roles. Approaches are intended to develop skills to overcome barriers caused by an individual's

behavioral health disorder and promote independence and full community participation.

Community Psychiatric Support and Treatment (CPST)

Community Psychiatric Support and Treatment (CPST) includes goal-directed supports and solution-focused interventions with the intent to achieve person-centered goals and objectives. This is a multi-component service that consists of therapeutic interventions such as clinical counseling and therapy, which assist the individual in achieving stability and functional improvement. CPST addresses behavioral health barriers that impact daily living, finances, housing, education, employment, personal recovery and/or resilience, family and interpersonal relationships, and community participation.

CPST is designed to provide mobile treatment services to individuals who have difficulty engaging in site-based programs, or who have not been previously engaged in services, including those who had only partially benefited from traditional treatment. CPST allows for delivery of services within a variety of permissible of-site settings including, but not limited to, community locations where the individual lives, works, learns, and/or socializes.

Empowerment Services – Peer Supports

Empowerment Services – Peer Support (Peer Support) are non-clinical, peer-delivered services with focus on rehabilitation, recovery, and resilience. They are designed to promote skills for coping with and managing behavioral health symptoms while facilitating the utilization of natural supports and community resources.

Peer Support must include the identified goals or objectives in the individual's ISP, with interventions tailored to the individual. These goals should promote utilization of natural supports and community services, supporting the person's recovery and enhancing the quality of their personal and family life. The intentional, goal-directed activities provided by this service emphasize the opportunity for peers to model skills and strategies necessary for recovery, thereby developing the individual's skills and self-efficacy. These services are provided through the perspective of a shared personal experience of recovery, enhancing the individual's sense of empowerment and hope.

Family Support and Training

Family Support and Training (FST) offers instruction, emotional support, and skill building necessary to facilitate engagement and active participation of the family in the individual's recovery process. The FST practitioner partners with families through a person-centered or person-directed, recovery oriented, trauma-informed approach.

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Family is defined as the individual's family of choice. This may include persons who live with or provide support to a person, such as a parent, spouse, significant other, children, relatives, foster family, in-laws, or others defined as family by the individual receiving services. Family does not include individuals who are employed to care for the individual receiving services.

RELATED POLICIES/DOCUMENTS

Home and Community Based Services for Adults, 1370/20.000489
Home and Community Based Services for Children, 1370/20.000503

POSITION STATEMENT

CORE services defined in this policy are available for a HARP enrollee 21 years of age or older who receive a recommendation from a Licensed Practioner of the Healing Arts (LPHA). Enrollees may learn about and be referred to CORE services through multiple sources including: the MCO, care manager, inpatient and outpatient clinicians, primary care practitioners, family and friends or provider outreach and education efforts. CORE providers must notify CDPHP within three (3) business days after the first date of initiating a new CORE service. CORE service initiation for new referrals will begin with intake and evaluation sessions, which must be completed within 30 days of the initial visit or the first five (5) visits, whichever occurs later. CORE service providers must submit a service initiation template and CDPHP will confirm there are no duplication of services. These services are not case management, personal care services, nor a replacement for custodial care receive services in his/her own home or community through a person-centered plan of care that meets the individual's needs. NYS has recommended CORE service unit ranges, intended to illustrate the scope of service and program design which may be exceeded when clinically appropriate.

POLICY CONSIDERATIONS

Psychosocial Rehabilitation (PSR)

Psychosocial Rehabilitation is provided individually and in groups. PSR includes the following components:

- Person-Centered Assessment, Recovery Planning, Documentation, and Collaboration: A person-centered planning process is used support the individual's recovery goal. This component includes but is not limited to:
    - Engaging the individual in shared decision making around service and recovery planning.
    - Regular assessment of progress toward goals and updating the ISP, as needed. The PSR practitioner may include record keeping exercises designed to support the individual in monitoring their progress. Staff may use a person-driven concurrent or collaborative documentation process to support this work; and,

  - Communicating with collaterals, including other providers, to ensure integrated, collaborative services and access to necessary supports/resources.
- Individual Psychoeducation and Skill Building: Interventions designed to develop or improve personal coping strategies, prevent crises, and promote recovery. These interventions are tailored to the individual's goal and are adapted to where the individual lives, works, learns, and socializes. Providers may utilize the Wellness Self-Management (WSM) approach. This component includes but is not limited to:
  - Mental health and addiction psychoeducation.
  - Coping skills and stress reduction/management skills training.
  - Problem-solving skills training.
  - Medication education and self-management skills training; and
  - Crisis prevention planning.
- Rehabilitation Counseling: Individualized, goal-driven interventions that facilitate, promote, and improve functioning in living, working, learning, and social environments. Rehabilitation Counseling is used to help the individual choose, get, and keep valued life roles. This component includes but is not limited to:
  - Identification of strengths and resources which may aid the individual in achieving recovery; supporting the individual's personal development, work, and academic performance, and functioning in social and family environments through teaching skills/strategies to ameliorate the effect of behavioral health symptoms.
  - Resource and support coordination to help an individual identify, assess, develop, and secure available supports to ensure their success and satisfaction in their stated rehabilitation goals. This may include working with the individual to use their existing supports, finding new supports, and modifying available supports to meet their needs.
  - Identification of personal, environmental, and behavioral health barriers that may impede the development of skills necessary for functioning in work or school, with peers, and with friends and family.
  - Develop, strengthen, and support the individual's independent community living skills and community participation through self-advocacy and system navigation; promoting access to necessary rehabilitative, medical, social, academic, and other services and supports.
  - Instruction in accessing and using community resources such as transportation, translation, and communication assistance; for example, helping to secure TTY services, language services, or other adaptive equipment needs.
  - Instruction and skill building to increase the individual's capacity to independently manage their own financial resources, including public benefits and entitlements, scholarships and financial aid, work incentives, and earned income.

Community Psychiatric Support and Treatment (CPST)

CPST may be provided to an individual and their family of choice. Components may be

delivered to the family with or without the individual present if the intervention is for the benefit of the individual and with the individual's informed consent. Interventions should be evidence-based. CPST includes the following components:

- Person-Centered Assessment, Service Planning, Documentation, and Collaboration
- Individual and Family Psychotherapy and Counseling
- Integrated Co-Occurring Disorder Treatment
- Crisis Prevention
- Intensive Rehabilitation Counseling

CPST may also include the following optional components:

- Health Monitoring
- Medication Treatment

Empowerment Services – Peer Support

Peer Support is provided individually. It includes the following components

- Person-Centered Recovery Planning, Documentation, and Collaboration
- Advocacy Support
- Activation and Engagement in Recovery
- Community Participation
- Transitional Support
- Pre-Crisis and Crisis Support

Family Support and Training

Family Support and Training is provided individually and in groups. It may be provided to an individual and their family of choice. Components may be delivered to the family with or without the individual present if the intervention is for the benefit of the individual and with the individual's informed consent. Components may also be delivered to the individual without the family present, as appropriate. FST includes the following components:

- Person-Centered Recovery Planning, Documentation, and Collaboration
- Education
- Skill Building and Support

EXCLUSIONS/LIMITATIONS

Psychosocial Rehabilitation (PSR)

- Services may complement, not duplicate, services aimed at supporting enrollee to achieve employment-related goals in his/her plan of care.
- PSR must be provided by staff who meet the minimum criteria for unlicensed behavioral health staff and who have completed the required trainings within timeframes specified in the NYS Staff Training Memo. The Staff Training Memo includes enhanced training for staff delivering PSR to individuals with employment and education-related goals.

  - Unlicensed behavioral health staff must receive clinical supervision by a qualified supervisor.
  - Psychosocial Rehabilitation does not include task-specific job training (i.e., job coaching).
  - There is a 1-12 recommended daily unit range for individual PSR.
  - PSR groups may last from 15 minutes to 1 hour and may be delivered on the same day as a 1:1 PSR session with an individual. There is a 1-4 recommended daily unit range for group PSR.
  - 1:1 PSR services may be delivered in any combination on a single day, including PSR with Employment Focus and PSR with an Educational Focus, up to a total of 12 units per day.
  - Benefit excluded if enrolled in: ACT and PROS
- **PSR with Education Focus**
  - Services may complement, not duplicate, services aimed at supporting enrollee to achieve employment-related goals in his/her plan of care.
  - Benefit excluded if enrolled in: ACT, PROS and BH Home and Community Based Education Support Service.
- **PSR with Employment Focus**
  - Services may complement, not duplicate, services aimed at supporting enrollee to achieve employment-related goals in his/her plan of care.
  - Benefit excluded if enrolled in: ACT, PROS, and BH Home and Community Based Pre-vocational, Transitional Employment,Intensive Supported Employment Service, or Ongoing Support Employment Service.

Community Psychiatric Support and Treatment (CPST)

- Community treatment for eligible enrollee can continue if needed, within the limits, based on the enrollee's needs.
- Intent of service is to eventually transfer care to a site-based setting.
- Services comparable to CORE CPST are available through OMH Clinic. Enrollees may access non-duplicative services through CORE CPST and Article 31 OMH Outpatient Clinic in a single month for the following purposes:
  - Access to a psychiatric prescriber (e.g. psychiatric assessment/evaluation, medication management, health monitoring) if the CPST provider does not have a prescriber. Receiving psychotherapy through CPST and the Article 31 Clinic is duplicative. Medication management and supporting activities through the Article 31 Clinic are duplicative if the CPST provider has a prescriber on staff.
  - Transition from CPST to clinic-based services, allowing for a warm-handoff during the clinic pre-admission process (3 sessions).
- The CPST provider should maintain communication with the prescriber to ensure integrated treatment/care.
- CPST may be delivered by the following qualified staff, within their scope of practice. Qualified staff must complete required trainings within timeframes specific in the NYS

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Staff Training Memo.

Component	Qualified Staff Who May Deliver
Person-Centered Assessment, Service Planning, Documentation, and Collaboration; Intensive Rehabilitation Counseling	Psychiatrist, Psychiatric Nurse Practitioner, Psychologist, Social Worker, Mental Health Counselor, Marriage and Family Counselor, Psychoanalyst, Creative Arts Therapist, Certified Rehabilitation Counselor
Individual and Family Psychotherapy; Integrated Co-Occurring Disorder Treatment; Crisis Prevention	Psychiatrist, Psychiatric Nurse Practitioner, Psychologist, Social Worker, Mental Health Counselor, Marriage and Family Counselor, Psychoanalyst, Creative Arts Therapist
Health Monitoring	Psychiatrist, Physician, Nurse Practitioner, Psychiatric Nurse Practitioner, Physician's Assistant, RN, LPN
Medication Treatment	Psychiatrist, Psychiatric Nurse Practitioner
Student Interns may also deliver components appropriate to their educational program. See Provider Types in Appendix for details on degrees, licenses, and/or permits required for each of the above qualified staff.	

- CPST group services are not allowed.
- There is a recommended daily unit range of 1-6 for CPST
- Benefit excluded if enrolled in: ACT, PROS, CDT, or PHP.

Empowerment Services – Peer Support

- Enrollee receiving an OASAS state plan peer service may also receive CORE Peer Supports. The providers should work together to ensure there is no service duplication. The allowable peer services shall complement, not duplicate one another.
    - Note: Peer services while an enrollee is incarcerated or institutionalized are not Medicaid reimbursable. Time spent on the phone with enrollee is not Medicaid reimbursable. The cost of admission to an event (i.e., sports event or concert) is not Medicaid reimbursable. Advocacy for community improvement (not specific to the Medicaid eligible enrollee) is not Medicaid reimbursable.
- Peer Support must be provided by a Certified Peer who has completed the required trainings within timeframes specified in the NYS Staff Training Memo.
- Certified Peers must receive clinical supervision by a qualified supervisor.

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- Empowerment Peer support groups services are not allowed as this service should be rendered under the PSR benefit.
- There is a 1-16 recommended daily unit range for Empowerment Services- Peer Support.
- Benefit excluded if enrolled in: ACT program.

Family Support and Training

- FST must be provided by staff who meet the minimum criteria for unlicensed behavioral health staff and who have completed the required trainings within timeframes specified in the NYS Staff Training Memo.
- Unlicensed behavioral health staff must have access to clinical supervision by a qualified supervisor.
- This service is provided only at the request of the individual. All FST must be included in the individual's ISP and for the benefit of the Medicaid covered participant.
- There is a 1-12 recommended daily unity range for individual FST.
- Groups may last from 15 minutes to 90 minutes and may be delivered on a same day as single-family session. Groups are made up of 2-3 HARP members' families. While FST is only delivered at the request of the individual, the individual is not required to attend group sessions. There is no limit on how many family members may participate per HARP member. There us a 1-6 recommended daily unit range for group FST.
- Benefit excluded if enrolled in: ACT or PROS program

For all CORE services, the Individual Service Plan (ISP) should be developed utilizing the recommended ranges for each service. The recommended unit range does not apply to an individual in crisis, although the crisis should be clearly documented.

These ranges may be exceeded when a short-term increase in intensity supports goal acquisition. Outside of crisis situations, the decision to exceed the recommended range by the CORE provider should only be made in consultation with their Clinical Supervisor, who should consider whether a higher level of care is needed. An example of when it might be appropriate to exceed the recommended range is an individual who is returning to school and requires Psychosocial Rehabilitation to take day-long college tours and attend college fairs.

CDPHP PRODUCT VARIATIONS

CDPHP, CDPHP UBI, & CDPHN:	CDPHP does not provide coverage for behavioral health community-oriented recovery and empowerment services identified above except for HARP as outlined below.
CHILD HEALTH PLUS:	Child Health plus does not provide coverage for behavioral health

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	community-oriented recovery and empowerment services.
MEDICARE ADVANTAGE:	Medicare Advantage does not provide coverage for behavioral health community-oriented recovery and empowerment services.
SELECT PLAN/HARP:	Select Plan does not provide coverage for behavioral health community-oriented recovery and empowerment services. **FOR HARP ONLY**

SOURCES

1. New York State: Health and Recovery Plan (HARP) Home and Community Based Services (HCBS) Provider Manual, December 2015, NYS OMH.
2. New York State: Community Oriented Recovery and Empowerment Services (CORE) Benefit and Billing Guidance, October 2021, NYS OMH
3. New Work State Community Oriented Recovery and Empowerment Service An 1115 Waiver Demonstration of Adult Rehabilitation Services Operations Manual for Designated providers, October 2021

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Date 1/6/25

CDPHP Behavioral Health

POLICY APPROVAL DATES

New: 2/22

Revised: 4/26

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Reviewed: 12/22, 12/23, 12/24

BEHAVIORAL HEALTH RESOURCE COORDINATION POLICY

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POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
4/26	Added engagement in Ongoing Support Employment Service to exclusions for PSR with Employment Focus service.

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MEDICAL POLICY

Medical Policy Title	**Bioengineered Tissue Products for Wound Treatment and Surgical Interventions**
Policy Number	**7.01.35**
Current Effective Date	**September 1, 2026**
Next Review Date	**August 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

This policy does not address fibrin sealants (e.g., Tisseel) or repair of ocular defects.

I. The following bioengineered tissue products are considered **medically appropriate** for the listed indications, when criteria are met:

A. Diabetic Foot Ulcers (AlloPatch, Apligraf, AmnioBand Membrane, Biovance, Dermagraft, EpiCord, EpiFix, Grafix CORE, Grafix PRIME, Integra, Integra Dermal Regeneration Matrix (Omnigraft), Oasis Wound Matrix, TheraSkin) when meeting **ALL** of the following criteria:

1. The patient has adequate arterial blood supply as evidenced by ankle-brachial index (ABI) of 0.65 or greater in the limb being treated;
2. The patient is competent or has support system required to participate in follow-up care associated with treatment with a bioengineered tissue product;
3. Ulcers are full thickness, extend through the dermis but without tendon, muscle, capsule, or bone exposure, and of greater than three (3) weeks' duration for which standard wound therapy has failed;
4. Patient has adequate treatment of underlying disease process(es) contributing to the ulcer;
5. Ulcers are located on foot or toes and are free of infection, redness, drainage, underlying osteomyelitis, surrounding cellulitis, tunnels and tracts, eschar, or any necrotic material that would interfere with adherence of a bioengineered tissue product and wound healing;
6. Patient's current HbA1C does not exceed 12%; and
7. Absence of the following contraindications:
   a. Known hypersensitivity to bovine collagen, silicone, or chondroitin materials;
   b. Pregnancy;
   c. Clinically diagnosed infected wounds.

B. Venous Ulcers (Apligraf, AmnioBand, EpiFix, Oasis Wound Matrix, TheraSkin) when meeting

ALL of the following criteria:

1. The patient has adequate arterial blood supply as evidenced by ankle-brachial index (ABI) of 0.65 or greater in the limb being treated;
2. The patient is competent or has support system required to participate in follow-up care associated with treatment with a bioengineered tissue product;
3. Ulcers are partial or full thickness and have failed to respond to conservative measures of at least one (1) month duration that have, at a minimum, included regular dressing changes, debridement of necrotic tissue, and standard therapeutic compression. ("Failure to respond" is defined as increase in size or depth or no change in size or depth with no sign or indication that improvement is likely, such as granulation, epithelialization, or progress toward closing);
4. Patient has adequate treatment of the underlying disease process(es) contributing to the ulcer; and
5. Ulcers are free of infection, redness, drainage, underlying osteomyelitis, surrounding cellulitis, tunnels and tracts, eschar or any necrotic material that would interfere with adherence of a bioengineered tissue product and wound healing.

C. Breast Reconstruction (Alloderm, AlloMax/Cortiva, DermACELL AWM, DermaMatrix, FlexHD, GraftJacket, Surgimend)
   1. Breast reconstruction surgery following surgical mastectomy
      a. Evidence on acellular dermal matrix (ADM) in post-mastectomy expander/implant breast reconstruction is varied and conflicting. Surgeons should evaluate each clinical case individually and objectively determine the use of ADM.

D. Nasal Repairs (Alloderm)
   1. Septal repair, septal perforation repair, or reconstructive septorhinoplasty

E. Non-Primary Hernia Repair (Alloderm)
   1. When chronic infection contraindicates the use of mesh or other conventional repair

F. Parotidectomy (Alloderm)

G. Burns
   1. Integra Dermal Regeneration Matrix (Omnigraft) when meeting **ALL** of the following criteria:
      a. Insufficient autograft is available at the time of burn excision; **and**
      b. When used for **ANY** of the following indications:
         i. post excisional treatment of a full thickness or deep partial thickness burn;
         ii. for repair of scar contractures secondary to third-degree burns;

2. Biobrane
    a. When used as a temporary covering for clean, debrided superficial and partial thickness burns and donor sites;
3. Epicel
    a. deep dermal or full thickness burns over greater than 30% of the body;
4. TransCyte
    a. When used for temporary covering of a surgically excised deep partial or full thickness burn wound as a covering prior to autografting.

II. After initial treatment has been completed, reinitiated treatment on the same wound site less than one (1) year after successful treatment is considered treatment failure and **not medically appropriate**.

III. **ALL** other bioengineered tissue products are considered **investigational** for **ANY** indication.

RELATED POLICIES

Corporate Medical Policy

10.01.01 Breast Reconstruction Surgery

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Specific products should only be used in accordance with US Food and Drug Administration (FDA) product approval and when the above policy criteria are met.

II. If a product is not FDA approved for the indication for which it is being used (i.e.., "off label" use), documentation of a shared decision-making process and informed consent is required.

III. The FDA requests prompt reporting of adverse effects associated with bioengineered tissue products through MedWatch, the FDA Safety Information and Adverse Event Reporting Program.

IV. If a wound has not responded to standard of care by achieving a 50% or better wound reduction after four weeks of standard of care, a single application of a bioengineered tissue product was thought to be all that was required to affect wound healing in wounds likely to be improved by this treatment. Based on clinical input from wound specialists, refractory wounds rarely heal with one graft application and may require additional graft applications, no more frequently than once per week, until the wound heals. Re-application of a product is appropriate only if there has been measurable response to the first application.

V. Treatment of venous stasis ulcers that extend above the malleoli is beyond the scope of practice of podiatrists.

DESCRIPTION

Bioengineered tissue products are cellular (contain living cells) or acellular (no biological component)

matrices that can be derived from human tissue (autologous or allogeneic), nonhuman tissue (xenographic), synthetic materials, or a composite of these materials. Manufacturing processes vary, but generally involve seeding selected cells onto a matrix, where they receive proteins and growth factors necessary for them to develop into the desired tissue. The tissue may then be used for a variety of procedures, including breast reconstruction, treatment of severe burns, and healing of diabetic and venous ulcers.

SUPPORTIVE LITERATURE

Diabetic Foot Ulcers (AlloPatch, Apligraf, AmnioBand Membrane, Biovance, Dermagraft, EpiCord, EpiFix, Grafix CORE, Grafix PRIME, Integra, Integra Dermal Regeneration Matrix (Omnigraft), Oasis Wound Matrix)

Tettelbach et al (2018) conducted a multicenter prospective randomized controlled comparative parallel study at 11 centers in the United States. The aim of this study was to determine the safety and effectiveness of dehydrated human umbilical cord allograft (EpiCord) compared with alginate wound dressings for the treatment of chronic, non-healing diabetic foot ulcers (DFU). Individuals with a confirmed diagnosis of Type 1 or Type 2 diabetes presenting with a 1 to 15 cm2 ulcer located below the ankle that had been persisting for at least 30 days were eligible for the 14-day study run-in phase. After 14 days of weekly debridement, moist wound therapy, and off-loading, those with ≤30% wound area reduction post-debridement (n = 155) were randomized in a 2:1 ratio to receive a weekly application of EpiCord (n = 101) or standardized therapy with alginate wound dressing, non-adherent silicone dressing, absorbent non-adhesive hydropolymer secondary dressing, and gauze bandage roll (n = 54). Study visits were conducted for 12 weeks. Data for randomized subjects meeting study inclusion criteria were included in an intent-to-treat (ITT) analysis. Additional analysis was conducted on a group of subjects (n = 134) who completed the study per protocol (PP) (EpiCord, n = 86, alginate, n = 48) and for those subjects receiving adequate debridement (EpiCord, n = 67, alginate, n = 40). ITT analysis showed that DFUs treated with EpiCord were more likely to heal within 12 weeks than those receiving alginate dressings, 71 of 101 (70%) vs 26 of 54 (48%) for EpiCord and alginate dressings, respectively, P = 0.0089. Healing rates at 12 weeks for subjects treated PP were 70 of 86 (81%) for EpiCord-treated and 26 of 48 (54%) for alginate-treated DFUs, P = 0.0013. For those DFUs that received adequate debridement (n = 107, ITT population), 64 of 67 (96%) of the EpiCord-treated ulcers healed completely within 12 weeks, compared with 26 of 40 (65%) of adequately debrided alginate-treated ulcers, P < 0.0001. Seventy-five subjects experienced at least one adverse event, with a total of 160 adverse events recorded. There were no adverse events related to either EpiCord or alginate dressings. The authors conclude these results demonstrate the safety and efficacy of EpiCord as a treatment for non-healing DFUs.

A review article (Zelen 2015a) addresses the use of human amnion/chorion membrane (dHACM) for lower extremity repair. The article states:

Although there is limited data available regarding most amniotic membrane-based products, there is substantial preclinical and clinical evidence supporting the rationale and effectiveness of dHACM allograft as a treatment modality. The rapidly growing body of evidence suggests that the properties inherent in dHACM promote tissue regeneration and healing, recruiting patients' own stem cells into

the wounded area. Randomized controlled trials evaluating dHACM now include more than 200 patients collectively and the results consistently show improved healing. Use of dHACM has been shown to be more clinically effective and cost-effective than other frequently used advanced wound care products. This cost-effectiveness results from dHACM showing higher healing rates and more rapid healing than other advanced wound care products. Cost-effectiveness is also enhanced through the availability of grafts of multiple sizes, which reduces wastage, and through ease of handling and storage for clinical use. Ongoing and future studies will further define and establish the value of amniotic membrane for chronic tissue repair and regeneration.

A small, industry-sponsored, non-blinded, RCT comparing the use of EpiFix (n=13) with SOC (moist wound therapy, n=12) for diabetic foot ulcers of at least four weeks' duration (Zelen 2013). EpiFix was applied every two weeks if the wound had not healed, with weekly dressing changes consisting of non-adherent dressing, moisture retentive dressing, and a compression dressing. Standard moist wound dressing was changed daily. After four weeks of treatment, EpiFix-treated wounds had reduced in size by a mean of 97.1%, compared with 32.0% for the SOC group. Healing rate (complete epithelialization of the open area of the wound) was 77% for EpiFix, compared with 0% for SOC. After six weeks of treatment, wounds were reduced by 98.4% with EpiFix treatment, compared with -1.8% for SOC. The healing rate was 92% with EpiFix, compared with 8% with standard treatment alone.

Treatment with EpiFix, Apligraf, or standard wound care was compared in a multicenter randomized, controlled study (Zelen2015b). Sixty patients with chronic lower extremity diabetic ulcers were randomized to treatment with Epifix (dehydrated human amniotic membrane), Apligraf (human skin allograft with living fibroblasts and keratinocytes), or standard wound care. Although the patient and site investigator could not be blinded due to differences in products, wound healing was verified by three independent physicians who evaluated photographic images. The median wound size was 2.0 cm^2 (range, 1.0-9.0), and the median duration of the index ulcer was 11 weeks (range, 5-54). After six weekly treatments, the mean percent wound area healed was 97.1% for EpiFix, 80.9% for Apligraf, and 27.7% for standard care; 95% of wounds had healed in the EpiFix group compared with 45% treated with Apligraf and 35% who received standard wound care ($p<0.003$). The estimated median time to wound closure, based on Kaplan-Meier analysis, was 13 days for EpiFix, compared with 49 days for both Apligraf and SOC ($p<0.001$).

In 2015, Kirsner et al reported an industry-sponsored observational study comparing the effectiveness of Apligraf and EpiFix for the treatment of diabetic foot ulcers in a real-world setting. Data were obtained from a wound care–specific database from 3000 wound care facilities. The database included 1458 diabetic ulcers treated for the first time in 2014 with Apligraf (n=994) or EpiFix (n=464). After study inclusion criteria, data were included on the treatment of 226 diabetic foot ulcers from 99 wound care centers. Foot wounds were included with size between 1 cm2 and 25 cm2, duration of one year or less, and wound reduction of 20% or less in the 14 days prior to treatment. Although wounds for the two groups were comparable at baseline, the rationale for using a particular product was not reported. There were 163 wounds treated with Apligraf (mean, 2.5 applications) and 63 treated with EpiFix (mean, 3.5 applications, p=0.003). By week 24, 72% of wounds treated with Apligraf and 47% of wounds treated with EpiFix had closed (p=0.01).

Treatment with Grafix or standard wound care was compared in a small, multi-centered RCT for diabetic foot ulcers (Lavery 2014). Although the results were positive, the sample size was small, with 50 treated with Grafix and 47 in the control group treated with SOC. The primary end point was complete wound closure by 12 weeks. Grafix patients who achieved full closure was 62% versus 21% in the control group receiving SOC. Ananian et al (2018) reported a prospective, randomized, single-blind study comparing the efficacy of Grafix with Dermagraft. The end result of this study was measured by wound closure and showed that Grafix (48.4% closure) is non-inferior to Dermagraft (38.7% closure).

AmnioBand was compared to SOC for treatment of non-healing diabetic foot ulcers in an industry-sponsored, multi-center study (DiDomenico 2016). Forty patients were randomized to SOC or SOC with AmnioBand for up to 12 weeks. Complete healing by six weeks was observed for 70% of wounds treated with SOC and AmnioBand versus 15% treated with SOC alone. At 12 weeks, complete healing was observed in 85% of the SOC and AmnioBand group versus 25% treated with SOC alone. Limitations of the study were small sample size, a drop-out rate of 9/40, and the wound area in the control group was larger than in the treatment group.

Smiell et al (2015) reported on an industry-sponsored, multicenter registry study of Biovance d-HAM for the treatment of various chronic wound types; about a third (n=47) were diabetic foot wounds. Of those treated, 28 ulcers had failed prior treatment with advanced biologic therapies. For all wound types, 41.6% closed within a mean time of 8 weeks and a mean of 2.4 amniotic membrane applications.

AlloPatch, which is a pliable human reticular, acellular dermis, was compared to SOC in the treatment of diabetic foot ulcers in an industry-sponsored, multicenter trial (Zelen 2017). The trial was powered to detect a 45% difference between groups in percentage healing at six weeks with 20 patients per group. Evaluation of the outcome measures was not blinded. At six weeks, 65% (13/20) of wounds treated with AlloPatch had healed, compared to 5% (1/20) in the SOC-alone group ($p<0.001$). After adjusting for wound area at baseline, the hazard ratio for healing was 168 (95% CI, 10 to 2704; $p<0.001$), indicating a lack of precision in the estimate. Per protocol, 10 patients in the SOC group and one in the AlloPatch group exited the study at six weeks because their wounds failed to reduce in area by at least 50%. According to ITT analysis with last observation carried forward, the percentage of wounds healed at 12 weeks was 80% in the AlloPatch group, compared to 20% in the SOC group. However, because there was a high (50%) withdrawal rate in the SOC group, this result has a high risk of bias.

Integra Dermal Regeneration Template*,* marketed as Omnigraft*,* randomized, controlled studies have been shown to improve healing of chronic, non-healing diabetic foot ulcers with the use of Omnigraft (Driver 2015). The Foot Ulcer New Dermal Replacement (FOUNDER) multicenter study on the use of Integra Dermal Regeneration Template for chronic, non-healing diabetic foot ulcers was conducted under an FDA-regulated investigational device exemption. A total of 307 patients with at least one chronic diabetic foot ulcer were randomized to treatment with the Integra Template or a control condition (0.9% sodium chloride gel). Treatment was given for 16 weeks or until wound closure. There was a modest increase in wound closure with the Integra Template (51% versus 32%) and a

shorter median time to closure (43 days versus 78 days). There was a strong correlation between investigator-assessed and computerized planimetry assessment of wound healing (r=0.97). Kaplan-Meier analysis showed the greatest difference between groups in wound closure up to 10 weeks, with diminishing differences after 10 weeks. Strengths of the study included adequate power to detect an increase in wound healing of 18%, which was considered to be clinically significant, as well as secondary outcomes of wound closure and time to wound closure by computerized planimetry and intention-to-treat (ITT) analysis.

The Oasis Wound Matrix (Cook Biotech) is a xenogeneic collagen scaffold derived from porcine small intestinal mucosa. Niezgoda et al (2005) compared healing rates at 12 weeks for full-thickness diabetic foot ulcers treated with the OASIS Wound Matrix (an acellular wound care product) to Regranex Gel. This industry sponsored, multicenter RCT was conducted at nine outpatient wound care clinics and involved 73 patients with at least one diabetic foot ulcer. Patients were randomized to receive either Oasis Wound Matrix (n=37) or Regranex Gel (n=36) and a secondary dressing. Wounds were cleansed and debrided, if needed, at a weekly visit. The maximum treatment period for each patient was 12 weeks. After 12 weeks, 18 (49%) Oasis-treated patients had complete wound closure, compared with 10 (28%) Regranex-treated patients. Oasis treatment met the noninferiority margin, but the study did not demonstrate that healing in the Oasis group was statistically superior (p=0.055). Post hoc subgroup analysis showed no significant difference in incidence of healing in patients with type 1 diabetes (33% versus 25%) but showed a significant improvement in patients with type 2 diabetes (63% versus 29%). There was also an increased healing of plantar ulcers in the Oasis group (52% versus 14%).

TheraSkin was reported in a small (n=23), industry-funded, randomized comparison of TheraSkin (human skin allograft with living fibroblasts and keratinocytes) to Dermagraft (human-derived fibroblasts cultured on mesh) for diabetic foot ulcers (Sanders 2014). Wound size at baseline ranged from 0.5 to 18.02 cm^2; the average wound size was about 5 cm^2 and was similar for the two groups (p=0.51). Grafts were applied according to the manufacturer's instructions over the first 12 weeks of the study until healing, with an average of 4.4 TheraSkin grafts (every two weeks) compared with 8.9 Dermagraft applications (every week). At week 12, complete wound healing was observed in 63.6% of ulcers treated with TheraSkin and 33.3% of ulcers treated with Dermagraft (p<0.049). At 20 weeks, complete wound healing was observed in 90.9% of the TheraSkin-treated ulcers, compared with 66.67% of the Dermagraft group (p=0.428).

Venous Ulcers (Apligraf, Oasis Wound Matrix)

Hankin et al (2012) explains venous leg ulcers (VLUs) are commonly associated with substantial disability, impaired quality of life, and high economic costs. Compression therapy, which has remained the standard care for VLUs over several decades, is often insufficient to heal VLUs in a timely manner. VLU-related treatment costs are directly related to time to achieve complete wound closure. Advanced wound care matrices (AWCMs) developed to stimulate wound healing may reduce VLU-related costs associated with delayed healing.

Mostow et al (2005) conducted a prospective, randomized, controlled multicenter trial to compare the effectiveness of Oasis wound matrix with compression vs compression alone in healing chronic leg

ulcers within 12 weeks. Participants included 120 patients with at least one (1) chronic leg ulcer, randomly assigned to receive either weekly topical treatment of Oasis plus compression therapy (n = 62) or compression therapy alone (n = 58). Ulcer size was determined at enrollment and weekly throughout the treatment. Healing was assessed weekly for up to 12 weeks. Recurrence after 6 months was recorded. The primary outcome measure was the proportion of ulcers healed in each group at 12 weeks. After 12 weeks of treatment, 55% of the wounds in the Oasis group were healed, as compared with 34% in the standard-care group (P = .0196). None of the healed patients treated with Oasis wound matrix and seen for the 6-month follow-up experienced ulcer recurrence. The authors concluded the study showed Oasis wound matrix, as an adjunct therapy, significantly improves healing of chronic leg ulcers over compression therapy alone.

A prospective, head-to-head, single site randomized clinical trial pilot study evaluated the effectiveness of two (2) biologically active grafts, TheraSkin and Apligraf, in conjunction with compression therapy (Towler 2018). The study was not industry-sponsored and was designed and conducted to assess differences in healing rates, adverse outcomes, and treatment costs. Although there were higher venous leg ulcer (VLU) healing rates with the TheraSkin cohort compared with the Apligraf cohort at both 12 weeks (93.3% vs 75.0%) and 20 weeks (93.3% vs 83.3%), these healing rate differences were not statistically significant. There was no statistically significant difference in the number of grafts required to achieve wound closure within limitations of the small sample size presented and there were no adverse outcomes. There was a statistically significant 42.2% decrease in cost for the appropriate graft sizes in the TheraSkin cohort ($2495.33/subject) compared with the Apligraf cohort ($4316.67/subject), even though the initial wound sizes were not significantly different between groups. This suggests that TheraSkin may provide equivalent or superior outcomes to Apligraf while reducing costs though the authors concluded that the use of either of these biologics in conjunction with compression therapy is a safe and effective way to treat VLUs.

Landsman et al (2011) published a study examining TheraSkin for safety and efficacy in the treatment of venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs). The objective was to determine if TheraSkin could serve as a safe and effective alternative to bioengineered skin substitutes such as Apligraf and Dermagraft. The authors conducted a retrospective study of 214 consecutive patients seen at the Inova Wound Center (Mt Vernon, Virginia), with either a DFU or a VLU. After excluding patients who did not meet the study criteria, the final eligible cohort consisted of 188 subjects, with 134 VLUs and 54 DFUs. Multivariate logistic regression was used to evaluate the relationship between baseline wound size and the proportion of healed wounds after 12 and 20 weeks from initial allograft application. The authors found that by the 12th week, DFUs closed 60.38% of the time and VLUs closed 60.77% of the time. After 20 weeks, the number of closed DFUs increased to 74.1% and the number of VLUs increased to 74.6%. The mean wound size in the DFU group was 6.2 cm (2) (±11.8) and 11.8 cm (2) (±22.5) in the VLU group. The mean number of TheraSkin allografts required ranged from 1 to 8, with an average of 2.03 (±1.47) at the 12-week point and an average of 3.23 (±2.77) at the 20-week point. Multivariate logistic regression was used to calculate the odds of wound healing by week 12 and week 20 in each group. The authors also analyzed adverse events and found TheraSkin to be noncontributory to any adverse events, verifying the safety of TheraSkin in this study population. The authors concluded, TheraSkin has been shown

to be highly effective for the treatment of both VLUs and DFUs with an acceptable safety profile.

A randomized, controlled, multicenter clinical trial was conducted to evaluate the efficacy of dehydrated human amnion/chorion membrane (EpiFix) allograft as an adjunct to multilayer compression therapy for the treatment of non-healing full-thickness venous leg ulcers (Bianchi 2018). The authors randomly assigned 128 subjects initially though only 109 subjects finished the trial. They received EpiFix and multilayer compression (n = 52) or dressings and multilayer compression therapy alone (n = 57). Patients were recruited from 15 centers around the United States and were followed up for 16 weeks. The primary end point of the study was defined as time to complete ulcer healing. Participants receiving weekly application of EpiFix and compression were significantly more likely to experience complete wound healing than those receiving standard wound care and compression (60% versus 35% at 12 weeks, P = 0·0128, and 71% versus 44% at 16 weeks, P = 0·0065). A Kaplan-Meier analysis was performed to compare the time-to-healing performance with or without EpiFix, showing a significantly improved time to healing using the allograft (log-rank P = 0·0110). Cox regression analysis showed that subjects treated with EpiFix had a significantly higher probability of complete healing within 12 weeks (HR: 2·26, 95% confidence interval 1·25-4·10, P = 0·01) versus without EpiFix. The authors concluded these results confirm the advantage of EpiFix allograft as an adjunct to multilayer compression therapy for the treatment of non-healing, full-thickness venous leg ulcers.

Bianchi et al (2019) published further analysis on the previously mentioned cohort of patients in a follow-up study. The purpose of this study is to report intention-to-treat (ITT) results on all 128 randomized subjects and assess if both ITT and per-protocol (PP) data analyses arrive at the same conclusion of the efficacy of EpiFix as a treatment for VLU. Rates of healing for the ITT and PP populations were, respectively, 50% and 60% for those receiving EpiFix and 31% and 35% for those in the standard care cohort. Within both ITT and PP analyses, these differences were statistically significant; P = 0.0473, ITT and P = 0.0128, PP. The Kaplan-Meier plot of time to heal within 12 weeks for the ITT and PP populations demonstrated a superior wound-healing trajectory for EpiFix compared with VLUs treated with standard care alone. The authors concluded that these data provide clinicians and health policymakers with an additional level of assurance regarding the effectiveness of EpiFix.

An open label randomized controlled trial including patients with chronic venous leg ulcers was conducted at eight (8) wound care centers across the United States (Serena 2022). This industry sponsored trial evaluated the safety and effectiveness of weekly and biweekly applications of dehydrated human amnion and chorion allograft (dHACA) (AmnioBand Membrane; MTF Biologics) plus standard of care compared to standard of care alone on chronic venous leg ulcers. The primary endpoint was the proportion of healed ulcers at 12 weeks. Secondary endpoints included the proportion of ulcers achieving 40 percent closure at 4 weeks and the incidence of adverse events. Among 101 patients screened for eligibility, 60 were eligible and enrolled. At 12 weeks, significantly more venous leg ulcers healed in the two dHACA-treated groups (75 percent) than in the standard-of-care group (30 percent) (p = 0.001) even after adjustment for wound area (p = 0.002), with an odds ratio of 8.7 (95 percent CI, 2.2 to 33.6). There were no significant differences in the proportion of wounds with percentage area reduction greater than or equal to 40 percent at 4 weeks among all

groups. The adverse event rate was 63.5 percent. Among the 38 adverse events, none were graft or procedure related, and all were resolved with appropriate treatment. The authors concluded, dHACA and standard of care, either applied weekly or biweekly, significantly healed more venous leg ulcers than standard of care alone, suggesting that the use of aseptically processed dHACA (AmnioBand Membrane; MTF Biologics) is advantageous and a safe and effective treatment option in the healing of chronic venous leg ulcers.

Breast Reconstruction (Alloderm, AlloMax/Cortiva, DermACELL AWM, DermaMatrix, FlexHD, GraftJacket, Surgimend)

A prospective study was completed which evaluated limited submuscular direct-to-implant technique utilizing AlloMax where only the upper few centimeters of the implant is covered by the pectoralis, whereas the majority of the implant including the middle and lower poles are covered by acellular dermal matrix (Brichacek 2017). Nineteen consecutive patients with 37 reconstructed breasts were studied and followed up to six (6) months postoperatively. Average age was 50 years, average BMI was 24.3, ptosis ranged from grade 0-III, and average cup size was B (range, A-DDD). Early minor complications included one (1) seroma, three (3) minor postoperative hematomas managed conservatively, and 3 minor wound healing problems. Three breasts experienced mastectomy skin flap necrosis and were managed with local excision. There were no cases of postoperative infection, red breast syndrome, grade III/IV capsular contractures, or implant loss. A single patient complained of animation postoperatively. One patient desired fat grafting for rippling. The limited submuscular direct-to-implant technique utilizing AlloMax appears to be safe with a low complication rate at 6 months. This technique minimizes the action of the pectoralis on the implant, reducing animation deformities but still providing muscle coverage of the upper limit of the implant. Visible rippling is reduced, and a vascularized bed remains for fat grafting of the upper pole if required.

Zheng et al (2025) reported a single, academic institution's experience with two (2) ADM brands in breast reconstruction and provides data on clinical and financial outcomes. A retrospective chart review of patients who underwent two-staged breast reconstruction with Cortiva Allograft Dermis was matched with a cohort who received AlloDerm RTU. Comparison of clinical outcomes, such as complications and revision surgeries, in addition to a cost analysis was completed. The study cohort included 24 patients who received Cortiva and 24 patients who received AlloDerm. There were no statistical differences in demographics or breast-specific characteristics between the cohorts. Major complications were not statistically increased with Cortiva use [Hazard Ratio 1.78 (0.421-7.66)], but the rate of revision following second-stage reconstruction trended toward significance with Cortiva use [3.41 (0.99-11.80), p=0.05]. The material base cost and total cost following surgeries were lower for Cortiva (44% of the AlloDerm costs), but the incremental costs did not display significant difference secondary to comparable complication and revision rates. The authors concluded that the use of Cortiva Allograft Dermis was shown to have a decreased cost in base material and total cost associated with surgery while also displaying comparable clinical outcomes and complication rate.

A single-blinded randomized controlled trial comparing Cortiva with AlloDerm in prepectoral and subpectoral immediate prosthetic breast reconstruction was performed at two (2) academic hospitals from March of 2017 to December of 2021 (Keane 2024). Reconstructions were direct to implant (DTI)

or tissue expander (TE). Primary outcome was reconstructive failure, defined as TE explantation before planned further reconstruction, or explantation of DTI reconstructions before 3 months postoperatively. Secondary outcomes were additional complications, patient-reported outcomes (PROs), and cost. There were 302 patients including: 151 AlloDerm (280 breasts), 151 Cortiva (277 breasts). The majority of reconstructions in both cohorts consisted of TE (62% versus 38% DTI), smooth device (68% versus 32% textured), and prepectoral (80% versus 20% subpectoral). Reconstructive failure was no different between ADMs (AlloDerm 9.3% versus Cortiva 8.3%; P = 0.68). There were no additional differences in any complications or PROs between ADMs. Seromas occurred in 7.6% of Cortiva but 12% of AlloDerm cases, in which the odds of seroma formation were two-fold higher (odds ratio, 1.93 [95% CI, 1.01 to 3.67]; P = 0.047). AlloDerm variable cost was 10% to 15% more than Cortiva, and there were no additional cost differences. The authors concluded, when assessing safety, clinical performance, PROs, and cost, Cortiva is noninferior to AlloDerm in immediate prosthetic breast reconstruction, and may be less expensive, with lower risk of seroma formation.

Kaplan HY and Rysin R (2025) published a retrospective study evaluating a patient cohort that underwent primary or revisional breast reconstruction (DTI) utilizing DermaCell, from Jan 2017 to Jan 2024 by a single surgeon. A total of 230 consecutive patients, 410 breasts, and 801 DermaCell sheets were evaluated. All were DTI breast reconstructions. Complication rate was described per breast. A total of 92 cases of complication occurred (22.4%). Rippling was seen in 18 breasts (4.39%), skin ischemia in 21 breasts (5.12%), hematoma in 5 (1.21%), and seroma in 9 (2.19%). Seventeen breasts experienced capsular contraction. In the nonirradiated group, capsular contracture (CC), Baker grade 3 to 4, was seen in 4 breasts (1.11%), with 9 (18%) in the irradiated group. The postoperative follow-up period was 18 months (range: 6-84 months). BREAST-Q satisfaction with the breast increased by a mean of 10.45. Satisfaction with the implant was 6.61 out of 8. The authors concluded that DermaCell ADM offers a safe and reliable option and is an important component in prepectoral breast reconstruction, contributing to better results, an improved complication profile, and patient satisfaction.

Glynou SP et al (2024) conducted a network meta-analysis to compare outcomes of different ADMs that are commonly used during implant-based reconstruction (IBR). A total of 51 studies were captured by the search, of which 27 were included in the network meta-analysis. Alloderm was the most used ADM (54%), followed by Porcine (17%), Bovine (11%), Dermacell (11%), and FlexHD (7%). The mean follow-up was 27.8 months. The complication rates varied. Porcine ADMs had the highest rate of seroma formation (10.3%) and of hematoma formation (2.7%). AlloDerm FD had the highest rate of wound dehiscence (3.1%). Implant failure was highest in AlloDerm FD ADMs (11.8%), followed by Porcine ADMs (11.2%). Infections were most common in Porcine (11.2%) and AlloDerm FD ADMs (11.0%). Capsular contracture was rare across all ADM types, with no significant differences observed. In the network meta-analysis (NMA), AlloDerm FD showed significantly higher risks of infection, explantation, and wound dehiscence compared to AlloDerm RTU. The overall complication profiles of ADMs used in IBR are similar, except for the higher risks associated with AlloDerm FD compared to RTU. These findings suggest that the choice of ADM may not significantly impact overall outcomes, except in specific cases like AlloDerm FD. Further high-quality, long-term,

double-arm studies are necessary to confirm comparative profile of specific ADM types and to account for potential confounding variables through multivariable regression analysis.

Davison SP et al (2024) conducted a prospective, patient-blind study of patients undergoing bilateral nipple and/or skin-sparing mastectomies with either tissue expander or silicone implant insertion between 2019 and 2022 were selected for this study. The study design used patients as their own controls between two (2) products randomly assigned to the left or right breast. Outcomes between the products included average time for drain removal, infection rate, seroma rate, and incorporation rates. The prospective clinical data of 55 patients (110 breasts) were recorded for 90 days. There were no significant differences between drain removal time, average drain output, or seroma aspiration amount. A higher percentage of seromas was recorded in the breasts with AlloDerm (30.91%) compared with breasts containing DermACELL (14.55%, P < .05), and a statistically significant difference between the incorporation rates of AlloDerm (93.4%) and DermACELL (99.8%, P < .05) was observed. Irrespective of patient demographic disparities, both products had a 94.55% success rate for reconstruction outcomes. AlloDerm was determined to have a higher incidence of seroma as a postoperative complication and a trend to lower incorporation.

The Breast Reconstruction Evaluation of Acellular Dermal Matrix as a Sling Trial (BREASTrial) is a blinded, randomized trial comparing the outcomes of tissue expander breast reconstruction using AlloDerm or DermaMatrix (Mendenhall 2023). In this final stage of the trial, outcomes 3 months to 2 years after definitive reconstruction are reported along with patient satisfaction data. A randomized trial was conducted to compare complication rates between groups of patients who underwent reconstruction with AlloDerm and DermaMatrix. Regression models were used to analyze the impact of matrix type, age, chemotherapy, radiation therapy, and reconstructive type on complication rates. Premastectomy and postmastectomy questionnaires were used to assess patient satisfaction and were also analyzed using regression models. Of the 128 patients (199 breasts) who were randomized in the trial, 108 patients (167 breasts) were available for analysis in stage III. There was no difference in the overall complication rates between the AlloDerm and DermaMatrix groups (6% versus 13.2%; P = 0.3) or the severity of those complications (P = 0.7). Obesity was a positive predictor for complications, regardless of reconstruction group (P = 0.02). Patient satisfaction was positive overall and did not grossly vary between AlloDerm and DermaMatrix groups. Findings from the BREASTrial conclude that AlloDerm and DermaMatrix exhibit similar histologic and clinical outcomes. Patient satisfaction is also similar between matrices. Obesity is a predictor of complications, and acellular dermal matrices should be used with caution in these patients.

Broyles et al (2021) conducted a Level 1 prospective, randomized, controlled, multicenter clinical trial to assess complications associated with the use of two human acellular dermal matrices in immediate postmastectomy implant-based breast reconstruction across seven clinical sites. Group A patients received FlexHD Pliable (113 patients with 187 breast reconstructions), and group B patients received AlloDerm RTU (117 patients with 197 breast reconstructions). There was no significant difference with respect to patient demographics, indications, comorbidities, and reconstruction approach between groups. Mean follow-up time was 10.7 ± 3.2 months. There was no statistical difference in the overall matrix-related complications between groups A and B (4.3 percent versus 7.1 percent, p = 0.233). Obesity (OR, 1.14; 95 percent CI, 1.05 to 1.24; p = 0.001) and prepectoral placement of

matrix (OR, 4.53; 95 percent CI, 1.82 to 11.3; p = 0.001) were independently associated with greater risks of overall matrix-related complications. The authors concluded that the results support the use of human acellular dermal matrices in implant-based breast reconstruction and demonstrates no significant difference in matrix-related complication rates between FlexHD Pliable and AlloDerm RTU.

Berger et al (2024) published a multicenter retrospective comparative study of patients undergoing immediate prosthesis-based breast reconstruction (iPBR) with SurgiMend PRS, AlloDerm, or DermACELL between January 2014 to July 2022. Primary outcomes included rates of unplanned explantation and total reconstructive failure. Secondary outcomes included 90-day postoperative complications and long-term rates of capsular contracture development. A total of 738 patients (1228 breasts) underwent iPBR during the study period; 405 patients received DermACELL (54.9%), 231 received AlloDerm (31.3%), and 102 received SurgiMend PRS (13.8%). Rates of short-term complications, total reconstruction failure, reoperation within 90 days, capsular contracture, and unplanned explantation were comparable. These findings remained true upon multivariate analysis accounting for baseline differences between cohorts, whereby ADM type was not an independent predictor of any outcome of interest. Conversely, factors such as body mass index, diabetes mellitus, smoking history, neoadjuvant and adjuvant chemotherapy, adjuvant radiation, skin-sparing mastectomy, Wise pattern and peri-areolar incisions, use of tissue expanders, and a subpectoral plane of insertion were significant predictors of postoperative complications. The authors concluded that low rates of complications support the equivalency of fetal bovine and human-derived ADMs in iPBR. Patient characteristics and operative approach are likely more predictive of postoperative outcomes than ADM derivative alone.

Asaad et al (2023) performed a retrospective review of consecutive patients who underwent immediate prepectoral IBR from January of 2018 through December of 2019. Surgical outcomes and PROs (using the BREAST-Q) were compared among the AlloDerm, SurgiMend, and Dermacell ADMs. Overall, 557 breasts (383 patients) were included (78.6% AlloDerm, 14% SurgiMend, 7.4%Dermacell). Patients in the Dermacell group were older (P = 0.001) and more likely to have diabetes (P = 0.001) compared with AlloDerm and SurgiMend patients. Other patient characteristics were similar among the three groups. The overall complication rate was equivalent among the three ADM groups (AlloDerm 27% vs SurgiMend 33% vs Dermacell 39%; P = 0.209). Multivariable frailty models demonstrated that the type of ADM was not significantly associated with overall complications, infection, major complications, or device explantation. BREAST-Q satisfaction with breasts, psychosocial well-being, and sexual well-being were also similar among the three ADM groups (P =0.109, P = 0.439, P = 0.152, respectively). The authors concluded this study shows three (3) of the most commonly used ADMs in the United States have similar surgical outcomes and PROs when used for prepectoral IBR. No significant differences in infection, overall complications, or device removal rates were identified among AlloDerm, SurgiMend, and Dermacell.

A retrospective review compared complication rates following breast reconstruction with AlloDerm or FlexHD in 382 consecutive women (547 breasts) (Liu 2014). A total of 81% of the patients underwent immediate reconstruction; 165 used AlloDerm, and 97 used FlexHD. Mean follow-up was 6.4 months. Compared with breast reconstruction without use of AlloDerm or FlexHD, ADM had a

higher rate of delayed healing (20.2% versus 10.3%), although this finding might be related to differences in fill volumes. In univariate analysis, there were no significant differences in complications (return to the operating room, surgical site infection, seroma, hematoma, delayed healing, or implant loss) between AlloDerm and FlexHD. In multivariate analysis, there were no significant differences between AlloDerm and FlexHD for the return to the operating room, surgical site infection, seroma, or delayed healing. Independent risk factors for implant loss included the use of FlexHD, single-stage reconstruction, and smoking.

Another retrospective review compared complication rates following use of AlloDerm (n=136) or FlexHD (n=233) in a consecutive series of 255 patients (369 breasts) (Seth 2013). Total complication rates for the two products were similar (19.1% for AlloDerm and 19.3% for FlexHD). Analysis by type of complication showed no significant difference between the products, and regression analysis controlling for differences in baseline measures found that the type of ADM was not a risk factor for any complication.

A retrospective review of complication rates when AlloDerm (n=49), DermaMatrix (n=110), or FlexHD (n=62) was used for tissue expander breast reconstruction (Brooke 2012). Clinically significant complications were defined as cellulitis, abscess, seroma, expander leak or puncture, skin necrosis, wound dehiscence, or hematoma. The total clinically significant complication rate was 22% with AlloDerm, 15% with DermaMatrix, and 16% with FlexHD (not significantly different). Infectious complication rates for the three products were the same at 10%. When compared with breast reconstruction without an ADM (n=64), there was no significant difference in the total complication rate (17% vs 11%), but there was a trend toward a higher incidence of infectious complications (10% vs 2%, p=0.09).

Nasal Repairs, Hernia Repair, and Parotidectomy (Alloderm)

There is limited scientific evidence in the form of retrospective case series (Kissane 2012) to support the use of AlloDerm in rare cases of non-primary hernia repair when chronic infection contraindicates the use of mesh or other conventional repair.

Literature regarding the use of AlloDerm in parotidectomy also consists of small case series; however, the studies support that AlloDerm is beneficial in preventing Frey's syndrome after parotidectomy. A network meta-analysis sought to determine the best method for prevention of Frey syndrome after parotidectomy (Mashrah 2021). Thirty-four studies (n = 2987 patients) with five interventions, namely Alloderm (ADM), temporoparietal fascia (TPF), sternocleidomastoid muscle (SCM), superficial musculoaponeurotic system (SMAS), and free fat graft (FFG), were compared together and with no interposition barrier (NB). The results of NMA showed a statistically significant reduction in both subjective Frey syndrome (SFS) and objective Frey syndrome (OFS) when ADM, TPF, SMAS, FFG, and SCM were compared with NB. No statistical differences were observed when comparing ADM, SCM, SMAS, FFG, and TPF. TPF ranked the best of all treatments (59.4%) and was associated with the least incidence of SFS; whereas ADM ranked the best of all treatments (61.1%) and was associated with the least incidence of OFS.

A sponsored, retrospective study of real-world use of AlloDerm acellular dermal matrix in head and neck procedures in the U.S. was conducted for the period of October 2015 to March 2022

(Dominguez 2024). Descriptive statistics were used to describe surgery types and 30-day follow-up reoperations, graft complications, and all-cause healthcare resource utilization (HCRU). Among 431 patients (51.7% women), mean (SD) age was 52.2 (15.8) years. AlloDerm was most used with oral cavity reconstruction (35.3%), septal perforation repair/rhinoplasty (16.5%), and parotidectomy (13.0%). Most procedures were performed in outpatient settings (hospital, 90.0%; ambulatory surgical center, 8.6%). Over 30 days, less than 1% of patients (4 of 431) required reoperation with AlloDerm; 0.5% (2 of 431) had graft-related complications. Most (75.6%) patients had outpatient visits; few had an emergency room visit (7.9%) or inpatient claim (3.0%). The authors concluded real-world evidence indicates that AlloDerm is used in head- and neck-related procedures in US adults. Post-procedure complications and reoperations were uncommon during the follow-up period.

Burns (Integra Dermal Regeneration Matrix (Omnigraft), Biobrane, Epicel)

Carsin et al (2000) reported 5-year experience in a large, single center series of severely burned and otherwise traumatized patients given cultured epithelial autografts (CEA) (Epicel) from a single commercial laboratory. From 1991 to 1996, CEA were applied to a mean 37+/-17% of total body surface area (TBSA) of 30 patients. These patients had 78+/-10% average burn size, 65+/-16% average third-degree burn size, 90% prevalence of endoscopically confirmed inhalation injury and 37% prevalence of other serious conditions. CEA achieved permanent coverage of a mean 26+/-15% of TBSA, an area greater than that covered by conventional autografts (a mean 25+/-10% of TBSA). Survival was 90% of these severely burned and otherwise traumatized patients. Final CEA take was a mean 69+/-23%. In subset analyses, only younger age was significantly associated with better CEA take ($p = 0.0001$ in univariate analysis, $p<0.04$ in multivariate analysis, Student's t-test). Epicel CEA successfully provided extensive, permanent burn coverage in severely traumatized patients, proving an important adjunct to achievement of a high survival rate in a patient population whose prognosis previously had been poor. The authors concluded that CEA appeared to have a very high beneficial value in the management of burns >60% TBSA and in some cases it was very likely that CEA was a life-saving treatment.

Biobrane (Dow Hickman/Bertek Pharmaceuticals, Sugar Land, TX), a semi-permeable silicone device embedded with a nylon mesh and a porcine-derived collagen matrix, offers a promising alternative with advantages such as improved wound healing, reduced pain, and fewer dressing changes. A systematic review and meta-analysis (Jabarkhyl 2025) assessed the efficacy of Biobrane. Primary outcomes included burn wound healing time, hospital length of stay and infection rate, while secondary outcomes assessed the need for split-thickness skin grafts (STSGs), pain, and the number of dressing changes. Their data encompassed 781 burn wounds across 12 studies. The results showed that Biobrane significantly shortened wound healing time (mean difference, MD: 5.168 days, $p = 0.001$) and hospital length of stay (MD: 2.009 days, $p < 0.001$) compared to standard dressings. The infection rate was comparable (odds ratio, OR: 2.457, $p = 0.132$), and there was no difference in the requirement for STSGs (OR: 0.965, $p = 0.956$). This systematic review and meta-analysis demonstrate that Biobrane is an effective treatment for superficial pediatric burn injuries, offering faster wound healing, reduced pain and shorter hospital stays compared to traditional dressings.

A systematic review and meta-analysis were conducted to evaluate the role of various dermal

regeneration templates (DRTs) in comparison with split-thickness skin grafting in managing acute burn injuries after excision and debridement (Alkhonizy 2024). A total of 28 randomized clinical trials were assessed, encompassing a wide array of DRTs. The most frequently evaluated DRT, Integra Dermal Regeneration Template, not only showed potential for peripheral nerve reinnervation but also indicated a potential for a longer initial healing time, aligning with previous studies highlighting its efficacy in reducing scar formation and wound contracture. TransCyte displayed impressive rates of re-epithelialization and was found suitable for acute partial-thickness burns. Moreover, its low infection rate substantiates its antimicrobial properties and aligns with prior research.

The ReCell device has been evaluated in 2 manufacturer (AVITA Medical) sponsored RCTs (Holmes 2018, 2019). One RCT evaluated ReCell as an adjunct to meshed autologous skin grafting and the other compared ReCell head-to-head with skin grafting. Although the ReCell device was comparable to standard care on outcomes such as complete wound closure, confidence in the strength of the overall body of evidence is limited by individual study limitations and heterogeneity of populations, interventions, and outcome measures across studies. Additional RCT evidence regarding the intended use population is needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Manning et al (2022) conducted a randomized, open-label trial with one of the investigators of the study being the developer of ReCell and the products were donated from their foundation. Forty-nine eligible foot wounds in 45 participants were randomized to receive an application of non-cultured autologous skin cells ("spray-on" skin; ReCell) or standard care interventions for large (>6 cm2), adequately vascularized wounds. A total of 32 (65.3%) index wounds were completely healed at 6 months, including 16 of 24 (66.7%) in the spray-on skin group and 16 of 25 (64.0%) in the standard care group (unadjusted OR [95% CI]: 1.13 (0.35-3.65), P = .845). Lower body mass index (P = .002) and non-plantar wounds (P = .009) were the only patient- or wound-related factors associated with complete healing at 6 months. The authors concluded that spray-on skin resulted in high rates of complete healing at 6 months in patients with large diabetes-related foot wounds but was not significantly better than standard care.

PROFESSIONAL GUIDELINE(S)

In February 2020, the Agency for Health Research and Quality (AHRQ) completed a technology assessment addressing Skin Substitutes for Treating Chronic Wounds. The assessment addresses 76 products commercially available in the U.S. that are used to manage or treat chronic wounds and are regulated by FDA. Based on FDA regulations, skin substitutes can be organized into four groups:

- human-derived products regulated as HCT/Ps (human cells, tissues, and tissue-based products)
- human- and human/animal-derived products regulated through PMA or humanitarian device exemption (HDE)
- animal-derived products regulated under the 510(k) process
- synthetic products regulated under the 510(k) process

Of those included in the tech assessment, 68 (89%) were categorized as acellular dermal substitutes,

mostly replacements from human placental membranes and animal tissue sources. Three systematic reviews and 22 RCTs examined use of 16 distinct skin substitutes, including acellular dermal substitutes, cellular dermal substitutes, and cellular epidermal and dermal substitutes in diabetic foot ulcers, pressure ulcers, and venous leg ulcers. Twenty-one ongoing clinical trials (all RCTs) examined an additional nine skin substitutes with similar classifications. Studies rarely reported clinical outcomes, such as amputation, wound recurrence at least two weeks after treatment ended, or patient related outcomes, such as return to function, pain, exudate, and odor. The large majority of skin substitute products listed in the report did not have efficacy data from RCTs. Industry funds most published studies and funded 20 of 22 RCTs included in this report, which raises significant concerns about possible publication bias or selective outcome reporting. The clearest implications of this Technical Brief are the lack of studies examining the effectiveness of most skin substitute products and the need for better designed and better reported studies providing more clinically relevant data.

The National Institute for Health and Care Excellence (NICE 2019) guidelines for diabetic foot problems: prevention and management recommend the following:

- Consider dermal or skin substitutes as an adjunct to standard care when treating diabetic foot ulcers, only when healing has not progressed and on the advice of the multidisciplinary foot care service.

NICE guidance on the ReCell system for treating skin loss, scarring, and depigmentation after burn injury (2020) recommended that there is insufficient evidence on its use in clinical practice, particularly in relation to which patients might benefit most from its use, to support the case for its routine adoption in the NHS.

The Association of Breast Surgery and the British Association of Plastic, Reconstructive and Aesthetic Surgeons published joint practice guidelines (Whisker 2021) regarding biological and synthetic mesh assisted breast reconstruction procedures. They make the following recommendations:

- Biological or synthetic mesh may be used in the following settings:
    - Implant-based total breast reconstruction after mastectomy; both for breast cancer patients and in women undergoing risk-reducing surgery
        - Immediate reconstruction
        - Total pre-pectoral or partially sub-pectoral reconstruction
    - Revision of cosmetic concerns following breast surgery
        - In the clinical setting of revising implant-based reconstructions e.g., correction of "bottoming out," symmastia and implant rippling
        - Revision of cosmetic concerns following oncoplastic breast conserving surgery e.g., correction of "bottoming out" after mammoplasty or mastopexy
    - Congenital asymmetry/deformity surgery

- There are a large number of products available, and the product range is rapidly evolving. There is no clear consensus on the ideal biological or synthetic mesh or evidence to inform mesh selection. The guideline group recommends consideration of the following when selecting a product:
    - Biological versus synthetic
        - Biological products (e.g., ADMs) are usually animal derived. Ensure the patient is informed and comfortable with the mesh origin.
        - Synthetic mesh may be composed from absorbable and/or non-absorbable materials.

The International Society for Burn Injury (ISBI) published practice guidelines for burn care (2016) which make the following recommendations:

- Modern dressings and biologic membranes are the preferred dressing choices as they ensure the best means against infection as well as scar quality outcome.
- Raw area, similar to the superficial partial thickness burn and graft donor site, is an area of the body that lacks epithelial covering. Raw areas should be dressed with a closed technique. Biologic dressings seem to be superior to nonbiologic dressings. Type (temporary or semi-permanent) and frequency of dressing are decided according to the wound condition and availability of these products.
- Amniotic membrane—whether it was used as fresh, lyophilized, and/or irradiated—showed superiority in most of the studies compared to conventional dressing, particularly in chronic burn wounds. Amniotic membrane was very effective, even with resistant strains like Pseudomonas, in areas with scarce blood supply, such as the cornea.
- After excision or debridement of the deep burn wound, it is essential that the wound is covered with autograft skin or an appropriate skin substitute. A wound too large to be safely repaired with autograft should be repaired with allograft or skin substitute. Failure to achieve adequate wound coverage after excision commonly results in invasive infection, or at best, desiccation of the exposed wound surface.
- Five substitute alternatives can be used to replace autograft following excision or debridement of deep burn wounds. These alternatives are described below.
    - Human allograft skin
        - Cryopreserved allograft is widely used and can provide good quality temporary skin cover for excised wounds for several weeks, until rejection occurs. Cryopreservation allows full donor-virus testing to be carried out so as to avoid risk of transmission of illness. Fresh allograft is the most effective skin replacement, and takes for many weeks, but fresh cadaveric allograft is seldom readily available. Fresh donor-related allograft (typically from a parent) may be suitable for small children but is not widely used. Glycerol-preserved or

lyophilized skin is nonviable, and functions as a very good biologic dressing rather than a vascularized graft. It can be very effective as a short-term cover (up to approximately 2 weeks) for excised wounds.

- Dermal regeneration matrices (or templates)
    - Following the successful introduction of a bovine collagen–based dermal regeneration template, a number of dermal regeneration products have been used. These biosynthetic products have been derived from bovine collagen, human allograft dermis, and porcine dermis, and also from synthetic substances. These acellular products are commonly based on collagen and produce a matrix on which a "neodermis" may regenerate. Broadly, these acellular products can be divided into those for either two- or one-stage use. The two-stage products are most suitable for acute major burns, as they provide temporary wound closure, prior to secondary autografting later with thin autograft or cultured cells (for instance: with Integra short-term wound closure is achieved with a surface silicone layer, which is removed prior to autografting at approximately 3 weeks, when ideally the patient is more stable). The one-stage use products offer the advantage of enhanced dermal reconstruction with very thin autograft harvest, but if used immediately after burn injury, they require a donor site of the full extent of the wound. Of techniques evolved to date for major burn injuries, the dermal regeneration matrices are probably the closest to producing a widely available, reliable "synthetic skin. However, they do require full coverage with autograft epithelium. Disadvantages of the dermal regeneration matrices include a higher risk of problems with infection than with autograft or allograft, and relatively high cost which precludes anything but the most occasional use in an RLS.
- Xenograft-derived temporary wound coverage
    - The most common source of xenograft material for use in burns has been porcine-derived materials. These include untreated pigskin; cryopreserved pigskin; lyophilized porcine dermis; and popular biosynthetic products composed of porcine collagen with nylon and silicone. Considerable evidence supports the value of many of these materials when used as dressings in treatment of partial thickness wounds. For excised deep burn wounds, these xenograft products produce only short-term reliable wound cover (a few days). This can be useful in getting a patient safely through a major burn excision, before later application of definitive wound cover; but if used for more prolonged periods on excised wounds, the risks of invasive infection are higher.
- Amniotic membrane
    - Amniotic membrane is potentially universally available as good short-term coverage for excised wounds, and as a biologic dressing. In some RLS, its availability has been restricted by the cost of virus testing and by resultant

practical barriers to its use. Amniotic membrane can be stored as cryopreserved, irradiated, or glycerol-preserved and in many parts of the world this has proved a useful technique for short-term coverage of excised wounds.

- Cell-based therapies
    - Cultured epithelial cells have been widely used in burn treatment, both as autograft and allograft. Autograft takes time to grow, so it is not available as an immediate skin substitute for early major burn excision. Although cultured epithelium has gained acceptance for many indications in burn-wound management, problems with failure of adhesion of cultured epithelium to full thickness wound beds and poor durability of cover mean that cultured cells have not achieved a consistently effective role as the sole skin replacement for full thickness wounds. Cultured epithelium serves best where a native or regenerated dermis is present in the wound bed. Similarly, autologous epithelial cells in suspension, or stem cells of a variety of origins, have been shown to have significant potential for enhanced healing of a variety of burn wounds: partial thickness wounds, wounds covered with meshed skin grafts, or wounds where dermis (native or regenerated) is present. These techniques have huge potential for skin replacement therapies in future.

The Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine published joint clinical practice guidelines for the management of the diabetic foot (Hingorani 2016). Their recommendations are as follows:

- "For DFUs that fail to demonstrate improvement (>50% wound area reduction) after a minimum of 4 weeks of standard wound therapy, we recommend adjunctive wound therapy options. These include negative pressure therapy, biologics (platelet-derived growth factor [PDGF], living cellular therapy, extracellular matrix products, amnionic membrane products), and hyperbaric oxygen therapy. Choice of adjuvant therapy is based on clinical findings, availability of therapy, and cost-effectiveness; there is no recommendation on ordering of therapy choice. Re-evaluation of vascular status, infection control, and off-loading is recommended to ensure optimization before initiation of adjunctive wound therapy (Grade 1B)."
- "Standard, comprehensive care should include wound off-loading, local wound debridement, control of edema, control of bioburden, and wound moisture balance with appropriate dressings. Standard of care for diabetic foot ulcerations will lead to improvement in the majority of cases, and only in those cases without improvement should adjunctive modalities be used."
- "We suggest consideration of living cellular therapy using a bilayered keratinocyte/fibroblast construct or a fibroblast-seeded matrix for treatment of DFUs when recalcitrant to standard therapy (Grade 2B)."
- "Apligraf (Organogenesis, Canton, Mass) is a cultured bilayer skin substitute originating from neonatal foreskin. A bovine collagen lattice is used as a base to support the organization of dermal fibroblasts and epithelial cells seeded after expansion of the separated neonatal cells. A

layer of allogeneic keratinocytes is cultured over the fibroblast layer to form a stratified epidermis. The bilayer has a structure similar to human skin, with the absence of hair follicles or sweat glands. The growth factors and cytokines secreted by the cellular components of Apligraf include fibroblast growth factor, VEGF, PDGF, transforming growth factor b, and multiple interleukins, paralleling those secreted by healthy human skin. The product requires a well-granulated wound bed in which exudate and bacterial levels have been controlled to yield positive results."

- "Dermagraft (Organogenesis) is an allogeneic dermal fibroblast culture derived from human neonatal foreskin samples and grown on a biodegradable scaffold. The resulting three-dimensional matrix can be implanted into chronic nonhealing wounds to supply functional fibroblasts and their corresponding expressed proteins. The scaffold biodegrades during a 1- to 2-week period, leaving behind only cellular components and proteins. Several in vitro studies have evaluated the ability of Dermagraft to express clinically significant quantities of growth factors after cryopreservation and thawing. VEGF, PDGF-A, and insulin-like growth factor I were all found to recover to significant levels as measured by enzyme-linked immunosorbent assay in wounds to which Dermagraft was applied."
- "We suggest consideration of the use of extracellular matrix products employing acellular human dermis or porcine small intestinal submucosal tissue as an adjunctive therapy for DFUs when recalcitrant to standard therapy (Grade 2C)."
- "A variety of tissue constructs have recently become available, approved through the 510K mechanism as adjunctive therapies for the healing of chronic wounds including DFUs. This includes products incorporating human tissue (acellular dermis, amniotic membrane, cryopreserved skin, others) or animal tissue (bladder tissue, pericardial tissue, intestinal submucosa). Of the multitude of these products, only two have been found to provide benefit compared with standard DFU treatment. A porcine small intestinal submucosa (SIS) construct (OASIS; Cook Biotech, West Lafayette, Ind) has been tested in a prospective randomized trial."
- "An acellular human dermal matrix (Graftjacket; Wright Medical Technology, Memphis, Tenn) was studied in a prospective randomized multicenter trial in 87 patients with DFUs compared with standard care. Significantly more wounds treated with the human dermal matrix healed at 12 weeks (69.6%) than with control."
- "We recommend that patients with DFU have pedal perfusion assessed by ABI, ankle and pedal Doppler arterial waveforms, and either toe systolic pressure or transcutaneous oxygen pressure (TcPO2) annually (Grade 1B)."

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) does not refer to any single product or class of products as "skin substitutes". Products in this review cover products that do not require FDA approval or clearance as well as a number of products cleared through the 510(k) pathway with a variety of FDA product codes. A large number of artificial skin and soft-tissue products are commercially available or in development. Commercial availability is not a reflection of a product's

regulatory status.

Human Amniotic Membrane and Acellular Dermal Matrix Products

Allograft ADM products derived from donated cadaveric human skin tissue are supplied by tissue banks compliant with standards of the American Association of Tissue Banks and FDA guidelines. The processing removes the cellular components (i.e., epidermis, all viable dermal cells) that can lead to rejection and infection. ADM products from human skin tissue are regarded as minimally processed and not significantly changed in structure from the natural material; FDA classifies ADM products as banked human tissue and, therefore, not requiring FDA approval for homologous use.

Human amniotic membrane is classified by the FDA as banked human tissue and, therefore, does not require FDA approval.

AlloDerm (LifeCell Corp.) is an ADM (allograft) tissue-replacement product created from native human skin and processed so that the basement membrane and cellular matrix remain intact. Originally, AlloDerm required refrigeration and rehydration before use. It is currently available in a ready-to-use product stored at room temperature. An injectable micronized form of AlloDerm (Cymetra) is available. AlloDerm is classified by the FDA as human tissue and is approved for use in burns and full-thickness wounds.

AlloPatch (Musculoskeletal Transplant Foundation) is an acellular human dermis allograft derived from the reticular layer of the dermis and marketed for wound care. This product is also marketed as FlexHD for post mastectomy breast reconstruction.

Cortiva (previously marketed as AlloMax Surgical Graft and before that NeoForm) is an acellular non-cross-linked human dermis allograft.

DermACELL (LifeNet Health) is an allogeneic ADM processed with proprietary technologies MATRACELL and PRESERVON.

DermaMatrix (Synthes) is a freeze-dried ADM derived from donated human skin tissue. DermaMatrix Acellular Dermis is processed by the Musculoskeletal Transplant Foundation.

Epicord Dehydrated Human Umbilical Cord (DHUC) Allograft (MIMEDX Group, Inc.) is a placental-based tissue product that acts as a barrier and provides a protective environment to help support the healing process. It is comprised of an extracellular matrix of hyaluronic acid (HA) and collagen. Epicord is regulated as a human cell, tissue, or cellular or tissue-based product.

EpiFix (MIMEDX Group, Inc.) is a placental tissue allograft composed of dehydrated human amnion/chorion membrane (DHACM). EpiFix is regulated as a human cell, tissue, or cellular or tissue-based product.

FlexHD and the newer formulation FlexHD® Pliable (Musculoskeletal Transplant Foundation) are acellular hydrated reticular dermis allograft derived from donated human skin.

GRAFIX (Smith and Nephew) lyopreserved and cryopreserved placental membrane products and surgical applications retain all components of placental tissue, including native placental cells.

GraftJacket Regenerative Tissue Matrix (also called GraftJacket Skin Substitute; KCI) is an acellular

regenerative tissue matrix that has been processed from human skin supplied from U.S. tissue banks. The allograft is minimally processed to remove the epidermal and dermal cells while preserving dermal structure. GraftJacket Xpress is an injectable product.

TheraSkin (LifeNet Health) is a cryopreserved split-thickness human skin allograft composed of living fibroblasts and keratinocytes and an extracellular matrix in epidermal and dermal layers. TheraSkin® is derived from human skin allograft supplied by tissue banks compliant with the American Association of Tissue Banks and FDA guidelines. It is considered a minimally processed human cell, tissue, and cellular- and tissue-based product by the FDA.

Although frequently used by surgeons for breast reconstruction, FDA does not consider this homologous use and has not cleared or approved any surgical mesh device (synthetic, animal collagen-derived, or human collagen-derived) for use in breast surgery. The indication of surgical mesh for general use in "Plastic and reconstructive surgery" was cleared by the FDA before surgical mesh was described for breast reconstruction in 2005. FDA states that the specific use of surgical mesh in breast procedures represents a new intended use and that a substantial equivalence evaluation via 510(k) review is not appropriate and a pre-market approval evaluation is required.

The FDA issued a statement on March 31, 2021, stating while used for other types of reconstruction, the FDA has not cleared or approved ADM for use in breast reconstruction. The statement informed patients, caregivers, and health care providers that certain ADM products used in implant-based breast reconstruction may have a higher chance for complications or problems. The FDA requests prompt reporting of adverse events to help evaluate the risks.

FDA product codes: FTM, OXF.

<u>Xenogeneic Products</u>

Oasis Wound Matrix (Cook Biotech) is a collagen scaffold (extracellular matrix) derived from porcine small intestinal submucosa. In 2000, it was cleared for marketing by the FDA through the 510(k) process for the management of partial- and full-thickness wounds, including pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled undermined wounds, surgical wounds, trauma wounds, and draining wounds.

PriMatrix (TEI Biosciences; a subsidiary of Integra Life Sciences) is a xenogeneic ADM processed from fetal bovine dermis. It was cleared for marketing by the FDA through the 510(k) process for partial- and full-thickness wounds; diabetic, pressure, and venous stasis ulcers; surgical wounds; and tunneling, draining, and traumatic wounds.

The FDA issued a class II recall for PriMatrix on September 30, 2024, for possible out of specification endotoxin test results due to issues with in-process and finished goods endotoxin testing.

SurgiMend PRS (TEI Biosciences, a subsidiary of Integra Life Sciences) is a xenogeneic ADM processed from fetal and neonatal bovine dermis.

FDA Product codes: KGN, FTL, FTM.

<u>Living Cell Therapy</u>

Apligraf (Organogenesis) is a bilayered living cell therapy composed of an epidermal layer of living human keratinocytes and a dermal layer of living human fibroblasts. Apligraf is supplied as needed, in 1 size, with a shelf-life of 10 days. In 1998, it was approved by the FDA for use in conjunction with compression therapy for the treatment of noninfected, partial- and full-thickness skin ulcers due to venous insufficiency and in 2001 for full-thickness neuropathic diabetic lower-extremity ulcers nonresponsive to standard wound therapy.

Dermagraft (Organogenesis) is composed of cryopreserved human-derived fibroblasts and collagen derived from newborn human foreskin and cultured on a bioabsorbable polyglactin mesh scaffold. Dermagraft has been approved by the FDA for repair of diabetic foot ulcers.

Epicel (Genzyme Biosurgery) is an epithelial autograft composed of a patient's own keratinocytes cultured ex vivo and is FDA-approved under a humanitarian device exemption for the treatment of deep dermal or full-thickness burns comprising a total body surface area of 30% or more. It may be used in conjunction with split-thickness autografts or alone in patients for whom split-thickness autografts may not be an option due to the severity and extent of their burns.

FDA product codes: FTM, PFC, OCE, ODS.

Autologous Cell Harvesting Device

Recell (Avita Medical) was initially approved by the FDA in September 2018 under the premarket approval (PMA) process (PMA BP170122). It is an autologous cell harvesting device indicated for the treatment of acute partial-thickness thermal burn wound when used by an appropriately licensed healthcare professional at the patient's point of care to prepare autologous RES Regenerative Epidermal Suspension. The initial indication was for use in patients 18 years of age and older in combination with meshed autografting. Subsequently, indications were expanded to include direct application to acute partial-thickness thermal burn wounds in patients 18 years of age and older or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric as well as adult patients and for and full-thickness skin defects after traumatic avulsion (e.g., degloving) or surgical excision (e.g., necrotizing tissue infection) or resection (e.g., skin cancer) in patients 15 years of age and older.

FDA product code: QCZ.

Biosynthetic Products

Biobrane/Biobrane-L (Smith and Nephew) is a biosynthetic wound dressing constructed of a silicon film with a nylon fabric partially embedded into the film. The fabric creates a complex 3-dimensional structure of trifilament thread, which chemically binds collagen. Blood/sera clot in the nylon matrix, adhering the dressing to the wound until epithelialization occurs. Biobrane was granted pre-market approval by the FDA as a temporary covering of full thickness burns until autografting is clinically appropriate.

Integra Dermal Regeneration Template (also marketed as Omnigraft Dermal Regeneration Matrix; Integra Life Sciences) is a bovine, collagen/glycosaminoglycan dermal replacement covered by a silicone temporary epidermal substitute. It was approved by the FDA for use in the post excisional

treatment of life-threatening full-thickness or deep partial-thickness thermal injury where sufficient autograft is not available at the time of excision or not desirable because of the physiologic condition of the patient, for the repair of scar contractures when other therapies have failed.

In January 2016, the FDA approved the Integra Dermal Regeneration Template, marketed as Omnigraft, for use in the treatment of partial- and full-thickness neuropathic diabetic foot ulcers that are greater than six weeks in duration, with no capsule, tendon, or bone exposed, when used in conjunction with standard diabetic ulcer care.

TransCyte (Advanced Tissue Sciences) consists of human dermal fibroblasts grown on nylon mesh, combined with a synthetic epidermal layer, and was approved by the FDA in 1997. TransCyte is intended as a temporary covering over burns until autografting is possible. It can also be used as a temporary covering for some burn wounds that heal without autografting.

FDA product codes: FRO, MDD, MGR.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
15011 (E/I)	Harvest of skin for skin cell suspension autograft; first 25 sq cm or less
15012 (E/I)	Harvest of skin for skin cell suspension autograft; each additional 25 sq cm or part thereof (List separately in addition to code for primary procedure)
15013 (E/I)	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin
15014 (E/I)	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; each additional 25 sq cm of harvested skin or part thereof (List separately in addition to code for primary procedure)
15015 (E/I)	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; first 480 sq cm or less
15016 (E/I)	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)
15017 (E/I)	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 480 sq cm or less

Code	Description
15018 (E/I)	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure)
15271	Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15272	each additional 25 sq cm wound surface area, or part thereof
15273	Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15274	each additional 100 sq cm wound surface area, or part thereof, or each additional 1% body area of infants and children, or part thereof
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15276	each additional 25 sq cm wound surface area, or part thereof
15277	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
15278	each additional 100 sq cm wound surface area, or part thereof, or each additional 1% body area of infants and children, or part thereof
15777	Implantation of biologic implant (e.g., acellular dermal matrix) for soft tissue reinforcement (i.e., breast, trunk)
15778	Implantation of absorbable mesh or other prosthesis for delayed closure of defect(s) (i.e., external genitalia, perineum, abdominal wall) due to soft tissue infection or trauma

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HCPCS Codes

Code	Description
A2001 (E/I)	Innovamatrix ac, per sq cm
A2002 (E/I)	Mirragen advanced wound matrix, per sq cm
A2004 (E/I)	Xcellistem, 1 mg
A2005 (E/I)	Microlyte matrix, per sq cm
A2007 (E/I)	Restrata, per sq cm
A2008 (E/I)	TheraGenesis, per sq cm
A2009 (E/I)	Symphony, per sq cm
A2010 (E/I)	Apis, per sq cm
A2011 (E/I)	Supra SDRM, per sq cm

Code	Description
A2012 (E/I)	SUPRATHEL, per sq cm
A2013 (E/I)	Innovamatrix FS, per sq cm
A2014 (E/I)	Omeza collagen matrix, per 100 mg
A2015 (E/I)	Phoenix wound matrix, per sq cm
A2016 (E/I)	PermeaDerm B, per sq cm
A2017 (E/I)	PermeaDerm glove, each
A2018 (E/I)	PermeaDerm C, per sq cm
A2019 (E/I)	Kerecis Omega3 MariGen shield, per sq cm
A2020 (E/I)	AC5 Advanced Wound System (AC5)
A2021 (E/I)	NeoMatrix, per sq cm
A2026 (E/I)	Restrata MiniMatrix, 5 mg
A2027 (E/I)	MatriDerm, per sq cm
A2028 (E/I)	MicroMatrix Flex, per mg
A2029 (E/I)	MiroTract Wound Matrix sheet, per cc
A2030 (E/I)	Miro3d fibers, per milligram
A2031 (E/I)	Mirodry wound matrix, per square centimeter
A2032 (E/I)	Myriad matrix, per square centimeter
A2033 (E/I)	Myriad morcells, 4 milligrams
A2034 (E/I)	Foundation drs solo, per square centimeter
A2035 (E/I)	Corplex p or theracor p or allacor p, per milligram
A2036 (E/I)	Cohealyx Collagen Dermal Matrix, per sq cm
A2037 (E/I)	G4Derm Plus, per ml
A2038 (E/I)	MariGen Pacto, per sq cm
A2039 (E/I)	InnovaMatrix FD, per sq cm
A4100	Skin substitute, FDA-cleared as a device, not otherwise specified
C5271	Application of low-cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
C5272	Application of low-cost skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure)
C5273	Application of low-cost skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
C5274	each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof
C5275	Application of low-cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
C5276	each additional 25 sq cm or less wound surface area, or part thereof

Code	Description
C5277	Application of low-cost skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; first 100 sq cm wound surface area, or 1% of body area of infants and children
C5278	each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof
C9354 (E/I)	Acellular pericardial tissue matrix of non-human origin (Veritas), per sq cm
C9356 (E/I)	Tendon, porous matrix of cross-linked collagen and glycosaminoglycan matrix (TenoGlide Tendon Protector Sheet), per sq cm
C9358	Dermal substitute, native, nondenatured collagen, fetal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm
C9360	Dermal substitute, native, nondenatured collagen, neonatal bovine origin (SurgiMend Collagen Matrix), per 0.5 sq cm
C9363 (E/I)	Skin substitute (Integra Meshed Bilayer Wound Matrix), per sq cm
C9364 (E/I)	Porcine implant, Permacol, per sq cm
Q4100	Skin substitute, not otherwise specified
Q4101	Apligraf, per sq cm
Q4102	Oasis wound matrix, per sq cm
Q4103 (E/I)	Oasis burn matrix, per sq cm
Q4104 (E/I)	Integra bilayer matrix wound dressing (BMWD), per square cm
Q4105	Integra dermal regeneration template (DRT) or Integra Omnigraft dermal regeneration matrix, per sq cm
Q4106	Dermagraft, per sq cm
Q4107	GRAFTJACKET, per sq cm
Q4108	Integra matrix, per sq cm
Q4110 (E/I)	PriMatrix, per sq cm
Q4111 (E/I)	GammaGraft, per sq cm
Q4112 (E/I)	Cymetra, injectable, 1 cc
Q4113 (E/I)	GRAFTJACKET XPRESS, injectable, 1 cc
Q4114 (E/I)	Integra flowable wound matrix, injectable, 1 cc
Q4115 (E/I)	AlloSkin, per sq cm
Q4116	AlloDerm, per sq cm
Q4117 (E/I)	HYALOMATRIX, per sq cm
Q4118 (E/I)	MatriStem micromatrix, 1 mg
Q4121	TheraSkin, per sq cm
Q4122	DermACELL, DermACELL AWM or DermACELL AWM Porous, per sq cm
Q4123 (E/I)	AlloSkin RT, per sq cm
Q4124 (E/I)	OASIS ultra tri-layer wound matrix, per sq cm
Q4125 (E/I)	ArthroFlex, per sq cm
Q4126 (E/I)	MemoDerm, DermaSpan, TranZgraft or IntéguPly, per sq cm

Code	Description
Q4127 (E/I)	Talymed, per sq cm
Q4128	FlexHD, AllopatchHD, per sq cm
Q4130 (E/I)	Strattice TM, per sq cm
Q4132	Grafix Core and GrafixPL Core, per sq cm
Q4133	Grafix PRIME, GrafixPL PRIME, Stravix and StravixPL, per sq cm
Q4134 (E/I)	HMatrix, per sq cm
Q4135 (E/I)	Mediskin, per sq cm
Q4136 (E/I)	E-Z Derm, per sq cm
Q4137 (E/I)	AmnioExcel, AmnioExcel Plus or BioDExcel, per sq cm
Q4138 (E/I)	BioDFence DryFlex, per sq cm
Q4139 (E/I)	AmnioMatrix or BioDMatrix, injectable, 1 cc
Q4140 (E/I)	BioDFence, per sq cm
Q4141 (E/I)	AlloSkin AC, per sq cm
Q4142 (E/I)	XCM biologic tissue matrix, per sq cm
Q4143 (E/I)	Repriza, per sq cm
Q4145 (E/I)	EpiFix, injectable, 1 mg
Q4146 (E/I)	Tensix, per sq cm
Q4147 (E/I)	Architect, Architect PX, or Architect FX, extracellular matrix, per sq cm
Q4148 (E/I)	Neox Cord 1K, Neox Cord RT, or Clarix Cord 1K, per sq cm
Q4149 (E/I)	Excellagen, 0.1 cc
Q4150 (E/I)	AlloWrap DS or dry, per sq cm
Q4151	AmnioBand or Guardian, per sq cm
Q4152 (E/I)	DermaPure, per sq cm
Q4153 (E/I)	Dermavest and Plurivest, per sq cm
Q4154	Biovance, per sq cm
Q4155 (E/I)	Neox Flo or Clarix Flo, 1 mg
Q4156 (E/I)	Neox 100 or Clarix 100, per sq cm
Q4157 (E/I)	Revitalon, per sq cm
Q4158 (E/I)	Kerecis Omega3, per sq cm
Q4159 (E/I)	Affinity, per sq cm
Q4160 (E/I)	NuShield, per sq cm
Q4161 (E/I)	Bio-ConneKt wound matrix, per sq cm
Q4162 (E/I)	WoundEx Flow, BioSkin Flow, 0.5 cc
Q4163 (E/I)	WoundEx, BioSkin, per sq cm
Q4164 (E/I)	Helicoll, per sq cm
Q4165 (E/I)	Keramatrix or Kerasorb, per sq cm
Q4166 (E/I)	Cytal, per sq cm
Q4167 (E/I)	Truskin, per sq cm
Q4168 (E/I)	AmnioBand, 1 mg
Q4169 (E/I)	Artacent wound, per sq cm

Code	Description
Q4170 (E/I)	Cygnus, per sq cm
Q4171 (E/I)	Interfyl, 1 mg
Q4173 (E/I)	PalinGen or PalinGen Xplus, per sq cm
Q4174 (E/I)	PalinGen or ProMatrX, 0.36 mg per 0.25 cc
Q4175 (E/I)	Miroderm, per sq cm
Q4176 (E/I)	Neopatch or therion, per square centimeter
Q4177 (E/I)	FlowerAmnioFlo, 0.1 cc
Q4178 (E/I)	FlowerAmnioPatch, per sq cm
Q4179 (E/I)	FlowerDerm, per sq cm
Q4180 (E/I)	Revita, per sq cm
Q4181 (E/I)	Amnio Wound, per sq cm
Q4182	Transcyte, per sq cm
Q4183 (E/I)	Surgigraft, per sq cm
Q4184 (E/I)	Cellesta or Cellesta Duo, per sq cm
Q4185 (E/I)	Cellesta Flowable Amnion (25 mg per cc); per 0.5 cc
Q4186	Epifix, per sq cm
Q4187	Epicord, per sq cm
Q4188 (E/I)	AmnioArmor, per sq cm
Q4189 (E/I)	Artacent AC, 1 mg
Q4190 (E/I)	Artacent AC, per sq cm
Q4191 (E/I)	Restorigin, per sq cm
Q4192 (E/I)	Restorigin, 1 cc
Q4193 (E/I)	Coll-e-Derm, per sq cm
Q4194 (E/I)	Novachor, per sq cm
Q4195 (E/I)	PuraPly, per sq cm
Q4196 (E/I)	PuraPly AM, per sq cm
Q4197 (E/I)	PuraPly XT, per sq cm
Q4198 (E/I)	Genesis Amniotic Membrane, per sq cm
Q4199 (E/I)	Cygnus matrix, per sq cm
Q4200 (E/I)	SkinTE, per sq cm
Q4201 (E/I)	Matrion, per sq cm
Q4202 (E/I)	Keroxx (2.5 g/cc), 1cc
Q4203 (E/I)	Derma-Gide, per sq cm
Q4204 (E/I)	XWRAP, per sq cm
Q4205 (E/I)	Membrane Graft or Membrane Wrap, per sq cm
Q4206 (E/I)	Fluid Flow or Fluid GF, 1 cc
Q4208 (E/I)	Novafix, per sq cm
Q4209 (E/I)	SurGraft, per sq cm
Q4211 (E/I)	Amnion Bio or axoBioMembrane, per sq cm
Q4212 (E/I)	AlloGen, per cc

Code	Description
Q4213 (E/I)	Ascent, 0.5 mg
Q4214 (E/I)	Cellesta Cord per sq cm
Q4215 (E/I)	Axolotl Ambient or Axolotl Cryo, 0.1 mg
Q4216 (E/I)	Artacent Cord, per sq cm
Q4217 (E/I)	WoundFix, BioWound, WoundFix Plus, BioWound Plus, WoundFix Xplus or BioWound Xplus, per sq cm
Q4218 (E/I)	SurgiCORD, per sq cm
Q4219 (E/I)	SurgiGRAFT-DUAL, per sq cm
Q4220 (E/I)	BellaCell HD or Surederm, per sq cm
Q4221 (E/I)	Amnio Wrap2, per sq cm
Q4222 (E/I)	ProgenaMatrix, per sq cm
Q4224 (E/I)	Human Health Factor 10 Amniotic Patch (HHF10-P), per sq cm
Q4225 (E/I)	AmnioBind, per sq cm
Q4226 (E/I)	MyOwn Skin, includes harvesting and preparation procedures, per sq cm
Q4227 (E/I)	AmnioCore TM, per sq cm
Q4229 (E/I)	Cogenex Amniotic Membrane, per sq cm
Q4230 (E/I)	Cogenex Flowable Amnion, per 0.5 cc
Q4232 (E/I)	Corplex, per sq cm
Q4233 (E/I)	SurFactor or NuDyn, per 0.5 cc
Q4234 (E/I)	XCellerate, per sq cm
Q4235 (E/I)	AMNIOREPAIR or AltiPly, per sq cm
Q4236 (E/I)	CarePATCH, per sq cm
Q4237 (E/I)	Cryo-Cord, per sq cm
Q4238 (E/I)	Derm-Maxx, per sq cm
Q4239 (E/I)	Amnio-Maxx or Amnio-Maxx Lite, per sq cm
Q4240 (E/I)	CoreCyte, for topical use only, per 0.5 cc.
Q4241 (E/I)	PolyCyte, for topical use only, per 0.5 cc
Q4242 (E/I)	AmnioCyte Plus, per 0.5 cc
Q4245 (E/I)	AmnioText, per cc
Q4246 (E/I)	CoreText or ProText, per cc
Q4247 (E/I)	Amniotext patch, per sq cm
Q4248 (E/I)	Dermacyte Amniotic Membrane Allograft, per sq cm
Q4249 (E/I)	AMNIPLY, for topical use only, per sq cm
Q4250 (E/I)	AmnioAmp-MP, per sq cm
Q4251 (E/I)	VIM per sq cm
Q4252 (E/I)	Vendaje, per sq cm
Q4253 (E/I)	Zenith Amniotic Membrane, per sq cm
Q4254 (E/I)	Novafix DL, per sq cm
Q4255 (E/I)	REGUaRD, for topical use only, per sq cm
Q4256 (E/I)	MLG-Complete, per sq cm

Code	Description
Q4257 (E/I)	Relese, per sq cm
Q4258 (E/I)	Enverse, per sq cm
Q4259 (E/I)	Celera Dual Layer or Celera Dual Membrane, per sq cm
Q4260 (E/I)	Signature APatch, per sq cm
Q4261 (E/I)	TAG, per sq cm
Q4262 (E/I)	Dual Layer Impax Membrane, per sq cm
Q4263 (E/I)	SurGraft TL, per sq cm
Q4264 (E/I)	Cocoon Membrane, per sq cm
Q4265 (E/I)	NeoStim TL, per sq cm
Q4266 (E/I)	NeoStim Membrane, per sq cm
Q4267 (E/I)	NeoStim DL, per sq cm
Q4268 (E/I)	SurGraft FT, per sq cm
Q4269 (E/I)	SurGraft XT, per sq cm
Q4270 (E/I)	Complete SL, per sq cm
Q4271 (E/I)	Complete FT, per sq cm
Q4272 (E/I)	Esano A, per sq cm
Q4273 (E/I)	Esano AAA, per sq cm
Q4274 (E/I)	Esano AC, per sq cm
Q4275 (E/I)	Esano ACA, per sq cm
Q4276 (E/I)	ORION, per sq cm
Q4278 (E/I)	EPEFFEICT, per sq cm
Q4279 (E/I)	Vendaje AC, per sq cm
Q4280 (E/I)	Xcell Amnio Matrix, per sq cm
Q4281 (E/I)	Barrera SL or Barrera DL, per sq cm
Q4282 (E/I)	Cygnus Dual, per sq cm
Q4283 (E/I)	Biovance Tri-Layer or Biovance 3L, per sq cm
Q4284 (E/I)	DermaBind SL, per sq cm
Q4285 (E/I)	NuDYN DL or NuDYN DL MESH, per sq cm
Q4286 (E/I)	NuDYN SL or NuDYN SLW, per sq cm
Q4287 (E/I)	DermaBind DL, per sq cm
Q4288 (E/I)	DermaBind CH, per sq cm
Q4289 (E/I)	RevoShield+ Amniotic Barrier, per sq cm
Q4290 (E/I)	Membrane Wrap-Hydro, per sq cm
Q4291 (E/I)	Lamellas XT, per sq cm
Q4292 (E/I)	Lamellas, per sq cm
Q4293 (E/I)	Acesso DL, per sq cm
Q4294 (E/I)	Amnio Quad-Core, per sq cm
Q4295 (E/I)	Amnio Tri-Core Amniotic, per sq cm
Q4296 (E/I)	Rebound Matrix, per sq cm
Q4297 (E/I)	Emerge Matrix, per sq cm

Code	Description
Q4298 (E/I)	AmniCore Pro, per sq cm
Q4299 (E/I)	AmniCore Pro+, per sq cm
Q4300 (E/I)	Acesso TL, per sq cm
Q4301 (E/I)	Activate Matrix, per sq cm
Q4302 (E/I)	Complete ACA, per sq cm
Q4303 (E/I)	Complete AA, per sq cm
Q4304 (E/I)	GRAFIX PLUS, per sq cm
Q4305 (E/I)	American Amnion AC Tri-Layer, per sq cm
Q4306 (E/I)	American Amnion AC, per sq cm
Q4307 (E/I)	American Amnion, per sq cm
Q4308 (E/I)	Sanopellis, per sq cm
Q4309 (E/I)	VIA Matrix, per sq cm
Q4310 (E/I)	Procenta, per 100 mg
Q4311 (E/I)	Acesso, per sq cm
Q4312 (E/I)	Acesso AC, per sq cm
Q4313 (E/I)	DermaBind FM, per sq cm
Q4314 (E/I)	Reeva FT, per sq cm
Q4315 (E/I)	RegeneLink Amniotic Membrane Allograft, per sq cm
Q4316 (E/I)	AmchoPlast, per sq cm
Q4317 (E/I)	VitoGraft, per sq cm
Q4318 (E/I)	E-Graft, per sq cm
Q4319 (E/I)	SanoGraft, per sq cm
Q4320 (E/I)	PelloGraft, per sq cm
Q4321 (E/I)	RenoGraft, per sq cm
Q4322 (E/I)	CaregraFT, per sq cm
Q4323 (E/I)	alloPLY, per sq cm
Q4324 (E/I)	AmnioTX, per sq cm
Q4325 (E/I)	ACApatch, per sq cm
Q4326 (E/I)	WoundPlus, per sq cm
Q4327 (E/I)	DuoAmnion, per sq cm
Q4328 (E/I)	MOST, per sq cm
Q4329 (E/I)	Singlay, per sq cm
Q4330 (E/I)	TOTAL, per sq cm
Q4331 (E/I)	Axolotl Graft, per sq cm
Q4332 (E/I)	Axolotl DualGraft, per sq cm
Q4333 (E/I)	ArdeoGraft, per sq cm
Q4334 (E/I)	AmnioPlast 1, per sq cm
Q4335 (E/I)	AmnioPlast 2, per sq cm
Q4336 (E/I)	Artacent C, per sq cm
Q4337 (E/I)	Artacent Trident, per sq cm

Code	Description
Q4338 (E/I)	Artacent Velos, per sq cm
Q4339 (E/I)	Artacent Vericlen, per sq cm
Q4340 (E/I)	SimpliGraft, per sq cm
Q4341 (E/I)	SimpliMax, per sq cm
Q4342 (E/I)	TheraMend, per sq cm
Q4343 (E/I)	Dermacyte AC Matrix Amniotic Membrane Allograft, per sq cm
Q4344 (E/I)	Tri-Membrane Wrap, per sq cm
Q4345 (E/I)	Matrix HD Allograft Dermis, per sq cm
Q4346 (E/I)	Shelter DM Matrix, per sq cm
Q4347 (E/I)	Rampart DL Matrix, per sq cm
Q4348 (E/I)	Sentry SL Matrix, per sq cm
Q4349 (E/I)	Mantle DL Matrix, per sq cm
Q4350 (E/I)	Palisade DM Matrix, per sq cm
Q4351 (E/I)	Enclose TL Matrix, per sq cm
Q4352 (E/I)	Overlay SL Matrix, per sq cm
Q4353 (E/I)	Xceed TL Matrix, per sq cm
Q4354 (E/I)	Palingen dual-layer membrane, per square centimeter
Q4355 (E/I)	Abiomend xplus membrane and abiomend xplus hydromembrane, per square centimeter
Q4356 (E/I)	Abiomend membrane and abiomend hydromembrane, per square centimeter
Q4357 (E/I)	Xwrap plus, per square centimeter
Q4358 (E/I)	Xwrap dual, per square centimeter
Q4359 (E/I)	Choriply, per square centimeter
Q4360 (E/I)	Amchoplast fd, per square centimeter
Q4361 (E/I)	Epixpress, per square centimeter
Q4362 (E/I)	Cygnus disk, per square centimeter
Q4363 (E/I)	Amnio burgeon membrane and hydromembrane, per square centimeter
Q4364 (E/I)	Amnio burgeon xplus membrane and xplus hydromembrane, per square centimeter
Q4365 (E/I)	Amnio burgeon dual-layer membrane, per square centimeter
Q4366 (E/I)	Dual layer amnio burgeon x-membrane, per square centimeter
Q4367 (E/I)	Amniocore sl, per square centimeter
Q4368 (E/I)	AmchoThick, per sq cm
Q4370 (E/I)	AeroGuard, per sq cm
Q4371 (E/I)	NeoGuard, per sq cm
Q4372 (E/I)	AmchoPlast EXCEL, per sq cm
Q4373 (E/I)	Membrane Wrap-Lite, per sq cm
Q4375 (E/I)	duoGRAFT AC, per sq cm
Q4376 (E/I)	Duograft AA, per sq cm
Q4377 (E/I)	triGRAFT FT, per sq cm
Q4378 (E/I)	Renew FT Matrix, per sq cm

Code	Description
Q4379 (E/I)	AmnioDefend FT Matrix, per sq cm
Q4380 (E/I)	AdvoGraft One, per sq cm
Q4382 (E/I)	AdvoGraft Dual, per sq cm
Q4383 (E/I)	Axolotl Graft Ultra, per sq cm
Q4384 (E/I)	Axolotl DualGraft Ultra, per sq cm
Q4385 (E/I)	Apollo FT, per sq cm
Q4386 (E/I)	Acesso TrifACA, per sq cm
Q4387 (E/I)	NeoThelium FT, per sq cm
Q4388 (E/I)	NeoThelium 4L, per sq cm
Q4389 (E/I)	NeoThelium 4L Plus, per sq cm
Q4390 (E/I)	Ascendion, per sq cm
Q4391 (E/I)	AmnioPlast Double, per sq cm
Q4392 (E/I)	GRAFIX Duo, per sq cm
Q4393 (E/I)	SurGraft AC, per sq cm
Q4394 (E/I)	SurGraft ACA, per sq cm
Q4395 (E/I)	Acelagraft, per sq cm
Q4396 (E/I)	Natalin, per sq cm
Q4397 (E/I)	Summit AAA, per sq cm

ICD10 Codes

Code	Description
C07	Malignant neoplasm of parotid gland
C50.011-C50.019	Malignant neoplasm of nipple and areola, female breast (code range)
C50.111-C50.119	Malignant neoplasm of central portion of female breast (code range)
C50.211-C50.219	Malignant neoplasm of upper-inner quadrant of female breast (code range)
C50.221-C50.229	Malignant neoplasm of upper-inner quadrant of male breast (code range)
C50.311-C50.319	Malignant neoplasm of lower-inner quadrant of female breast (code range)
C50.321-C50.329	Malignant neoplasm of lower-inner quadrant of male breast (code range)
C50.411-C50.419	Malignant neoplasm of upper-outer quadrant of female breast (code range)
C50.421-C50.429	Malignant neoplasm of upper-outer quadrant of male breast (code range)
C50.511-C50.519	Malignant neoplasm of lower-outer quadrant of female breast (code range)

Code	Description
C50.521-C50.529	Malignant neoplasm of lower-outer quadrant of male breast (code range)
C50.611-C50.619	Malignant neoplasm of axillary tail of female breast (code range)
C50.621-C50.629	Malignant neoplasm of axillary tail of male breast (code range)
C50.811-C50.819	Malignant neoplasm of overlapping sites of female breast (code range)
C50.821-C50.829	Malignant neoplasm of overlapping sites of male breast (code range)
C50.911-C50.919	Malignant neoplasm of unspecified site of female breast (code range)
C50.921-C50.929	Malignant neoplasm of unspecified site of male breast (code range)
D05.00-D05.92	Carcinoma in situ of breast (code range)
D11.0-D11.9	Benign neoplasm of major salivary gland (code range)
D37.030-D37.039	Neoplasm of uncertain behavior of the salivary glands (code range)
E08.621	Diabetes mellitus due to underlying condition with foot ulcer
E09.621	Drug or chemical induced diabetes mellitus with foot ulcer
E10.621	Type 1 diabetes mellitus with foot ulcer
E11.621	Type 2 diabetes mellitus with foot ulcer
E13.621	Other specified diabetes mellitus with foot ulcer
I83.001-I83.009	Varicose veins of unspecified lower extremity with ulcer (code range)
I83.011-I83.029	Varicose veins of lower extremity with ulcer (code range)
I83.201-I83.229	Varicose veins of lower extremity with both ulcer and inflammation (code range)
I87.311-I87.319	Chronic venous hypertension (idiopathic) with ulcer (code range)
K11.1-K11.9	Disease of salivary gland (code range)
K43.0-K43.2	Incisional hernia (code range)
L97.101-L97.929	Non-pressure chronic ulcer of lower limb, not elsewhere classified (code range)
T20.00XA-T25.399S	Burns - by site and degree of burn (code range)
T30.0	Burn of unspecified body region, unspecified degree
T30.4	Corrosion of unspecified body region, unspecified degree

Code	Description
T31.0-T31.99	Burns (code range)
T32.0-T32.99	Corrosions (code range)
Z85.3	Personal history of malignant neoplasm of breast
Z90.10-Z90.13	Acquired absence of breast and nipple (code range)

REFERENCES

Aggarwala S, et al. Treatment of partial thickness burns: a prospective, randomized controlled trial comparing four routinely used burns dressings in an ambulatory care setting. J Burn Care Res. 2021 Sep 30;42(5):934-943.

Alkhonizy SW, et al A. Effectiveness of dermal regeneration templates in managing acute full-thickness and deep dermal burn injuries: a comparison with split-thickness skin grafts. Plast Reconstr Surg Glob Open. 2024 Feb 2;12(2):e5572.

Álvaro-Afonso FJ, et al. Advances in dermoepidermal skin substitutes for diabetic foot ulcers. Curr Vasc Phamacol. 2020;18(2):182-192.

American Society of Plastic Surgeons [Internet]. ADM update: the use of acellular dermal matrices (ADMs). Published August 26, 2019 [accessed 2026 Jun 11]. Available from: https://www.plasticsurgery.org/for-medical-professionals/publications/psn-extra/news/adm-update-the-use-of-acellular-dermal-matrices

Ananian CE, et al. A multicenter, randomized, single-blind trial comparing the efficacy of viable cryopreserved placental membrane to human fibroblast-derived dermal substitute for the treatment of chronic diabetic foot ulcers. Wound Repair Regen. 2018 May;26(3):274-283

Asaad M, et al. No differences in surgical and patient-reported outcomes among AlloDerm, SurgiMend, and Dermacell for prepectoral implant-based breast reconstruction. Plast Reconstr Surg. 2023 May 1;151(5):719e-729e.

Berger LE, et al. Acellular dermal matrix-assisted, prosthesis-based breast reconstruction: a comparison of SurgiMend PRS, AlloDerm, and DermACELL. Ann Plast Surg. 2024 Jul 1;93(1):34-42.

Bianchi C, et al; EpiFix VLU Study Group. A multicentre randomised controlled trial evaluating the efficacy of dehydrated human amnion/chorion membrane (EpiFix) allograft for the treatment of venous leg ulcers. Int Wound J. 2018 Feb;15(1):114-122.

Bianchi C, et al. Variations in study outcomes relative to intention-to-treat and per-protocol data analysis techniques in the evaluation of efficacy for treatment of venous leg ulcers with dehydrated human amnion/chorion membrane allograft. Int Wound J. 2019 Jun;16(3):761-767.

Blok RD, et al. Cumulative 5-year results of a randomized controlled trial comparing biological mesh with primary perineal wound closure after extralevator abdominoperineal resection (BIOPEX-study). Ann Surg. 2022 Jan 1;275(1):e37-e44.

Brichacek M, et al. A Limited submuscular direct-to-implant technique utilizing AlloMax. Plast Reconstr Surg Glob Open. 2017 Jul 5;5(7):e1408.

Brooke S, et al. Complications in tissue expander breast reconstruction: a comparison of AlloDerm, DermaMatrix, and FlexHD acellular inferior pole dermal slings. Ann Plast Surg. 2012 Oct;69(4):347-9.

Broyles JM, et al. Acellular dermal matrix-associated complications in implant-based breast reconstruction: a multicenter, prospective, randomized controlled clinical trial comparing two human tissues. Plast Reconstr Surg. 2021 Sep 1;148(3):493-500.

Carsin H, et al. Cultured epithelial autografts in extensive burn coverage of severely traumatized patients: a five-year single-center experience with 30 patients. Burns. 2000 Jun;26(4):379-87.

Davison SP, et al. Comparison of different acellular dermal matrix in breast reconstruction: a skin-to-skin study. Aesthet Surg J. 2024 Jul 15;44(8):829-837.

De Virgilio A, et al. Different surgical strategies in the prevention of Frey syndrome: a systematic review and meta-analysis. Laryngoscope. 2021 Aug;131(8):1761-1768.

DiDomenico LA, et al. Aseptically processed placental membrane improves healing of diabetic foot ulcerations: prospective, randomized clinical trial. Plast Reconstr Surg Glob Open. 2016 Oct; 4(10): e1095.

Dominguez A, et al. Real-world use of Alloderm acellular dermal matrix in head and neck procedures in the United States. Plast Reconstr Surg Glob Open. 2024 Nov 26;12(11):e6339.

Driver VR, et al. A clinical trial of Integra Template for diabetic foot ulcer treatment. Wound Repair Regen. 2015 Nov 12;23(6):891-900.

Gardien KLM, et al. Short- and long-term outcomes of an acellular dermal substitute versus standard of care in burns and reconstructions: a phase I/II intrapatient randomized controlled trial. Adv Skin Wound Care. 2023 Oct 1;36(10):540-548.

Glynou SP, et al. A comparison of acellular dermal matrices (ADM) efficacy and complication profile in women undergoing implant-based breast reconstruction: a systematic review and network meta-analysis. BMC Cancer. 2024 Dec 31;24(1):1598.

Gurtner GC, et al. A retrospective matched-cohort study of 3994 lower extremity wounds of multiple etiologies across 644 institutions comparing a bioactive human skin allograft, TheraSkin, plus standard of care, to standard of care alone. Int Wound J. 2020 Feb;17(1):55-64.

Hankin CS, et al. Clinical and cost efficacy of advanced wound care matrices for venous ulcers. J Manag Care Pharm. 2012 Jun;18(5):375-84.

Hicks CW, et al. Outcomes and predictors of wound healing among patients with complex diabetic foot wounds treated with a dermal regeneration template (Integra). Plast Reconstr Surg. 2020 Oct;146(4):893-902.

Hingorani A, et al. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for

Vascular Medicine. J Vasc Surg. 2016 Feb;63(2 Suppl):3S-21S.

Holmes JH, et al. A comparative study of the ReCell device and autologous spit thickness meshed skin graft in the treatment of acute burn injuries. J Burn Care Res. 2018 Aug 17;39(5):694-702.

Holmes JH, et al. Demonstration of the safety and effectiveness of the RECELL System combined with split-thickness meshed autografts for the reduction of donor skin to treat mixed-depth burn injuries. Burns. 2019 Jun;45(4):772-782.

ISBI Practice Guidelines Committee; Steering Subcommittee; Advisory Subcommittee. ISBI practice guidelines for burn care. Burns. 2016 Aug;42(5):953-1021.

Jabarkhyl D, et al. The Efficacy of Biobrane in managing superficial paediatric burn injuries: a systematic review and meta-analysis. Cureus. 2025 Feb 4;17(2):e78508.

Jakob MO, et al. Biologic mesh implantation is associated with serious abdominal wall complications in patients undergoing emergency abdominal surgery: A randomized-controlled clinical trial. J Trauma Acute Care Surg. 2020 Dec;89(6):1149-1155.

Kaplan HY, Rysin R. Use of 801 acellular dermal matrices (adms) in direct-to-implant breast reconstruction: a clinical observation of complication profiles over a 7-year period. Aesthet Surg J. 2025 Feb 18;45(3):276-285.

Keane AM, et al. Cortiva versus AlloDerm in prepectoral and partial submuscular implant-based breast reconstruction: a randomized clinical trial. Plast Reconstr Surg. 2024 Oct 1;154(4S):13S-26S.

Kirsner RS, et al. Comparative effectiveness of a bioengineered living cellular construct vs. a dehydrated human amniotic membrane allograft for the treatment of diabetic foot ulcers in a real world setting. Wound Rep Reg. 2015 Sep;23(5):737-44.

Kissane NA, Itani KMF. A decade of ventral incisional hernia repairs with biologic acellular dermal matrix: what have we learned? Plast Reconstr Surg. 2012 Nov;130(5 Suppl 2):194S-202S.

Kumar NG, et al. Development of an evidence-based approach to the use of acellular dermal matrix in immediate expander-implant-based breast reconstruction. British Assoc of Plastic, Reconstructive and Aesthetic Surgeons. 2021 Jan; 74 (1): 31-40.

Landsman AS, et al. A retrospective clinical study of 188 consecutive patients to examine the effectiveness of a biologically active cryopreserved human skin allograft (TheraSkin) on the treatment of diabetic foot ulcers and venous leg ulcers. Foot Ankle Spec. 2011 Feb;4(1):29-41.

Lavery LA, et al. Grafix Diabetic Foot Ulcer Study Group. The efficacy and safety of Grafix for the treatment of chronic diabetic foot ulcers: results of a multi-centre, controlled, randomised, blinded, clinical trial. Int Wound J. 2014 Oct;11(5):554-60.

Liu DZ, et al. Comparison of outcomes using AlloDerm versus FlexHD for implant-based breast reconstruction. Annals Plast Surg. 2014 May;72(5):503-7.

Lohmander F, et al. Effect of immediate implant-based reconstruction after mastectomy with and without acellular dermal matrix among women with breast cancer: A randomized clinical trial. JAMA.

2021 Oct; 4(10).

Lohmander F, et al. Implant based breast reconstruction with acellular dermal matrix: Safety data from an open-label, multicenter, randomized, controlled trial in the setting of breast cancer treatment. Ann Surg. 2019 May;269(5):836-841.

Manning L, et al. Wound healing with "spray-on" autologous skin grafting (ReCell) compared with standard care in patients with large diabetes-related foot wounds: an open-label randomised controlled trial. Int Wound J. 2022 Mar;19(3):470-481.

Mashrah MA, et al. What is the best method for prevention of postparotidectomy Frey syndrome? Network meta-analysis. Head Neck. 2021 Apr;43(4):1345-1358.

Mendenhall SD, et al. The BREASTrial Stage III: acellular dermal matrix breast reconstruction outcomes from 3 months to 2 years postoperatively. Plast Reconstr Surg. 2023 Jan 1;151(1):17-24.

Mostow EN, et al; OASIS Venus Ulcer Study Group. Effectiveness of an extracellular matrix graft (OASIS Wound Matrix) in the treatment of chronic leg ulcers: a randomized clinical trial. J Vasc Surg. 2005 May;41(5):837-43.

National Institute for Health and Care Excellence (NICE) [Internet]. Guidelines for diabetic foot problems: prevention and management (NG19). 2019 Oct 11 [accessed 2026 Jun 11]. Available from: https://www.nice.org.uk/guidance/ng19

National Institute for Health and Care Excellence (NICE) [Internet]. The ReCell Spray-On Skin system for treating skin loss, scarring and depigmentation after burn injury (HTG356). 2020 Aug 7 [accessed 2026 Jun 11]. Available from: https://www.nice.org.uk/guidance/htg356

Niezgoda JA, et al. Randomized clinical trial comparing OASIS Wound Matrix to Regranex Gel for diabetic ulcers. Adv Skin Wound Care. 2005 Jun;18(5 Pt 1):258-66.

Sanders L, et al. A prospective, multicenter, randomized, controlled clinical trial comparing a bioengineered skin substitute to a human skin allograft. Ostomy Wound Manage. 2014 Sep;60(9):26-38.

Serena TE, et al. A randomized controlled clinical trial of a hypothermically stored amniotic membrane for use in diabetic foot ulcers. J Comp Eff Res. 2020 Jan;9(1):23-34.

Serena TE, et al. A multicenter, randomized, controlled, clinical trial evaluating dehydrated human amniotic membrane in the treatment of venous leg ulcers. Plast Reconstr Surg. 2022 Nov 1;150(5):1128-1136.

Smiell JM, et al. Real-world experience with a decellularized dehydrated human amniotic membrane allograft. Wounds. 2015 Jun;27(6):158-69.

Snyder DL, et al. Agency for Healthcare Research and Quality [Internet]. Skin substitutes for treating chronic wounds. Technology Assessment Program Project ID No. WNDT0818. (Prepared by the ECRI Institute-Penn Medicine Evidence-based Practice Center under Contract No. HHSA 290-2015-00005-I) Rockville, MD. 2018 Nov 27 [accessed 2026 Jun 11]. Available from: https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/skin-substitute_0.pdf

Seth AK, et al. A comparative analysis of cryopreserved versus prehydrated human acellular dermal matrices in tissue expander breast reconstruction. Ann Plast Surg. 2013 Jun;70(6):632-5.

Stein MJ, et al. A comparison of patient-reported outcomes between Alloderm and Dermacell in immediate alloplastic breast reconstruction: A randomized control trial. J Plast Reconstr Aesthet Surg. 2021 Jan;74(1):41-47.

Su YN, et al. Human amniotic membrane allograft, a novel treatment for chronic diabetic foot ulcers: A systematic review and meta-analysis of randomised controlled trials. Int Wound J. 2020 Jun;17(3):753-764.

Tettelbach W, et al. A multicentre prospective randomised controlled comparative parallel study of dehydrated human umbilical cord (EpiCord) allograft for the treatment of diabetic foot ulcers. Int Wound J. 2019 Feb;16(1):122-130.

Towler MA, et al. Randomized, prospective, blinded-enrollment, head-to-head venous leg ulcer healing trial comparing living, bioengineered skin graft substitute (Apligraf) with living, cryopreserved, human skin allograft (TheraSkin). Clin Podiatr Med Surg. 2018 Jul;35(3):357-365.

Whisker L, et al. Biological and synthetic mesh assisted breast reconstruction procedures: Joint guidelines from the Association of Breast Surgery and the British Association of Plastic, Reconstructive and Aesthetic Surgeons. Eur J Surg Oncol. 2021 Nov;47(11):2807-2813.

Zelen CM, et al. A prospective randomised comparative parallel study of amniotic membrane wound graft in the management of diabetic foot ulcers. Int Wound J. 2013 Oct;10(5):502-7.

Zelen CM, et al. The use of human amnion/chorion membrane in the clinical setting for lower extremity repair: a review. Clin Podiatr Med Surg. 2015a Jan;32(1):135-46.

Zelen CM, et al. A prospective, randomised, controlled, multi-centre comparative effectiveness study of healing using dehydrated human amnion/chorion membrane allograft, bioengineered skin substitute or standard of care for treatment of chronic lower extremity diabetic ulcers. Int Wound J. 2015b Dec;12(6):724-32.

Zelen CM, et al. A prospective, randomised, controlled, multicentre clinical trial examining healing rates, safety, and cost to closure of an acellular reticular allogenic human dermis versus standard of care in the treatment of chronic diabetic foot ulcers. Int Wound J. 2017 Apr;14(2):307-315.

Zheng EE, et al. The use of Cortiva Allograft Dermis in two-staged breast reconstruction: A matched-comparison and cost analyses study. J Plast Reconstr Aesthet Surg. 2025 Jan;100:294-301.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Skin substitutes are not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New:05/16 **Revised**:01/17, 05/17, 01/18, 03/18, 01/19, 11/19, 09/20, 11/20, 9/21, 11/21, 3/22, 7/22, 11/22, 1/23, 5/23, 7/23, 11/23, 1/24, 5/24, 7/24, 9/24, 3/25, 5/25, 7/25, 11/25 **Reviewed**:05/18, 05/19, 05/20, 5/21, 9/26	
Date	**Summary of Changes**
08/20/26	• Annual review, policy intent unchanged, code edit, added CPT codes 15011-15018.
1/1/2026	• Transitioned Skin Substitutes for Wound Healing & Surgical Intervention policy, 1370/20.000486 to Lifetime Healthcare Companies policy template.
09/30/25	• Off-cycle policy update, code edit, added HCPCS codes A2036-A2039 and Q4383-Q4397. Policy intent unchanged.
7/1/2025	• Clarified verbiage under General Requirements. • Added new codes Q4368 – Q4382 to Exclusions section. • Added statement to Exclusions section regarding all other skin substitutes not otherwise mentioned in policy.
4/1/2025	• Added new skin substitute codes A2030-A2035 and Q4354-Q4367 to Exclusions section.
3/1/2025	• Added new codes to Exclusions section.
1/1/2025	• Added Amniofix to Exclusions section.
10/1/2024	• Removed AmnioBand from the Exclusions section and added coverage criteria.

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7/1/2024	• Added new codes Q4311- Q4333 to Exclusions section.
4/1/2024	• Added new codes A2026, and Q4305-Q4310 to Exclusions section.
1/1/2024	• Added new codes Q4279, and Q4287-Q4304 to Exclusions section.
10/1/2023	• Added new codes A2022-A2025, and Q4285-Q4286 to Exclusions section.
7/1/2023	• Added new codes Q4272-Q4278 and Q4280-Q4284 to Exclusions section.
4/1/2023	• Removed deleted codes 49560-49566, 49568 and replaced with codes 49591-49596, 49600, 49605, 49606, 49610-49618. • **Added new codes A2019-A2021 and Q4265-Q4271 to exclusions section.**
2/1/2023	• Removed Flex HD (Q4128) from Exclusions and added coverage information under Position Statement. • **Added new codes effective 1/1/23 to Exclusions: Q4262, Q4263, and Q4264.**
10/1/2022	• Added new codes A2014-A2018 to Exclusions section.
7/1/22	• Added new codes Q4260 and Q4261 to Exclusions section.
4/1/22	• Updates made to Exclusions section to add new codes eff 1/1/22.
10/1/21* ***No change to effective date for this update**	• Updates made to Exclusions section to add new codes Q4251-Q4253 effective 10/1/21.
10/1/21	• Updated grid in Position Statement to align coverage with Medicare Advantage. • **Updated application limits for Apligraf, Primatrix, and Theraskin.**
3/1/21	• Updates made to Exclusions section.
1/1/21	• Removed termed code Q4172 from Exclusions. • **Revised code for Biovance.**
12/1/19	• Updates made to Exclusions section.

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
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POLICY NAME: BIOFEEDBACK

POLICY EFFECTIVE DATE:	5/1/2024
Policy Control #:	1370/20.000067
Next Annual Review:	March 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

90901, 90912, 90913, 90875, 90876, E0740

DESCRIPTION

Biofeedback is a therapeutic process that electronically monitors bodily functions, such as breathing, heart rate, blood pressure, skin temperature, and muscle tension, which are fed back to the individual by means of sounds, lights, or electronic gauges. It emphasizes relaxation and stress-reducing techniques. It is believed that by using these techniques, individuals can learn to control a variety of physiological responses formerly thought to be completely involuntary, and thereby help manage anxiety and pain commonly associated with stress reactions.

There are several different types of biofeedback. The biofeedback modality selected for therapy depends on the conditions to be treated. The most commonly used forms of biofeedback are (1) electromyography (EMG), which measures muscle tension; (2) thermal biofeedback, which measures skin temperature; and (3) neurofeedback or electroencephalography (EEG), which measures brain activity.

POSITION STATEMENT

CDPHP administers benefits for biofeedback therapy as indicated below.

Biofeedback Therapy

POLICY NAME: BIOFEEDBACK

CDPHP administers benefits for biofeedback therapy as a stand-alone procedure for the treatment of urinary stress and/or urge incontinence, or fecal incontinence and/or constipation.

Biofeedback Therapy and Electrostimulation

Biofeedback-assisted pelvic muscle exercise (PME) incorporates the use of an electronic or mechanical device to relay visual and/or auditory evidence of pelvic floor muscle tone, in order to improve awareness of pelvic floor musculature and to assist patients in the performance of PME.

CDPHP administers benefits for biofeedback therapy in conjunction with electrostimulation for the treatment of urinary incontinence or fecal incontinence and/or constipation, in cognitively intact patients who have failed a documented trial of PME* and have met all of the following criteria:

- Patient has had a complete genitourinary/gastrointestinal evaluation.
- Patient has tried and been unsuccessful at behavioral intervention to include appropriate muscle exercises or muscle reeducation, habit training, and diet modification.
- Patient must be cognitively intact and motivated to actively participate in a prescribed treatment plan, including practice and follow-through at home.

*A failed trial of PME is defined as no clinically significant improvement in urinary/fecal incontinence after completing four weeks of an ordered plan of pelvic muscle exercises.

Initial treatment for urinary/fecal incontinence utilizing biofeedback therapy in conjunction with electrostimulation is to be performed in a clinical setting (office or facility) under supervision.

- If documentation substantiates effectiveness of treatment, a non-implantable pelvic-floor electrical stimulation device will be approved for home use.

Non-Implantable Pelvic-Floor Electrical Stimulation (E0740)

Non-implantable pelvic-floor electrical stimulators provide neuromuscular electrical stimulation through the pelvic floor with the intent of strengthening and exercising pelvic-floor musculature. Stimulation is generally delivered by vaginal or anal probes connected to an external pulse generator.

CDPHP considers non-implantable pelvic-floor electrical stimulators to be durable medical equipment, and therefore subject to the terms and conditions of such as stated in the enrollee's contract.

The probes required for electrostimulation are considered to be a medical supply, and as such are not covered unless otherwise specified in the enrollee's contract.

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POLICY NAME: BIOFEEDBACK

Biofeedback Therapy & Electromyography
E0740

Biofeedback therapy differs from electromyography, which is a diagnostic procedure used to record and study the electrical properties of skeletal muscle. An electromyography device may be used to provide feedback with certain types of biofeedback.

- No additional benefits are available for electromyography (51784, 51785) when performed in conjunction with biofeedback therapy.

POLICY CONSIDERATIONS

Benefits are provided for biofeedback services up to six sessions.

EXCLUSIONS

All conditions, other than those listed within this policy, are excluded from coverage to include, but not limited to, the following:

- Ordinary muscle tension states
- Migraine or muscle contraction (tension) headaches
- Vulvodynia

Biofeedback therapy performed in a setting other than in an office or other facility setting (e.g., home use of biofeedback therapy).

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy. Biofeedback therapy is covered under Medicare when it is reasonable and necessary for muscle reeducation of specific muscle groups or for treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness, and more conventional treatments (heat, cold, exercise, support) have not been successful. Coverage is allowed for medically necessary biofeedback training when performed by a physician or by a qualified non-physician.
SELECT PLAN/HARP	Biofeedback is not a covered service under the Select Plan/HARP benefit package.

SOURCES

1. Biondi, DM, Physical treatments for headache: a structured review, Headache. 2005 Jun; 45(6): 738-46.
2. CDPHP's Technology Assessment Team
3. Centers for Medicare & Medicaid National Coverage Determination: Biofeedback Therapy (30.1) http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd
4. Centers for Medicare & Medicaid National Coverage Determination: Pelvic Floor Electrical Stimulation for the Treatment of urinary Incontinence (30.1.1), http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd
5. Hayes Inc. Medical Technology Directory: Biofeedback for Headaches and Chronic Musculoskeletal Pain, November 3, 2004. Update search 12/16/07. Accessed 1/8/09.
6. Hayes Inc. Medical Technology Directory: Pelvic Floor Electrical Stimulation for the Treatment of Urinary Incontinence, March 31, 2006. Update search 3/26/08. Accessed 1/8/09.
7. Hayes Inc. Search and Summary Report: Biofeedback for the Treatment of Fecal Incontinence in Adults, September 9, 2009.
8. Hayes, Inc. Medical Technology Directory: Biofeedback and Management of Pain, 1998.
9. Kaushik, R, Kaushik RM et al, Biofeedback assisted diaphragmatic breathing and systematic relaxation versus propranolol in long term prophylaxis of migraine, Complement Ther Med. 2005 Sep;13 (3): 165-74.
10. Medicare Decision Memorandum, Biofeedback for Treatment of Urinary Incontinence # CAG-00020, October 2000.
11. Medicare http://www.cms.hhs.gov (last accessed 8/19/04).
12. Medicare Part B Answer Book, Coverage Issues Manual, Biofeedback Therapy: Sections 35-27, 35-27.1, 2001 edition.
13. National Government Services Local Coverage Determination (L33631); Outpatient Physical and Occupational Therapy Services, https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33631&ContrId=298&ver=26&ContrVer=1&CntrctrSelected=298*1&Cntrctr=298&s=41&DocType=All&bc=AggAAAQAAAAA&
14. Office of Managed Care Response to Coverage Question on Biofeedback, 2/19/03.
15. Other Payers
16. Rains JC, Penzien DB et al, Behavioral headache treatment: history, review of the empirical literature, and methodological critique, Headache. 2005 May; 45 Suppl 2: S92-109.
17. Sager, P.; Pemberton, J.: Gastrointestinal Motility in Clinical Practice, Anorectal and Pelvic Floor Function. Gastroenterology Clinics Vol. 25, No. 1, March 1996, pp.163-182
18. Silberstein, S., Practice Parameter: Evidence – Based Guidelines for Migraine Headaches, American Academy of Neurology, 2000.

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: BIOFEEDBACK

POLICY APPROVAL DATES

New:	07/89
Revised:	06/90,12/91,05/93, 01/95, 01/96, 11/97, 11/98, 08/99, 09/99, 09/00, 10/01,01/03, 10/03,09/04, 05/05, 12/05, 04/07, 03/08, 01/09, 03/09, 09/09, 11/09, 03/10, 09/10, 11/10, 03/12, 09/14, 03/18, 03/20, 3/21, 3/22, 5/24
Reviewed:	01/94, 11/06, 03/11, 03/13, 03/14, 03/15, 03/16, 03/17, 03/19, 3/23, 3/24, 3/25, 3/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
5/1/2024	Relocated information on EEG Biofeedback/neurofeedback to the Non-Covered Technologies, 1370/20.000444 policy.
4/1/2022	Removed additional visits beyond the six-visit limitation will require documentation to support medical necessity.
7/1/2021	To clarify coverage, language updated to indicate coverage for urinary or fecal symptoms
1/1/2020	Removed deleted code 90911 and replaced with new codes 90912 and 90913 effective 1/1/2020.

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MEDICAL POLICY

Medical Policy Title	**Blepharoplasty and Brow Ptosis Repair**
Policy Number	**7.01.55**
Current Effective Date	**August 1, 2026**
Next Review Date	**March 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Blepharoplasty

I. Upper eyelid blepharoplasty (reconstructive or functional) with or without functional levator muscle advancement, is considered **medically appropriate** for **ANY** of the following indications:

A. Ptosis when **ALL** the following are documented (See Policy Guidelines):

1. Upper eyelid margin is approaching less than or equal to 2.5 mm (1/4 of the diameter of the visible iris) of the corneal light reflex (marginal reflex distance or MRD);
2. Photographs in primary gaze (head and gaze straight ahead) demonstrating light reflex;
3. Functional limitations to the patient's vision; **and**
4. Visual field testing, with a written interpretation, demonstrates a minimum of 30 percent loss of upper field of vision with upper lid skin or upper margin in repose and an increase of 12 degrees or more with elevation (by the taping of the lid) to demonstrate potential correction by proposed procedure or procedures.

B. Dermatochalasis when **ALL** the following are documented (See Policy Guidelines):

1. Severe, redundant skin resting upon the eyelashes;
2. Photographs in primary gaze and/or lateral view showing eyelid tissue resting on or pushing down on the eyelashes;
3. Functional limitations to the patient's vision; **and**
4. Visual field testing, with a written interpretation, demonstrates a minimum of 30 percent loss of upper field of vision with upper lid skin or upper margin in repose and an increase of 12 degrees or more with elevation (by the taping of the lid) to demonstrate potential correction by proposed procedure or procedures.

C. Anophthalmia Socket when **ALL** the following are documented (See Policy Guidelines):

1. Improper fit of the eye prosthesis;

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2. Difficulty wearing the prosthesis is caused by eyelid abnormality; **and**
3. Photographs showing the abnormality.

II. Lower eyelid blepharoplasty (reconstructive or functional) is considered **medically necessary** for **ALL** the following (See Policy Guidelines):

A. Diagnosis of **EITHER** of the following:

1. Vision is obstructed by the excess tissue; **or**
2. Eyes are dry and irritated; **and**

B. Clinical documentation includes **EITHER** of the following:

1. Functional limitation to the patient's vision; **or**
2. Eye irritation as shown in photographs and documentation of treatment.

III. Revisional blepharoplasty is considered **medically appropriate** when the criteria stated in Policy Statement I or II are met.

IV. If unilateral disease meets the above criteria, blepharoplasty of the opposite eyelid at the same time, may be considered **medically appropriate** as bilateral reconstructive blepharoplasty when **ALL** the following are met:

A. The opposite eyelid also exhibits abnormalities;

B. The opposite eyelid does not yet meet criteria for reconstructive blepharoplasty;

C. Clinical evidence indicates that the opposite eyelid will soon meet criteria for reconstructive blepharoplasty.

V. Cosmetic blepharoplasty is considered **not medically necessary** when performed to improve a patient's appearance, in the absence of any signs or symptoms of functional abnormalities.

Brow Ptosis Repair

VI. Brow ptosis repair (brow lift or browpexy) is considered **medically appropriate** when **ALL** the following are documented (See Policy Guidelines):

A. Brow ptosis causes functional visual impairment;

B. Photographs (lateral view preferred) showing the eyebrow below the supraorbital rim;

C. Visual field testing with a written interpretation.

RELATED POLICIES

Corporate Medical Policy

Cosmetic and Reconstructive Surgery, 1370/20.000071

POLICY GUIDELINE(S)

I. Peripheral visual field testing should be performed with the eyelid and brow in the resting

position to document a baseline superior visual field of 30 degrees or less from fixation and show an improvement of at least 12 degrees over baseline with eyelid and brow elevation. A superior visual field of 30 degrees or less that improves with eyelid and brow elevation corresponds to a functional superior visual field loss. If visual field testing is unable to be performed, a written explanation with photographs must accompany the request.

II. Documentation of the marginal reflex distance (MRD), which is the number of millimeters from the corneal light reflex or center of the pupil to the upper lid margin, is necessary for ptosis evaluation. For dermatochalasis MRD is not necessary but may be sufficient.

III. Photographic documentation of the patient while looking in primary gaze, upward-gaze, downward-gaze, and lateral views, which must be consistent with the degree of visual field impairment described in the medical records or demonstrated by the MRD measurements.

IV. Functional limitations may include:

A. Significant interference with vision or superior or lateral visual field (e.g., difficulty seeing objects approaching from periphery);

B. Difficulty reading due to superior visual field loss;

C. Looking through the eyelashes or seeing the upper eyelid skin; or

D. Significant congenital or acquired deformities or deformities beyond normal variations and accompanied by functional deficits. These must be evidenced by photographs. In some cases, visual fields may also be required.

DESCRIPTION

Blepharoplasty is eyelid surgery performed to remove fat, usually along with excess skin, from the upper and lower eyelids.

A functional blepharoplasty is performed when the range of vision is narrowed due to excessive redundant skin in the eyelid (dermatochalasis). During this procedure, various amounts of excess skin and sometimes fat are removed from the upper eyelid, thus increasing vision range. A blepharoplasty may be performed alone or in conjunction with other facial surgery procedures, such as a face lift or browlift, or to address cosmetic issues; however, it will not remove crow's feet or other wrinkles, eliminate dark circles under eyes, or lift sagging eyebrows.

Pseudoptosis is a condition in which the upper-lid skin becomes redundant and lax to such an extent that it "hoods" the eye, blocking peripheral vision on upward-gaze or the upper visual field when looking straight ahead. Dermatochalasis and/or muscle laxity is corrected with a reconstructive upper-lid blepharoplasty that removes excess tissue and restores visual function.

Eyelid ptosis, or blepharoptosis, is when the upper eyelid descends from its normal position or drops to approach or cover the pupil in one or both eyes. This condition can be caused by weakness of the levator muscle or tendon that lifts the eyelid. Treatment when vision is impaired is called a levator muscle advancement and involves tightening the levator muscle to lift the eyelid. In very severe cases involving weakened levator muscles, the eyelid is attached under the eyebrow. This allows the

forehead muscles to substitute for levator muscles in lifting the eyelid. A blepharoplasty may be performed along with levator muscle advancement when dermatochalasis is also present.

Cosmetic Blepharoplasty

When blepharoplasty is performed to improve a patient's appearance, in the absence of any signs and/or symptoms of functional abnormalities, the procedure is considered cosmetic.

Reconstructive Blepharoplasty

Reconstructive blepharoplasty is performed:

- to correct visual impairment caused by drooping of the eyelids (ptosis);
- to correct severe redundant skin (dermatochalasis) resting upon the eyelashes;
- to repair defects caused by trauma or tumor-ablative surgery;
- to treat periorbital sequelae of thyroid disease and nerve palsy;
- to relieve the painful symptoms of blepharospasm. This may involve rearrangement or excision of the structures within the eyelids and/or tissues of the cheek, forehead, and nasal areas.

Signs and symptoms commonly found in association with ptosis, pseudoptosis, blepharochalasis, and/or dermatochalasis include, but are not limited to, the following:

- visual field impairment in primary or downward gaze (e.g., reading position);
- lower than normal position of the eyelid relative to the pupil;
- excess skin that hangs over the edge of the eyelid;
- chronic dermatitis due to redundant skin;
- patients with anophthalmic socket experiencing prosthesis difficulties.

Primary essential (idiopathic) blepharospasm is a condition characterized by severe squinting, secondary to uncontrollable spasms of the periorbital muscles. Occasionally, it can be debilitating. Treatment includes extended blepharoplasty with wide resection of the orbicularis oculi muscle complex.

Cranial nerve palsy is the partial or complete palsy of the facial (seventh cranial) nerve or the oculomotor (third cranial) nerve and can cause true ptosis or pseudoptosis from marked periorbital muscle paralysis. Symptoms such as exposure keratitis and cornea erosion (facial nerve) or visual restriction (oculomotor nerve) may occur. When lesions involving the temporal branch of the facial nerve are present, treatment consists of reconstructive blepharoplasty, with or without browlift. Third-nerve palsy may require frontalis fascial suspension to obtain an adequate eyelid.

Thyroid disease symptoms may include unilateral or bilateral upper-eyelid retraction and proptosis (protruding eye). Frequently, medical therapy for the thyroid pathology will resolve these deformities, but occasionally, reconstructive blepharoplasty is necessary to prevent corneal exposure and erosion.

SUPPORTIVE LITERATURE

Ulas et al (2024) published results of a prospective study to evaluate the effect of upper eyelid

blepharoplasty surgery on corneal topography, visual field, ocular surface, meibography, corneal biomechanics and dry eye parameters. A total of 80 eyes of 40 patients were included. Following a detailed ophthalmological examination, standardized patient satisfaction questions were posed to patients before and after upper eyelid blepharoplasty surgery. Visual field test, non-invasive break up time (NIBUT), meibography, and corneal topography parameters were analyzed and evaluated. The mean (+) visible areas in the visual field were found to be 46.20±24.96 preoperatively, 56.73±21.98 at the 1st postoperative month and 65.96±18.5 at the 3rd month, which were statistically significant. NIBUT values preoperatively, at 1 month and at 3 months were 11.26±4.48, 11.16±4.5 and 10.14±4.0, respectively, which were statistically significant. Meibomian gland loss rates on meibography preoperatively and postoperatively at 1 and 3 months were found to be 30.24±8.3, 29.36±8.2 and 28.22±7.7 respectively and were statistically significant. With the scoring system after blepharoplasty, patients reported improvement in their symptoms. The authors concluded that upper eyelid blepharoplasty surgery is predicted to increase the quality of vision. It was observed that there was a functional and cosmetic improvement in the complaints of the patients after blepharoplasty. However, blepharoplasty may cause changes in eyelid dynamics and cause dry eye syndrome.

Hollander et al (2019) published results of a systematic review to assess the objective and subjective functional effects of upper blepharoplasty found in published literature. A total of 3525 studies were assessed, of which 28 studies were included. The intervention was defined as a solitary surgical upper blepharoplasty containing the removal of skin, with or without the removal of a strip of orbicularis oculi muscle and/or upper orbital fat. Eligible studies were randomized controlled trials, controlled trials, cohort studies, and case series ($n \geq 10$). Favorable outcomes after an upper blepharoplasty were reported and included enlarged visual field, enhanced quality of life related to fewer headaches and improved vision. Furthermore, sensitivity of the eyelids decreased, with differences in recovery. Outcomes for eyebrow height, astigmatism, contrast sensitivity, and eyelid kinematics were not consistent between the studies. No meta-analysis could be performed due to the limited scope of included studies and the great variety in outcomes and blepharoplasty techniques. The authors concluded, upper blepharoplasty is accompanied by a great variety of beneficial functional outcomes including an increased visual field and improvement in headache- and vision-related quality of life. Further research is needed, especially where results are conflicting (effects on eye dryness and eyebrow height) and/or the data are limited (contrast sensitivity, astigmatism).

PROFESSIONAL GUIDELINE(S)

The American Academy of Ophthalmology (AAO) published a report of Functional Indications for Upper Eyelid Ptosis and Blepharoplasty Surgery (Cahill 2011) that state blepharoplasty surgery was found to be functionally beneficial for the following quantitative findings: a MRD1 of ≤ 2 mm measured in primary gaze or a superior visual field loss of 12 degrees or 24%. They explain the unobstructed normal superior field measures approximately 50 degrees. Visual field impairment can occur when the MRD1 is less than 4 mm. With an MRD1 of 2 mm, the superior visual field impairment is in the range of 24–30%. This corresponds to 12-15 degrees of superior visual field loss. Preoperative indicators of improvement include margin reflex distance 1 (MRD1) of 2 mm or less, superior visual field loss of at least 12 degrees or 24%, down-gaze ptosis impairing reading and other

close-work activities, a chin-up backward head tilt due to visual axis obscuration, symptoms of discomfort or eye strain due to droopy lids, central visual interference due to upper eyelid position, and patient self-reported functional impairment.

AAO published a technology assessment regarding health-related quality of life (HRQL) outcomes for upper blepharoplasty and blepharoptosis surgery (Vagefi 2025). A meta-analysis of 20 studies utilizing validated instruments to assess HRQL and found blepharoptosis correction beneficial. The authors noted continued improvement at mean follow-up intervals ranging from 1.5 years to 3.6 years after surgery.

The American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS) published a white paper on functional blepharoplasty, blepharoptosis, and brow ptosis repair (2015). They recommend blepharoplasty when peripheral visual field testing performed with the eyelid and brow in the resting position documents a baseline superior visual field of 30 degrees or less from fixation and improvement of at least 12 degrees over baseline with eyelid and brow elevation. They further state unobstructed, the superior field normally measures approximately 45 to 50 degrees. An MRD of 2 mm corresponds to a superior visual field impairment of 12-15 degrees. Thus, a baseline superior visual field of 30-35 degrees corresponds to an MRD of 2mm. A superior visual field of 30 degrees or less that improves with eyelid and brow elevation corresponds to a functional superior visual field loss.

The American Society of Plastic Surgeons (ASPS) published a practice parameter for blepharoplasty in 2007. They state blepharoplasty is performed for both functional and aesthetic reasons. Functional issues include ptosis, floppy eyelid syndrome, blepharochalasis, dermatochalasis, herniated orbital fat, and visual field obstruction. Aesthetic reasons include a desire for a more youthful or less fatigued appearance. Preoperative consultation should evaluate the patient's reasons for seeking surgery. The physical examination should include an evaluation of the amount of skin on the upper and lower lids; distribution of orbital fat; vector of the lower eyelid; and physical characteristics of the skin including degree of elasticity and pigmentation. Ptosis of the upper eyelid is determined by measuring the palpebral fissure width and margin reflex distance. Levator excursion is also assessed. The forehead and eyebrow should be evaluated for brow ptosis. Preoperative photographs may be taken to meet the requirements of both the insurers and surgeons. Additional photographs may include upward and downward gaze as well as oblique views. Visual field assessment is required for functional blepharoplasty. Consultation with an optometrist or ophthalmologist may be arranged for field of vision examination. When there are visual field impairment blepharoplasty procedures are considered to be reconstructive. However, blepharoplasty procedures are most often performed to enhance appearance.

The American Society of Plastic Surgeons Evidence published evidenced based clinical practice guidelines regarding eyelid surgery for upper visual field improvement (Kim 2022). A group of experts from different disciplines was convened to develop guidelines for the management of upper visual field impairments related to eyelid ptosis and dermatochalasis. The goal was to provide evidence-based recommendations to improve patient care. A systematic literature review was performed including topics regarding documentation of the underlying cause for visual field impairment, selection of an appropriate surgical repair, assessment of the type of anesthesia, the use of

adjunctive brow procedures, and follow-up assessments. The review of the literature revealed varied complication rates and diverse treatment modalities for the correction of upper visual field deficit. Strong recommendations could not be made in most topic areas because of a paucity of methodologically sound studies in literature. More rigorously designed studies are needed to measure outcomes of interest, with fewer sources of potential error or bias. The workgroup recommends that for patients presenting with low upper eyelid position, clinicians obtain a clinical history, which should include an assessment of impact on visual field or activities of daily living; and perform a physical examination to assess upper eyelid position (ptosis) relative to the pupil (such as MRD-1) with photographic documentation and assessment of levator function (Level of evidence weak, moderate recommendation).

REGULATORY STATUS

Not Applicable

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
67901	Repair of blepharoptosis; frontalis muscle technique with suture or other material (e.g., banked fascia)
67902	Repair of blepharoptosis; frontalis muscle technique with autologous fascial sling (includes obtaining fascia)
67903	Repair of blepharoptosis; (tarso) levator resection or advancement, internal approach
67904	Repair of blepharoptosis; (tarso) levator resection or advancement, external approach

Code	Description
67906	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia)
67908	Repair of blepharoptosis; conjunctivo-tarso-Muller's muscle-levator resection (e.g., Fasanella-Servat type)
67909	Reduction of overcorrection of ptosis
67999	Unlisted procedure, eyelids

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

American Society of Ophthalmic Plastic and Reconstructive Surgery (ASOPRS). White paper on functional blepharoplasty, blepharoptosis, and brow ptosis repair. 2015 Jan.

American Society of Plastic Surgeons [Internet]. Practice parameter for blepharoplasty, 2007 Mar [accessed 2026 Feb 2]. Available from: http://www.plasticsurgery.org/Documents/medical-professionals/health-policy/evidence-practice/Blepharoplasty-Practice-Parameter.pdf

Cahill KV, et al. Functional indications for upper eyelid ptosis and blepharoplasty surgery: a report by the American Academy of Ophthalmology. Ophthalmology. 2011 Dec;118(12):2510-7.

Eid L and Tsirbas A. Subbrow blepharoplasty in Caucasians. Plast Reconstr Surg. 2021;147(3):604-607.

Hollander MHJ, et al. Functional outcomes of upper eyelid blepharoplasty: A systematic review. J Plast Reconstr Aesthet Surg. 2019 Feb;72(2):294-309.

Kim KK, et al. American Society of Plastic Surgeons evidence-based clinical practice guideline: eyelid surgery for upper visual field improvement. Plast Reconstr Surg. 2022 Aug 1;150(2):419e-434e.

Rodrigues C, et al. Upper eyelid blepharoplasty: surgical techniques and results-systematic review

and meta-analysis. Aesthetic Plast Surg. 2023 Oct;47(5):1870-1883.

Stein MJ, et al. Practice patterns in blepharoplasty: a 15-year review of continuous certification tracer data from the American Board of Plastic Surgery. Plast Reconstr Surg. 2025 May 1;155(5):895-901.

Ulas B, et al. Evaluation of visual field and ocular surface parameters by clinical comparison after blepharoplasty for dermatochalasis. J Fr Ophthalmol. 2024 Apr;47(4):104135.

Vagefi MR, et al. Health-related quality-of-life outcomes for upper blepharoplasty and blepharoptosis surgery: a report by the American Academy of Ophthalmology. Ophthalmology. 2025 Dec;132(12):1445-1456.

SEARCH TERMS

Transconjunctival blepharoplasty, Transcutaneous blepharoplasty

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Blepharoplasty is not addressed in National or Regional Medicare coverage determinations or policies. Blepharoplasty – (Medical Policy Article A52837) [accessed 2026 Feb 2]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 01/00

Revised: 11/00, 02/02, 02/05, 02/06, 12/07, 11/08, 11/09, 11/10, 11/11, 11/17, 09/18, 11/22, 11/23, 3/24, 3/25, 7/26

Reviewed: 01/01, 10/03, 06/04, 12/05, 12/06, 11/12, 11/13, 11/14, 11/15, 11/16, 11/18, 11/19, 11/20, 11/21, 11/24, 11/25

Date	Summary of Changes
8/1/2026	• Transitioned Blepharoplasty, Blepharoptosis & Brow Ptosis policy,

	1370/20.000225 to Lifetime Healthcare Companies policy template.
3/1/2024* *No Change to effective date of policy	• Updated requirements for submitting medical photographs.
3/1/2024* *No Change to effective date of policy	• Under photographs added information for lower lid blepharoplasty.
3/1/2024	• No criteria updates. Clarified brow lift and browpexy. • Under Visual Fields section added: **Visual field reports must include interpreted results.
12/1/22 *No change to effective date of policy	• Added language to require original photographs

Policy/Procedure Name: Blood Modifiers **Control Number: 1350/20.000588**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Anemia (defined as a hemoglobin [Hb] level <13 g/dL in men or <12 g/dL in women) is a common complication of chronic kidney disease (CKD). The anemia in CKD occurs as a normocytic anemia, meaning the red blood cells (RBCs) are a normal size but there is simply a low number of them. This occurs because the kidneys are responsible for producing a hormone called erythropoietin, which prompts the body to produce RBCs. Patients with CKD cannot make enough erythropoietin; therefore, low erythropoietin levels cause a low RBC count, leading to chronic anemia.

The risk for anemia increases with advancing stages of disease, with an estimated prevalence of 17% in Stage 3, 50% in Stage 4, and at least 54% in Stage 5 (end-stage renal disease [ESRD]). In individuals with CKD, severe anemia can increase the chance of developing cardiovascular (CV) problems because the heart gets less oxygen than normal and must work harder to pump enough RBCs to the organs and tissues. These patients are also at an increased risk for complications due to strokes. Cardiovascular disease is the leading cause of death in dialysis-dependent (DD) patients.

Epoetin alfa is a protein that stimulates the production of red blood cells by the same mechanism as endogenous erythropoietin. It is administered as an intravenous or subcutaneous injection and has multiple FDA approved indications. Epoetin alfa is available as both an innovator biologic reference product and as a biosimilar.

For a biological product to be labeled as a biosimilar, it must be shown that it is highly similar and has no differences from an existing FDA approved reference product (i.e., Epogen) by extensively analyzing the structure, purity, chemical identity, and bioactivity. It has been concluded that there are no clinically meaningful differences demonstrated through human pharmacokinetic/exposure and pharmacodynamic/responses, and assessment of immunogenicity. Biosimilars may be approved for all or a subset of the same indications as the reference product, depending on patent exclusivity. Biosimilars differ from generics in complexity, manufacturing processes, and in the data needed to demonstrate similarity for approval.

Summary

Effective Date of Policy:	2/12/26
Indications	Per product
Availability	Epogen, Procrit, Retacrit: available as single dose vials as 2,000 units (U)/mL, 3,000 U/mL, 4,000 U/mL, 10,000 U/mL, or 40,000 U/mL; available as multi-dose vials as 20,000 U/mL or 20,000 U/2 mL Aranesp: single dose vials as 25 mcg, 40 mcg, 60 mcg, 100 mcg, or 200 mcg; single dose prefilled syringes as 10 mcg/0.4 mL, 25 mcg/0.42 mL, 40 mcg/0.4 mL, 60 mcg/0.3 mL, 100 mcg/0.5 mL, 150 mcg/0.3 mL, 200 mcg/0.4 mL, 300 mcg/0.6 mL, or 500 mcg/1 mL Cosela: 300 mg single dose vial
Duration	Initial: 6 months Recertification: 6 months

Required Criteria for Approval

All of the following conditions for the requested indication must be met in order to approve therapy

Epoetin alfa		
Drug	**FDA Approved Indications**	**Preferred Product**
Epogen HCPCS: J0885 Procrit HCPCS: J0885 Retacrit HCPCS: Q5106	• Treatment of anemia due to zidovudine in patients with HIV infection • Treatment of anemia due to chronic kidney disease (CKD) in patients on dialysis and not on dialysis • Treatment of anemia due to concomitant myelosuppressive chemotherapy • Reduction of allogeneic red blood cell transfusions in patients undergoing elective, noncardiac, nonvascular surgery.	Retacrit and Procrit

A. Procrit and Retacrit are the preferred formulations of epoetin alfa and do not require prior authorization under the pharmacy or medical benefit.
B. Epogen does not require prior authorization under the medical or pharmacy benefit but may not be on all formularies.

Darbepoetin alfa	
Drug	**FDA Approved Indications**
Aranesp HCPCS: J0881	• Anemia Due to Chronic Kidney Disease • Anemia Due to Chemotherapy in Patients with Cancer

Aranesp does not require prior authorization under the medical or pharmacy benefit

Cosela (Trilaciclib)
 	
HCPCS Code: J1448
	• Must be ≥ 18 years of age AND
	• Must be prescribed by an oncologist or hematologist AND
	• Must have a diagnosis of extensive-stage small cell lung cancer (EC-SCLC) AND
	• Must be administered on the same day as of one of the following chemotherapy regimens:
	  ○ Etoposide, carboplatin, and Tecentriq (atezolizumab)
	  ▪ Cosela should be given on day 1, 2, and 3 of a 21-day cycle prior to etoposide administration for up to 4 cycles
	  ▪ Approval for this combination will be granted for 6 months
	  • More than 4 cycles of this combination will not be granted as it has not been studied beyond 4 cycles of induction therapy
	  ○ Etoposide and carboplatin
	  ▪ Cosela should be given on day 1, 2, and 3 of a 21-day cycle prior to etoposide administration until disease progression or unacceptable toxicities
	  ○ Topotecan
	  ▪ Cosela should be given on days 1-5 of a 21-day cycle prior to topotecan administration until disease progression or unacceptable toxicities

Continuation Criteria

- Requests will be reviewed per criteria every 6 months

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.

References

		Updated	Accessed
1	Epogen prescribing information. Amgen Inc. Thousand Oaks, CA	12/2024	1/2026

2	Procrit prescribing information. Amgen Inc. Thousand Oaks, CA	4/2024	1/2026
3	Retacrit prescribing information. Hospira, Inc., a Pfizer Company, Lake Forest, IL	6/2024	1/2026
4	Aranesp prescribing information. Amgen Inc. Thousand Oaks, CA	12/2024	1/2026
5	Cosela prescribing information. Pharmacosmos Therapeutics Inc.	8/2025	1/2026

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted in above application if administered under the medical benefit.
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application if administered under the medical benefit. Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program

CDPHP Pharmacy Services 2/12/2026

New: 2/2026

Revised	Reviewed

Revision Date	Changes Made

This Pharmacy Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI), and Capital District Physicians' Healthcare Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

MEDICAL POLICY

Medical Policy Title	**Bone Densitometry/Bone Density Studies**
Policy Number	**6.01.05**
Current Effective Date	**November 1, 2026**
Next Review Date	**August 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Bone mineral density (BMD) testing is considered **medically necessary** when **ONE** of the following methods are used:

A. Dual-energy x-ray absorptiometry (DEXA or DXA) with or without **either** of the following:

1. Vertebral fracture assessment (VFA);
2. Trabecular bone scoring (TBS); **or**

B. Quantitative computed tomography (QCT);

C. Single-energy x-ray absorptiometry (SEXA);

D. Bone density of the heel using ultrasound; **or**

E. Quantitative ultrasound (QUS);

AND

F. **One** of the following indications with associated criteria are met:

1. Women with **ANY** of the following indications:
   a. Aged 65 years and older, regardless of additional risk factors;
   b. Estrogen-deficient women at clinical risk for osteoporosis (please refer to description section for risk factors for osteoporosis in women);
   c. Post-menopausal women who have discontinued hormone replacement therapy within the past five (5) years; **or**
2. Post-menopausal women under age 65 years with **EITHER** of the following indications:
   a. One (1) or more additional risk factors for osteoporotic fracture (please refer to description section for risk factors for osteoporosis in women); **or**
   b. At increased risk of osteoporosis, as determined by a formal clinical risk assessment tool (e.g., FRAX); **or**
3. Men with **ANY** of the following indications:

a. Men aged 50 to 70 years with clinical risk factors for osteoporotic fracture (please refer to description section for risk factors for osteoporosis in men);

b. Aged 70 years and older, regardless of additional risk factors; **or**

c. Diagnosed with prostate cancer who have received either surgical or medical androgen deprivation therapy; **or**

4. Men and post-menopausal women aged 50 years and older with **EITHER** of the following indications:

   a. Other prior fractures and low bone mass (T-score between -1.0 and -2.5 at the femoral neck, total hip, or spine); **or**

   b. Current or prior hip or vertebral fracture; **or**

5. Individuals with **ANY** of the following indications:

   a. Vertebral abnormalities, as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia (low-bone mass), or vertebral fracture;

   b. Primary hyperparathyroidism;

   c. Suspected cases of secondary osteoporosis due to a broad range of disease states (e.g., hyperthyroidism, rheumatoid arthritis, or type 1 diabetes mellitus);

   d. Being monitored to assess the response to, or efficacy of an osteoporosis drug therapy approved by the U.S. Food and Drug Administration (FDA);

   e. Receiving (or expecting to receive) long-term glucocorticoid therapy (e.g., glucocorticoids in a daily dose greater than or equal to 5 mg prednisone or equivalent for greater than or equal to three (3) months);

   f. On a prescribed drug regimen (e.g., anticonvulsants, aromatase inhibitors, cytotoxic drugs, Depo-Provera contraceptive injection, or hormone replacement therapy) posing a significant risk of osteoporosis; **or**

   g. Previously diagnosed as having osteoporosis.

<u>Follow-up Testing</u>

II. Follow-up BMD testing is considered **medically appropriate** for **ANY** of the following indications:

A. Every two (2) years (at least 23 months have passed since the month the last BMD testing was performed);

B. Individuals starting on Bisphosphonate therapy, testing every three (3) years after initiation of therapy is recommended;

C. More frequently than every two (2) years, if medically necessary. Examples include, but are not limited to the following:

1. The testing is performed to monitor individuals on long-term glucocorticoid (steroid) therapy of more than three (3) months;
2. The testing is performed to obtain a confirmatory baseline (either central or peripheral) using a different BMD testing technique than was used in a patient's initial BMD test, to permit monitoring of the patient using the newer technique (e.g., if the initial test was performed using bone sonometry, and monitoring is anticipated using bone densitometry, a baseline measurement using bone densitometry is allowed); **or**

D. For women receiving estrogen replacement therapy (ERT), who should not be precluded from receiving follow-up or repeat BMD testing.

III. Osteoporosis screening procedures that are considered **investigational**, including but not limited to:

A. Pulse-echo ultrasound bone density measurement of the tibia;

B. Radiofrequency Echographic Multi Spectrometry (REMS);

C. VFA with **EITHER** of the following:

1. SEXA; **or**
2. Automated analysis of an existing Computed Tomography (CT) study

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Refer to the member's subscriber contract to confirm that the member's coverage is subject to the New York State BMD testing mandate.

II. A DEXA study is representative of one (1) or more sites; therefore, a study of multiple sites should be reported and will be processed as a single unit of service.

III. This policy addresses coverage for adults only. Requests for adolescents and children will be reviewed based on diseases and risk factors that are present. Per the Bone Health and Osteoporosis Foundation (BHOF), BMD measurement is not recommended in children or adolescents.

IV. Under the Affordable Care Act, non-grandfathered plans or policies are required to cover, in-network, without cost-sharing, the preventive services recommended by the United States Preventive Services Task Force (USPSTF), including osteoporosis screening for patients identified in the above Policy Statements

V. Changes in BMD may not be detected in less than two (2) years of treatment because of the measurement technique, but a follow-up scan may be appropriate sooner in selected patients.

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Follow-up scans can help to detect treatment failure and secondary disease.

VI. The decision to test BMD should be based on an individual's risk profile. Testing is not indicated unless the results influence a treatment decision.

VII. Whenever possible, use of central (axial skeleton) DEXA is preferred, as clinical evidence supports that this method has one of the lowest standard error rates in measurement and predictive accuracy. However, peripheral DEXA may be used as a substitute when technical problems preclude adequate imaging with a central DEXA machine or when a central DEXA machine is unavailable.

DESCRIPTION

Defining Osteoporosis by BMD

The World Health Organization has established the following definitions, based on BMD of the spine, hip or forearm by DEXA. T scores are reported as standard deviations (SD):

- Normal: T-score at -1.0 and above (within 1 SD of a young healthy adult);
- Osteopenia (low bone mass): T-score between -1 to -2.5 (1 to 2.5 SD below that of a young healthy adult);
- Osteoporosis: T-score at or below -2.5 (2.5 SD or more below that of a young healthy adult); and
- Severe osteoporosis: T-score of -2.5 or less with fragility fractures.

Although these definitions are necessary to establish the prevalence of osteoporosis, they should not be used as the sole determinant of treatment decisions.

Risk Factors for Osteoporosis in Women

There are certain symptoms, conditions, physiologic characteristics, and lifestyle factors indicative of a significant risk of osteoporosis. Per the NIH, risk factors for post-menopausal women under age 65 include, but are not limited to:

- Personal history of a non-traumatic fracture as an adult;
- Family history of osteoporosis (e.g., history of early, non-traumatic fracture in first-degree relative);
- Ethnicity - Caucasian and Asian women are at highest risk. African American and Latino women have a lower, but significant, risk;
- Poor health/frailty;
- Cigarette smoking;
- Body size – small, thin-boned women are at greater risk;
- Extended estrogen deficiency;

- Age - Risk increases with age, as bones become less dense and weaker with age;
- Eating disorders such as anorexia nervosa;
- Excessive use of alcohol;
- Low calcium and vitamin D intake (lifelong);
- Long-term use of certain medications, such as glucocorticoids;
- Sedentary lifestyle or extended bed rest; or
- Osteopenia.

Post-Menopause Definition

The American College of Obstetricians and Gynecologists defines post-menopausal as the time in a woman's life when she stops having menstrual periods - specifically, when she has gone 12 consecutive months with no menstrual period. Menopause marks the end of the reproductive years that began in puberty.

Risk Factors for Osteoporosis in Men

There are certain symptoms, conditions, physiologic characteristics or lifestyle factors indicative of a significant risk of osteoporosis. Per the NIH, risk factors for osteoporosis in men include:

- Chronic diseases that affect the kidneys, lungs, stomach, and/or intestines or alters hormone levels;
- Long-term use of certain medications, such as glucocorticoids;
- Low levels of testosterone;
- Unhealthy lifestyle habits (e.g., smoking, excessive alcohol use, low calcium intake, and inadequate physical exercise);
- Age – the older the individual, the greater the risk;
- Race – Caucasian men appear to be at particularly high risk, but all men can develop osteoporosis.

Quantitative Ultrasound (QUS)

QUS is a radiation-free bone assessment technique that uses high-frequency sound waves to evaluate bone health, most commonly at the calcaneus (heel bone). Unlike DXA, which measures bone mineral density (BMD), QUS characterizes bone tissue through its interaction with sound waves, providing information about both bone density and structural/qualitative properties. A QUS device positions the heel between two transducers — one emitting and one receiving ultrasound waves.

The calcaneus is the preferred measurement site because it consists of approximately 95% trabecular bone, has a high metabolic turnover rate, and possesses two lateral surfaces that facilitate ultrasound transmission. A limitation of QUS is it does not measure bone mineral density. The World Health Organization (WHO) diagnostic standard T-score thresholds cannot be applied to QUS values, lack of

standardization across devices, and not recommended for standalone treatment decisions or monitoring.

Pulse-echo Ultrasound

Bindex is a handheld pulse-echo ultrasound device used to measure apparent cortical bone thickness at the proximal tibia, to aid the physician in the diagnosis of osteoporosis.

Vertebral Fracture Assessment using Computed Tomography

Vertebral fracture evaluation can be performed using a pre-existing computed tomography dataset via assistive augmented intelligence. It is used for the detection of osteoporosis as evidenced by vertebral compression fractures that are below the threshold for human detection. For example, the data set from a CTA scan of the chest performed for the diagnosis of pulmonary embolism could be subsequently analyzed by an algorithm created for identification of additional findings such as subtle osteoporotic vertebral fractures.

Trabecular Bone Scoring

The trabecular bone score (TBS) is a diagnostic software tool that analyzes the internal structure of the lumbar spine bones. It is used in conjunction with dual-energy x-ray absorptiometry (DXA), which is an enhanced form of x-ray technology that is performed to measure bone mineral density (BMD). TBS uses standard DXA lumbar spine images to measure the structure of trabecular (cancellous) bone, providing additional information to be used in conjunction with BMD results in calculating fracture risk. Using a software program installed on a standard DXA computer, TBS provides an index of bone structure and quality without requiring additional radiation exposure or scan time. TBS received US FDA approval in 2012 for use as a complement to DXA analysis for the assessment of fracture risk and provides additional utility in fracture risk assessment among people with secondary causes of bone loss and fractures, such as type 2 diabetes.

REMS

REMS by Echolight is a diagnostic, non-invasive, radiation-free, office-based testing for bone density and fracture risk assessment at axial sites. It exploits all the spectral features of the native, unfiltered "raw" signals acquired during echographic scan. The algorithm automatically identifies the target bone interfaces within the sequence of the acquired echographic images, discarding "noisy" acquisitions and artifacts.

SUPPORTIVE LITERATURE

BMD Studies

While there are a number of tests available to assess bone mineral density, clinical evidence supports that DEXA of the hip or lumbar sacral spine and QCT have the lowest standard error in measurement and predictive accuracy. In addition, studies that show reduced fracture with treatment have used results from hip/spine DEXA machines.

Data from several studies showed women treated with bisphosphonates and other pharmacologic treatment benefited from reduced fractures with treatment, even if BMD did not increase. There is no

evidence from randomized, controlled trials regarding how often to monitor BMD during osteoporosis treatment. There is moderate-quality evidence suggesting that most women do not need regular monitoring.

Crandall et al (2020) conducted a cohort study assessing the need of a second BMD study approximately 3 years later after initial baseline measurement associated with improved ability to differentiate fracture risk in postmenopausal women. The study included 7,419 women mean age of 66.1 years, mean BMI 28.7 and 1,720 were non-Caucasian. During the follow-up period, 139 women experienced hip fractures, and 732 women experienced major osteoporotic fractures. When assessing the difference in the data between women who experience hip fractures and those who do not, area under the receiver operating characteristic curve (AU-ROC) values were 0.71(95% CI, 0.67-0.75) for baseline total hip BMD, 0.61 (95% CI, 0.56-0.65) for change in total hip BMD, and 0.73 (95% CI, 0.69-0.77) for the combination of baseline total hip BMD and change in total hip BMD. Femoral neck and lumbar spine BMD values had similar discrimination for hip fracture. For discrimination of major osteoporotic fracture, AU-ROC values were 0.61 (95% CI,0.59-0.63) for baseline total hip BMD, 0.53 (95% CI, 0.51-0.55) for change in total hip BMD, and 0.61 (95% CI, 0.59-0.63) for the combination of baseline total hip BMD and change in total hip BMD. Femoral neck and lumbar spine BMD values had similar ability to recognize the differences between women who experienced major osteoporotic fracture and those who did not. The change in bone density and fracture risk did not differ by subgroup, including diabetes, age, race/ethnicity, body mass index, or baseline BMD T score. Limitations for this study included that it was an observational design, and fractures were self-reported. However, strengths included prospective follow-up, and large number of participants. The researchers concluded that the evidence suggests that repeat BMD testing in postmenopausal women at three years after baseline BMD should not be routinely performed.

Vertebral Fracture Assessment using DEXA

Vertebral fractures are highly prevalent in the elderly populations, and epidemiologic studies have found that these fractures are associated with an increased risk of future spine or hip fractures independent of BMD. Only 20-30% of vertebral fractures are recognized clinically; the rest are discovered incidentally on lateral spine radiographs. Lateral spine x-rays have not been recommended as a component of risk assessment for osteoporosis, because of the cost, the radiation exposure, and the fact that the x-ray would require a separate procedure in addition to the BMD study. However, lateral spine images for vertebral fracture assessment (VFA) can be obtained using DEXA at the same time that a patient is undergoing assessment of BMD. Although VFA may be rapid and convenient, the images obtained are not of sufficient quality to establish the presence or absence of vertebral fractures. Literature suggests that densitometry may not accurately diagnose vertebral fractures in the population of interest (women with osteopenia or normal BMD). There is a lack of evidence that the test is accurate in detecting fractures among subjects without osteoporosis. Available evidence is insufficient to assess what health outcomes would result from VFA using DEXA as a screening test for osteoporosis.

Vertebral Fracture Assessment using Computed Tomography

There is currently limited research demonstrating the effectiveness of vertebral fracture assessment

using CT with assistive augmented intelligence.

Pulse-echo Ultrasound

The use of pulse-echo ultrasonometry is being promoted as a cost-effective screening option to determine appropriateness for DXA measurement. There is limited research, and no randomized, controlled trials, demonstrating the effectiveness of pulse-echo ultrasound as compared to DXA.

Algahtani et al (2025) conducted a comparative study on 168 participants, comparing the pulse-echo ultrasound versus the DXA and how they compare in acceptability, comfort, and preference. A bespoke questionnaire was given out to gather responses from the participants. The questionnaire showed that despite the discomfort from the gel application, the pulse-echo received significantly higher acceptability and comfort ratings and preferring that it is non-ionizing radiation.

Trabecular Bone Scoring

There is a lack of well-designed clinical trials including diverse populations in the peer-reviewed scientific literature addressing the impact of TBS on patient-specific health outcomes. Future prospective trials evaluating the use trabecular bone score in place of or in addition to established fracture prediction tools should report if long-term patient health outcomes are improved.

Jose et al (2021) conducted a cross-sectional single center study aimed to study the bone microarchitecture (TBS-trabecular bone score) and BMD in a total of 250 postmenopausal women with either morbid obesity, obese or non-obese. The participants were categorized based on body mass index (BMI). In the morbid obesity (BMI ≥ 35 kg/m2) group, with 85 participants was compared to 80 subjects with obesity (BMI ≥ 25–35 kg/m2) and 85 non-obese women (BMI ≤ 25 kg/m2). The BMI cut-off points for obesity were defined as per the Asia-Pacific guidelines by the WHO, suggesting lower thresholds for obesity, in order to identify individuals that are at higher risk at a lower BMI. The BMD and TBS were assessed in all subjects using a Hologic-QDR 4500-W Discovery-A DXA scanner. The mean BMD (gm/cm2) at the femoral neck in women with morbid obesity was found to be significantly lower as compared to the age-matched postmenopausal obese controls (0.723 versus 0.762). The BMD at the lumbar spine and hip showed similar trends but were not statistically significant. The bone microarchitecture was found to be significantly lower in those with morbid obesity (1.205) as compared to obesity (1.244) and non-obese (1.228). Though obesity was associated with a better bone density and bone microarchitecture in postmenopausal women, in those with morbid obesity a lower value was seen. Limitations included the lack of heterogeneity, and lacking details regarding bone reabsorption and formation markers and physical activity. Additional studies are needed to validate this study.

REMS

Al Refaie et al (2023) performed a systematic review of literature to evaluate the most recent data on the REMs technique for assessing bone mineral density. The literature obtained was from 2019 to 2023 using PubMed-Medline, Cochrane Library, ClinicalTrials.gov, and SCOPUS; cases found were cross-sectional observational studies. The authors state that the literature "confirmed diagnostic concordance between BMD values obtained using DXA and REMS. Furthermore, REMS has adequate precision and repeatability characteristics, is able to predict the risk of fragility fractures, and may be

able to overcome some of the limitations of DXA". The authors concluded that REMS could become the method of choice for the assessment of bone status in children, women of childbearing age or who are pregnant, and in several secondary osteoporosis conditions due to its good precision and replicability, transportability, and the absence of ionizing radiation. The authors did state that ongoing research is needed to better understand the role of REMS in diagnosis and follow-up in patients with osteoporosis with respect to DXA and understand what population would benefit from REMs versus DXA.

There are ongoing clinical trials but no reported results. The current studies being performed are looking at many different indications that may affect imaging for osteoporosis or may cause osteoporosis such as osteoarthritis, vitamin D deficiency, osteogenic perfecta, pregnancy. The studies are promising, showing reliable technology and the possibility to lead to earlier interventions for individuals with bone fragility. Further clinical trials are needed along with FDA approval.

PROFESSIONAL GUIDELINE(S)

Lems et al (2025) reported the results of the best practices report that made recommendations on standardization of VFA as part of standard clinical DXA assessment for osteoporosis care. The working group was endorsed by the American Association of Clinical Endocrinology (AACE), the American Society for Bone and Mineral Research (ASBMR) and representatives from 15 international societies. The recommendations state the following:

- "Ideally, VFA should be performed in all patients undergoing DXA (bone mineral density) testing."
- "If DXA access is limited, VFA should be prioritized in high-risk patients."
- "If VFA is not available on the DXA system, use conventional lateral spine X-rays to detect vertebral fractures."

The U.S. Preventive Services Task Force (USPSTF) currently recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in:

- Women aged 65 years and older screen for osteoporosis with DXA BMD testing, with or without fracture risk assessment.
- Post-menopausal women younger than age 65 years with one (1) or more risk factors for osteoporosis. For women at increased risk, screen for osteoporosis with DXA BMD testing, with or without fracture risk assessment. clinical risk assessment tool.
- The current evidence is insufficient to assess the balance of benefits and harms of screening for osteoporosis in men.

The Bone Health and Osteoporosis Foundation (BHOF), formally known as The National Osteoporosis Foundation (NOF) reported theClinicians Guide to Prevention and Treatment of Osteoporosis (LeBoff et al 2022), an it includes recommendation for BMD testing for:

- Women aged 65 years and older and for men aged 70 years and older, regardless of clinical risk factors.

- Post-menopausal women in the menopausal transition and men aged 50 to 69 years based on risk profile.
- Postmenopausal women and men aged greater or equal to 50 years with a history of adult-age fracture; and
- Adults who have a condition (e.g., rheumatoid arthritis) or are taking a medication (e.g., glucocorticoids in a daily dose ≥ 5 mg prednisone or equivalent for ≥ three (3) months) associated with low bone mass or bone loss.
- BMD measurement is not recommended in children or adolescents and is not routinely indicated in healthy young men or pre-menopausal women, unless there is a significant fracture history, or there are specific risk factors for bone loss.
- Follow-up testing is recommended one (1) to two (2) years after initiating medical therapy for osteoporosis and at appropriate intervals thereafter according to clinical circumstances such as high-risk individuals (multiple fractures, older age, very low BMD).
- Vertebral fracture imaging (X-ray or DXA vertebral fracture assessment) should be performed in high-risk individuals to detect subclinical vertebral fractures. Traditionally, conventional lateral thoracic/lumbar spine X-ray has been considered the gold standard for identification of vertebral fractures and minor vertebral deformities. However, DXA-assisted vertebral fracture assessment (DXA-VFA) is emerging as an alternative to radiography for its convenience, low cost, and minimal radiation exposure. Recently performed MRI or CT imaging studies done for other purposes can and should also be evaluated for presence of vertebral fractures or evidence of vertebral deformity.

American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis (Camacho 2020):

- An update to the guidelines in 2020 includes stratification of women with osteoporosis into high-risk and very-high-risk features to drive choice and duration of initial therapy.

The Endocrine Society Clinical Practice Guideline: Osteoporosis in Men (2012) recommends:

- Testing higher-risk men (men age greater than or equal to 70 years and men aged 50 to 69 years who have risk factors [e.g., low body weight, prior fracture as an adult, smoking, etc.]) using central dual-energy x-ray absorptiometry.
- The guideline suggests measuring forearm DXA (1/3 or 33% radius) when spine or hip BMD cannot be interpreted and for men with hyperparathyroidism or receiving androgen deprivation therapy for prostate cancer.

In 2023 a the European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (ESCEO), the International Osteoporosis Foundation (under the auspices of WHO Collaborating Center for Epidemiology of Musculoskeletal Health and Aging) conducted a systematic review on the clinical use of trabecular bone score. The four topics that were reviewed consisted of the use of TBS in fracture risk prediction, treatment initiation and assessing response to pharmacological interventions in postmenopausal osteoporosis, fracture risk in secondary

osteoporosis and for assessing response to pharmacological therapies in secondary osteoporosis. The recommendations are as follows:

- TBS should be used in conjunction with BMD and clinical risk factors (strongly recommended).
- TBS results should be interpreted within clinical context of the patient (strongly recommended).
- Reduction in TBS is observed in most secondary osteoporosis-related diseases, and predicts fracture risk in type 2 diabetes, chronic kidney disease, patients treated with glucocorticoids, rheumatological diseases and it is relatively unaffected by spinal changes (strongly recommended).
- TBS adds value when used with BMD in monitoring skeletal effects of aromatase inhibitors, glucocorticoids and response to antiosteoporosis therapy across both primary and secondary osteoporosis (strongly recommended).

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates bone mineral density devices as medical devices. All [device] including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Jul 17]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2026 Jul 17]

The New York Insurance Law mandates that coverage be provided for bone density tests, as well as prescription drugs and devices that are approved by the FDA, for the detection and treatment of osteoporosis. The law provides that individuals qualifying for coverage shall, at a minimum, include individuals who have any of the following:

- A previous diagnosis or family history of osteoporosis;
- Symptoms or a condition indicative of the presence or significant risk of osteoporosis;
- A prescribed drug regimen posing a significant risk of osteoporosis;
- Lifestyle factors posing a significant risk of osteoporosis; or
- Age, gender, and/or physiological characteristics posing a significant risk of osteoporosis.

Several DEXA central bone densitometers have been approved by the FDA, such as the Norland XR 46 DXA (Central) Bone Densitometer. Several bone ultrasonometers have been cleared for marketing by the FDA, such as Myriad's Soundscan (approved May 1998) and Hologic's Sahara Clinical Bone Sonometer (approved March 1998). To perform VFA on DEXA devices, additional software is needed and must also have Section 510(k) marketing clearance from the FDA.

Bone Index Finland, Ltd. received Section 510(k) approval from the FDA in May 2016 for Bindex BI-100 and Bindex BI-2 in January 2017.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method
76999*	Unlisted ultrasound procedure (e.g., diagnostic, interventional) (*Consider E/I when used to report pulse-echo ultrasound for bone density measurement testing.)
77078	Computed tomography, bone mineral density study, 1 or more sites, axial skeleton (e.g., hips, pelvis, spine)
77080	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)
77081	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)
77085	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine), including vertebral fracture assessment
77086	Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA)
77089	Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture-risk
77090	technical preparation and transmission of data for analysis to be performed elsewhere
77091	technical calculation only

Code	Description
77092	interpretation and report on fracture-risk only by other qualified health care professional
0554T (E/I)	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone mineral density, interpretation and report
0555T (E/I)	retrieval and transmission of the scan data
0556T (E/I)	assessment of bone strength and fracture risk and bone mineral density
0557T (E/I)	interpretation and report
0691T (E/I)	Automated analysis of an existing computed tomography study for vertebral fracture(s), including assessment of bone density when performed, data preparation, interpretation, and report
0743T (E/I)	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density (BMD), with concurrent vertebral fracture assessment, utilizing data from a computed tomography scan, retrieval and transmission of the scan data, measurement of bone strength and BMD and classification of any vertebral fractures, with overall fracture risk assessment, interpretation and report
0815T (E/I)	Ultrasound-based radiofrequency echographic multi-spectrometry (REMS), bone-density study and fracture-risk assessment, 1 or more sites, hips, pelvis, or spine

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HCPCS Codes

Code	Description
G0130	Single energy x-ray absorptiometry (SEXA) bone density study, one or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)

ICD10 Codes

Code	Description
E21.0-E21.5	Hyperparathyroidism and other disorders of parathyroid gland (code range)
E24.0-E24.9	Cushing's syndrome (code range)
E28.310-E28.319	Premature menopause (code range)

Code	Description
E28.39	Other primary ovarian failure
E29.1	Testicular hypofunction
E34.2	Ectopic hormone secretion, not elsewhere classified
E89.40	Asymptomatic postprocedural ovarian failure
E89.41	Symptomatic postprocedural ovarian failure
E89.5	Postprocedural testicular hypofunction
N91.0-N91.2	Amenorrhea (code range)
N92.4	Excessive bleeding in the premenopausal period
N95.0-N95.9	Menopausal and other perimenopausal disorders (code range)
M48.50-M48.58	Collapsed vertebra, not elsewhere classified (code range)
M80.0-M80.8	Age-related osteoporosis with current pathological fracture (code range)
M81.0-M81.8	Osteoporosis without current pathological fracture (code range)
M84.48-M84.9	Pathological fracture, other site (code range)
M85.80-M85.9	Other specified disorders of bone density and structure (code range)
Q96-Q96.9	Turner's syndrome (code range)
R29.890	Loss of height
Z08	Encounter for follow-up examination after completed treatment for malignant neoplasm
Z09	Encounter for follow-up examination after completed treatment for conditions other than malignant neoplasm
Z13.820	Encounter for screening for osteoporosis
Z78.0	Asymptomatic menopausal state
Z79.51-Z79.52	Long term (current) use of steroids (code range)

Code	Description
Z87.310-Z87.312	Personal history of (healed) fractures (code range)
Z90.721-Z90.722	Acquired absence of ovaries (code range)
Z90.79	Acquired absence of other genital organ(s)

REFERENCES

Agency for Healthcare Research and Quality. Osteoporosis in postmenopausal women: diagnosis and monitoring. Evidence Report/Technology Assessment 2001 Apr 9;28.

Agency for Healthcare Research and Quality (AHRQ) [Internet]. Guide to Clinical Preventive Services. Recommendations of the U.S. Preventive Services Task Force. Osteoporosis to prevent fractures: screening. 2025 January. [accessed 2026 June 09]. Available from: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/osteoporosis-screening

Algahtani A, et al. Participant perspectives on pulse-echo ultrasound technology versus dual energy x-ray absorptiometry (DXA): a comparative study. In Vivo. 2025 Mar-Apr;39(2):909-916.

Al Refaie A, et al. Radiofrequency echographic multi-spectrometry (R.E.M.S.): new frontiers for ultrasound use in the assessment of bone status - a current picture. Diagnostics (Basel). 2023 May 9;13(10):1666.

Al Refaie A, et al. Utility of REMS-derived fragility score and trabecular bone score in evaluating bone health in type 2 diabetes mellitus. Diagnostics (Basel). 2025 Nov 13;15(22):2877.

American College of Obstetricians and Gynecologists [Internet]. ACOG guidelines for the clinical management of osteoporosis. 2004 Mar 15 [accessed 2026 Jun 09]. Available from: http://www.aafp.org/afp/2004/0315/p1558.html

American College of Obstetricians and Gynecologists. Osteoporosis. ACOG Practice Bulletin No. 50, Obstet Gynecol 2004 Jan;103(1):203-16.

Bone Health & Osteoporosis Foundation (BHOF)/ International Society for Clinical Densitometry (ISCD) FRAX Implementation Guide [Internet]. [accessed 2026 Jun 09]. Available from: https://iscd.org/learn/resources/fracture-risk-models/

Camacho PM, et al. American Association of Clinical Endocrinologists/American College of Endocrinology clinical practice guidelines for the diagnosis and treatment of postmenopausal osteoporosis-2020 update. Endocr Pract. 2020 May;26(Suppl 1):1-46.

Crandall CJ, et al. Serial bone density measurement and incident fracture risk discrimination in postmenopausal women. JAMA Intern Med. 2020 Sep 1;180(9):1232-1240.

Eastell R, et al. Pharmacological management of osteoporosis in postmenopausal women: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2019 May 1;104(5):1595-1622.

Fuggle NR, et al. Radiofrequency echographic multi spectrometry (REMS) in the diagnosis and management of osteoporosis: state of the art. Aging Clin Exp Res. 2024 Jun 21;36(1):135.

Giovanni A, et al. Bone health status evaluation in men by means of REMS technology. Aging Clin Exp Res. 2024 Mar 18;36(1):74.

Hans D, et al. Long-term effect of denosumab on bone microarchitecture as assessed by tissue thickness-adjusted trabecular bone score in postmenopausal women with osteoporosis: results from FREEDOM and its open-label extension. Osteoporos Int. 2023 Jun;34(6):1075-1084.

Hans D, et al. Quantitative ultrasound (QUS) in the management of osteoporosis and assessment of fracture risk: an update. Adv Exp Med Biol. 2022;1364:7-34.

Jose A, et al. Trabecular bone score and bone mineral density in postmenopausal women with morbid obesity - a clinical paradox. Med Sci (Basel). 2021 Nov 9;9(4):69.

Keaveny TM, et al. Biomechanical computed tomography analysis (BCT) for clinical assessment of osteoporosis. Osteoporos Int. 2020 Jun;31(6):1025-1048.

Kim DK, et al. Effect of androgen-deprivation therapy on bone mineral density in patients with prostate cancer: a systematic review and meta-analysis. J Clin Med. 2019 Jan 18;8(1):E113.

LeBooff MS, et al. The clinicians guide to prevention and treatment of osteoporosis. Osteoporos Int 2022 Apr 28;33:2049-2102

Lems WF, et al. Making VFA part of standard clinical dxa assessment for osteoporosis care: recommendations from the International Working Group on DXA best practices. Mayo Clin Proc. 2025 Dec;100(12):2186-2205.

Lin JK, et al. Validation of biomechanical computed tomography for fracture risk classification in metastatic hormone-sensitive prostate cancer. Eur Urol Oncol. 2024 Aug;7(4):794-803.

Löffler MT, et al. Automatic opportunistic osteoporosis screening in routine CT: improved prediction of patients with prevalent vertebral fractures compared to DXA. European Radiology. 2021;31:6069–6077.

Merlijn T, et al. The effect of a screening and treatment program for the prevention of fractures in older women: a randomized pragmatic trial. Journal of Bone and Mineral Research. 2019 Nov;34(11):1993–2000.

Moonkum N, et al. Osteopenia and osteoporosis screening detection: calcaneal quantitative ultrasound with and without calibration factor comparison to gold standard dual x-ray absorptiometry. J Clin Densitom. 2024 Apr-Jun;27(2):101470.

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology. Prostate cancer. V.5.2026. 2025 Jan 28 [accessed 2026 Jun 10]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf?utm_source=openevidence#page

=37

National Institutes of Health Osteoporosis and Related Bone Diseases National Resource Center [Internet]. Osteoporosis overview. [reviewed 2025 Mar; accessed 2026 Jun 09]. Available from: http://www.niams.nih.gov/health-topics/bone-health-and-osteoporosis

National Institute of Health Osteoporosis and Related Bone Diseases National Resource Center [Internet]. Osteoporosis in men. last reviewed 2023 May. [accessed 2026 Jun 09]. Available from: http://www.niams.nih.gov/health-topics/osteoporosis-men

Pan Y, et al. Automatic opportunistic osteoporosis screening using low-dose chest computed tomography scans obtained for lung cancer screening. European Radiology 2020;30:4107–4116.

Pouilles J-M, et al. TBS in early postmenopausal women with severe vertebral osteoporosis. Bone. 2021;142:115698.

Qaseem A, et al. Treatment of low bone density or osteoporosis to prevent fracture in men and women: a clinical practice guideline update from the American College of Physicians. Ann Intern Med. 2017 Jun 6;166(11):818-839.

Salari N, et al. Global prevalence of osteoporosis among the world older adults: a comprehensive systematic review and meta-analysis. Journal of Orthopaedic Surgery and Research. 2021;16:669.

Shevroja E, et al. Update on the clinical use of trabecular bone score (TBS) in the management of osteoporosis: results of an expert group meeting organized by the European Society for Clinical and Economic Aspects of Osteoporosis, Osteoarthritis and Musculoskeletal Diseases (ESCEO), and the International Osteoporosis Foundation (IOF) under the auspices of WHO Collaborating Center for Epidemiology of Musculoskeletal Health and Aging. Osteoporos Int. 2023 Sep;34(9):1501-1529.

Shuhart C, et al. Executive Summary of the 2023 Adult Position Development Conference of the International Society for Clinical Densitometry: DXA Reporting, Follow-up BMD Testing and Trabecular Bone Score Application and Reporting. J Clin Densitom. 2024 Jan-Mar;27(1):101435.

State of New York Insurance Law §7657. Amendment 11723, effective 2003 Jan 1.

World Health Organization Fracture Risk Assessment Tool [Internet]. [accessed 2026 June 09] Available from: https://www.sheffield.ac.uk/FRAX/

Yang J, et al. Identification of prevalent vertebral fractures using Vertebral Fracture Assessment (VFA) in asymptomatic postmenopausal women: A systematic review and meta-analysis. Bone. 2020;136:doi115358.

Yu JS, et al. ACR Appropriateness Criteria® Osteoporosis and Bone Mineral Density: 2022 Update. J Am Coll Radiol. 2022 Nov;19(11S):S417-S432.

Zweig A, et al. Skip that repeat DXA scan in these postmenopausal women. J Fam Pract. 2021 Dec;70(10):510-512.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Bone (Mineral) Density Studies (NCD 150.3) [accessed 2026 Jun 09]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 7/26

Revised:

Reviewed:

Date	Summary of Changes
11/1/2026	• New

MEDICAL POLICY

Medical Policy Title	**Breast Reconstruction Surgery and Prophylactic Breast Cancer Risk-Reducing Mastectomy**
Policy Number	**10.01.01**
Current Effective Date	**September 1, 2026**
Next Review Date	**August 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Reconstructive breast surgery during or after surgical mastectomy, including partial mastectomy (e.g., lumpectomy, segmentectomy, quadrantectomy) for benign or malignant disease, is considered **medically appropriate**, and may include the following services:

   A. All stages of reconstruction, including, but not limited to:

      1. Breast implants;
      2. Abdominal flap reconstruction;
      3. Chest wall reconstruction;
      4. Nipple/areola reconstruction and tattooing; and
      5. Surgery for symmetry of the contralateral (opposite) breast;

   B. Basic breast prosthetic(s) and mastectomy bras;

   C. Treatment of physical complications of mastectomy, including lymphedema (in accordance with Corporate Medical Policy #1.01.17 Powered Compression Devices/Lymphedema Pumps).

II. A risk-reducing mastectomy is considered a **medically appropriate** prophylactic treatment for individuals with **ANY** of the following high-risk breast cancer factors:

   A. Lobular carcinoma in situ;

   B. A known BRCA1 or BRCA2 variant;

   C. Another gene variant associated with high risk (e.g., TP53 [Li-Fraumeni syndrome], PTEN [Cowden syndrome, Bannayan-Riley-Ruvalcaba syndrome], CDH1, STK11, and PALB2;

   D. Received radiotherapy to the chest between the ages of 10 and 30 years (e.g., Hodgkin's disease).

III. The following techniques are considered **medically appropriate** alternatives to a medically appropriate risk-reducing conventional mastectomy:

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

A. A skin-sparing mastectomy;

B. A nipple-sparing mastectomy;

C. A two-stage procedure including an oncoplastic breast reduction followed by a risk-reducing mastectomy and breast reconstruction.

RELATED POLICIES

Corporate Medical Policy

1.01.17 Powered Compression Devices/Lymphedema Pumps

7.01.11 Cosmetic and Reconstructive Procedures

7.01.35 Bioengineered Tissue Products for Wound Treatment and Surgical Interventions

7.01.39 Reduction Mammaplasty (Mammoplasty)

POLICY GUIDELINE(S)

I. The Federal Women's Health and Cancer Rights Act (WHCRA) of 1998, as well as the New York Insurance Law, mandate coverage of all stages of reconstructive surgery for individuals who have or have not been diagnosed with breast cancer, in the manner determined by the attending physician and the patient to be appropriate which can include surgery and reconstruction of the contralateral breast to produce symmetrical appearance, chest wall reconstruction, prosthesis, treatment of physical complications following mastectomy and prophylactic mastectomies for all group health plans, whether insured or self-funded, that provide medical and surgical benefits.

II. It is recommended that all individuals considering risk-based mastectomy have counseling provided by a health professional (other than the operating surgeon) who is skilled in assessing cancer risk. This discussion should include an explanation of the risks and benefits of various screening and treatment options (e.g., increased surveillance or chemoprevention).

DESCRIPTION

Reconstructive breast surgery is a surgical procedure that is designed to restore the normal appearance of the breast after surgery, accidental injury, or trauma. The nature and extent of the reconstructive breast surgery depends upon the initial surgery or treatment that an individual receives to remove all or a portion of a breast.

The reconstructive surgery may be performed in a single stage or several stages/phases and either during or after a surgical procedure to remove breast tissue. Reconstruction may include, but is not limited to:

- Insertion of saline or silicone filled prosthetic implants;
- Extensive flap reconstruction (e.g., deep inferior epigastric perforator [DIEP] flap, gluteal artery perforator [GAP] flap, latissimus dorsi flap, superficial inferior epigastric artery [SIEA]

flap, transverse rectus abdominus myocutaneous [TRAM] flap);

- Chest wall reconstruction;
- Nipple/areola reconstruction and tattooing;
- Surgery for symmetry of the contralateral (opposite) breast.

Conventional mastectomy is a surgical procedure that involves removing the entirety of the breast tissue, skin overlying the breast, and the nipple-areola complex. A risk-reducing mastectomy, also referred to as a preventative or prophylactic mastectomy, is the surgical removal of both breasts for the purpose of reducing cancer risk and is meant for individuals who are considered very high risk. The surgery may be performed as a total mastectomy, where the nipple and areola are removed or via a nipple-sparing technique that preserves the nipple and areola. Total mastectomy provides a vaguely higher level of risk reduction (as high as 95% in women who have disease causing variants [BRCA 1 /BRCA2]) compared to nipple-sparing mastectomy, which allows for more natural-looking breasts after reconstruction.

SUPPORTIVE LITERATURE

Wong et al (2017) updated and examined national trends in contralateral prophylactic mastectomy (CPM) and examined if survival differed for invasive breast cancer patients based on hormone receptor status and age. These investigators identified women diagnosed with unilateral stage I to III breast cancer between 1998 and 2012 within the Surveillance, Epidemiology, and End Results registry. They compared characteristics and temporal trends between patients undergoing breast-conserving surgery, unilateral mastectomy, and CPM. Of 496,488 women diagnosed with unilateral invasive breast cancer, 59.6% underwent breast-conserving surgery, 33.4% underwent unilateral mastectomy, and 7.0% underwent CPM. Overall, the proportion of women undergoing CPM increased from 3.9% in 2002 to 12.7% in 2012 ($p < 0.001$). Reconstructive surgery was performed in 48.3% of CPM patients compared with only 16.0% of unilateral mastectomy patients, with rates of reconstruction with CPM rising from 35.3% in 2002 to 55.4% in 2012 ($p < 0.001$). When compared with breast-conserving therapy, these researchers found no significant improvement in breast cancer-specific survival (BCSS) or overall survival (OS) for women undergoing CPM (BCSS: HR 1.08, 95% CI: 1.01 to 1.16; OS: HR 1.08, 95% CI: 1.03 to 1.14), regardless of hormone receptor status or age. The authors concluded that the use of CPM more than tripled during the study period despite evidence suggesting no survival benefit over breast conservation. They stated that further examination on how to optimally counsel women about surgical options is needed.

A Cochrane review by Carbine et al (2018) examined the impact of risk-reducing mastectomy on mortality and other health outcomes. Reviewers did not identify any randomized controlled trials. Sixty-one observational studies with some methodologic limitations were identified. The studies presented data on 15,077 individuals with a wide range of risk factors for breast cancer who underwent a risk-reducing mastectomy. Studies on the incidence of breast cancer and disease-specific mortality (n=21) reported reductions in both after a bilateral risk-reducing mastectomy, particularly for those with BRCA1 or BRCA2 variants.

The previously summarized Cochrane review by Carbine et al (2018) also assessed various outcomes, including mortality and disease-free survival, among individuals who received a contralateral risk-reducing mastectomy. Twenty-six observational studies assessed outcomes in these individuals. While results showed a reduced incidence of CBC among those who received a contralateral risk-reducing mastectomy, results on disease-specific mortality were inconsistent. Seven of the included studies showed no survival advantage. One additional study showed an improvement in all-cause mortality associated with contralateral risk-reducing mastectomy; however, significance was lost after adjustment for bilateral risk-reducing salpingo-oophorectomy. The authors attributed the variability in mortality findings, in part, to selection bias, since younger, healthier individuals may be more likely to opt for contralateral risk-reducing mastectomy.

Filipe et al (2022) performed a systematic review and meta-analysis that compared the postoperative complication rate of robotic nipple-sparring mastectomy (RNSM) to nipple-sparring mastectomy (NSM). The primary outcome was determining the overall postoperative complication rate of traditional NSM and RNSM. Secondary outcomes were comparing the specific postoperative complication rates: implant loss, hematoma, (flap)necrosis, infection, and seroma. Forty-nine studies containing 13,886 cases of (R)NSM were included. No statistically significant differences were found regarding postoperative complications (RNSM 3.9%, NSM 7.0%, $p = 0.070$), postoperative implant loss (RNSM 4.1%, NSM 3.2%, $p = 0.523$), hematomas (RNSM 4.3%, NSM 2.0%, $p = 0.059$), necrosis (RNSM 4.3%, NSM 7.4%, $p = 0.230$), infection (RNSM 8.3%, NSM 4.0%, $p = 0.054$) or seromas (RNSM 3.0%, NSM 2.0%, $p = 0.421$). Overall, there are no statistically significant differences in complication rates between NSM and RNSM.

Schelletter et al (2025) conducted a systematic review and meta-analysis aimed to provide a comprehensive, quantitative assessment on the risk associated with implant-based reconstruction in CPM versus therapeutic mastectomy (TM). Five studies were included in the final analysis, representing 3543 patients who underwent 6401 mastectomies (3260 TM and 3141 CPM), followed by prosthetic breast reconstruction including tissue expanders and direct-to-implant procedures. Reconstructions after TM were associated with a statistically significantly higher risk of postoperative infections (OR = 2.03 [95% CI: 1.50 – 2.73]) and explanation rates (OR = 2.41 [95% CI: 1.77 – 3.28]). No significant differences were observed between the two groups in the occurrence of hematoma, seroma, necrosis, and capsular contracture. Authors concluded that implant-based breast reconstruction after CPM demonstrates a lower risk of postoperative complications compared with TM.

PROFESSIONAL GUIDELINE(S)

NCCN Guidelines V.3.2026 Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic recommends that the option of risk reducing mastectomy (RRM) be discussed for carriers of the following genetic variants: BRCA-Pathogenic/Likely Pathogenic Variant-Positive, CDH1, PALB2, STK11, and Li-Fraumeni. For those with clinical Cowden syndrome/PTEN hamartoma tumor syndrome, consideration of risk-reducing surgery should be based on family history. Counseling should include a discussion regarding degree of protection, reconstruction options, and risks.

In 2021, The American College of Medical Genetics (ACMG) published a clinical practice resource for individuals with germline PALB2 variants. PALB2 is a major cancer susceptibility gene, and given this, The ACMG recommends that "Risk-reducing mastectomy can be considered as an option. The decision should be guided by a personalized risk assessment." In 2020, The American Society of Breast Surgeons (ASBrS) published a consensus statement on contralateral prophylactic mastectomy (CPM) (Boughey et al), concluding that CPM should be considered for those at significant risk of contralateral breast cancer who are documented BRCA1/2 carriers, strong family history where patient has not undergone genetic testing, and history of mantle chest radiation before age 30 years. CPM for those at lower risk of contralateral breast cancer but whom should be considered for CPM include Gene carriers of non-BRCA genes (e.g., CHECK-2, PALB2, p53, CDH1), strong family history where patient is BRCA negative and no known BRCA family member. CPM should additionally be considered for other reasons including to limit contralateral breast surveillance, improve reconstructed breast symmetry, manage risk aversion, to manage extreme anxiety. ASBrS discourages CPM in average-risk women with unilateral breast cancer, women with advanced index cancer, women at high-risk for surgical complications, women who have tested BRCA negative with a family of BRCA positive carriers, and for male breast cancer, including BRCA carriers.

The American Society of Clinical Oncology, American Society for Radiation Oncology, and Society of Surgical Oncology published joint guidelines for the management of hereditary breast cancer (Tung et al 2020). The guidelines include the following recommendations related to breast conserving surgery (BCS) which are based on formal consensus:

I. The following factors should be considered for assessing risk of contralateral breast cancer (CBC) and role of risk-reducing mastectomy in BRCA1/2 mutation carriers: age at diagnosis (the strongest predictor of future CBC), family history of breast cancer, overall prognosis from this or other cancers (e.g., ovarian), ability of patient to undergo appropriate breast surveillance (magnetic resonance imaging [MRI]), comorbidities, and life expectancy (Evidence quality: low; Strength of recommendation: moderate);

II. Patients with newly diagnosed breast cancer who have a mutation in a moderate-penetrance breast cancer susceptibility gene, mutation status alone should not determine local therapy decisions for the index tumor or contralateral risk-reducing mastectomy (CRRM) (Evidence quality: low, Strength of recommendation: moderate);

III. In patients with breast cancer with a mutation in a moderate-penetrance breast cancer susceptibility gene, BCT should be offered to those for whom BCT is an appropriate treatment option. There is a lack of data regarding ipsilateral breast cancer events after BCT among patients with moderate-risk mutations (Evidence quality: low; Strength of recommendation: moderate);

IV. For women with newly diagnosed breast cancer undergoing mastectomy who have a deleterious mutation in BRCA1/2, nipple-sparing mastectomy is a reasonable oncologic approach to consider in appropriately selected patients (Evidence quality: intermediate; Strength of recommendation: moderate);

V. For women with newly diagnosed breast cancer undergoing mastectomy who have a deleterious mutation in a moderate penetrance gene, nipple-sparing mastectomy is a reasonable oncologic approach to consider in appropriately selected patients (Evidence quality: low; strength of recommendation: moderate);

VI. Surgical management of the index malignancy (including BCT, ipsilateral therapeutic and contralateral risk-reducing mastectomy in BRCA1/BRCA 2 mutation carriers should be discussed (Evidence quality: intermediate, strength of recommendation: strong);

VII. For women with breast cancer who have a BRCA1/BRCA 2 mutation and who have been treated or are being treated with unilateral mastectomy, CRRM should be offered. CRRM is associated with a decreased risk of CBC; there is insufficient evidence for improved survival. The following factors should be considered for assessing risk of CBC and role of risk-reducing mastectomy: age at diagnosis (the strongest predictor of future CBC), family history of breast cancer, overall prognosis from this or other cancers (e.g., ovarian), ability of patient to undergo appropriate breast surveillance (MRI), comorbidities, and life expectancy (Evidence quality: intermediate; strength of recommendation: moderate).

VIII. For women with breast cancer who have a mutation in a moderate-penetrance breast cancer predisposition gene and who have been treated or are being treated with unilateral mastectomy, the decision regarding CRRM should not be based predominantly on mutation status. Additional factors that predict CBC such as age at diagnosis and family history should be considered, as they are in all cases. The impact of CRRM on decreasing risk of CBC is dependent on the risk of CBC for each individual gene. Data regarding the risk of CBC resulting from moderate-penetrance genes are limited (Type: formal consensus; Evidence quality: low; strength of recommendation: moderate);

IX. For patients with breast cancer with a deleterious germline BRCA1/2 mutation interested in CRRM, physicians should discuss the option of nipple-sparing mastectomy as a reasonable oncologic option (Type: formal consensus; Evidence quality: intermediate; strength of recommendation: strong).

X. For patients with breast cancer with a mutation in a moderate-penetrance gene who are interested in CRRM, physicians should discuss the option of nipple-sparing mastectomy as a reasonable oncologic option (Evidence quality: low; strength of recommendation: moderate).

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates breast reconstruction implants as medical devices. All breast reconstruction implants require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 June 30]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most

serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 June 30]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
11920	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq cm or less
11921	6.1 to 20.0 sq cm
11922	each additional 20.0 sq cm, or part thereof (List separately in addition to code for primary procedure)
13100	Repair, complex, trunk; 1.1 cm to 2.5 cm
13101	Repair, complex, trunk; 2.6 cm to 7.5 cm
14000	Adjacent tissue transfer or rearrangement, trunk; defect 10 sq cm or less
14001	Adjacent tissue transfer or rearrangement, trunk; defect 10.1 sq cm to 30 sq cm
14301	Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm
15650	Transfer, intermediate, of any pedicle flap (abdomen to wrist, Walking tube), any location
15738	Muscle, myocutaneous, or fasciocutaneous flap; lower extremity
15740	Flap; island pedicle requiring identification and dissection of an anatomically named axial vessel
15770	Graft; derma-fat-fascia
15771	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50cc or less injectate
15772	each additional 50cc injectate or part thereof (List separately in addition to code for primary procedure)
19316	Mastopexy

Code	Description
19318	Breast reduction
19325	Breast augmentation with implant
19328	Removal of intact breast implant
19330	Removal of ruptured breast implant, including implant contents (e.g., saline, silicone gel)
19340	Insertion of breast implant on same day of mastectomy (i.e., immediate)
19342	Insertion or replacement of breast implant on separate day from mastectomy
19350	Nipple/areola reconstruction
19355	Correction of inverted nipples
19357	Tissue expander placement in breast reconstruction, including subsequent expansion(s)
19361	Breast reconstruction with latissimus dorsi flap
19364	Breast reconstruction with free flap (e.g. fTRAM, DIEP, SIEA, GAP flap)
19367	Breast reconstruction; with single pedicled transverse rectus abdominis myocutaneous (TRAM) flap
19368	requiring separate microvascular anastomosis (supercharging)
19369	Breast reconstruction; with bipedicled transverse rectus abdominis myocutaneous (TRAM) flap
19370	Revision of peri-implant capsule, breast, including capsulotomy capsulorrhaphy, and/or partial capsulectomy
19371	Peri-implant capsulectomy, breast, complete, including removal of all intracapsular contents
19380	Revision of reconstructed breast (e.g., significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction
19396	Preparation of moulage for custom breast implant
19499	Unlisted procedure, breast
21601	Excision of chest wall tumor including rib(s)
21602	Excision of chest wall tumor involving rib(s) with plastic reconstruction, without mediastinal lymphadenectomy

Code	Description
21603	Excision of chest wall tumor including rib(s) with plastic reconstruction, with mediastinal lymphadenectomy
21740	Reconstructive repair of pectus excavatum or carinatum; open
21742	Reconstructive repair of pectus excavatum or carinatum minimally invasive approach (Nuss procedure), without thoracoscopy
21743	Reconstructive repair of pectus excavatum or carinatum minimally invasive approach (Nuss procedure), with thoracoscopy

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HCPCS Codes

Code	Description
L8001	Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, unilateral, any size, any type
L8002	Breast prosthesis, mastectomy bra, with integrated breast prosthesis form, bilateral, any size, any type
L8600	Implantable breast prosthesis, silicone or equal
S2066	Breast reconstruction with gluteal artery perforator (GAP) flap, including harvesting of the flap, microvascular transfer, closure of donor site and shaping the flap into a breast, unilateral
S2067	Breast reconstruction of a single breast with "stacked" deep inferior epigastric perforator (DIEP) flap(s) and/or gluteal artery perforator (GAP) flap(s), including harvesting of the flap(s), microvascular transfer, closure of donor site(s) and shaping the flap into a breast, unilateral
S2068	Breast reconstruction w/ deep inferior epigastric perforator (DIEP) flap or superficial inferior epigastric artery (SIEA) flap, including harvesting of the flap, microvascular transfer, closure of donor site, and shaping the flap into a breast, unilateral

ICD10 Codes

Code	Description
C48.1	Malignant neoplasm of specified parts of peritoneum
C50.A0	Malignant inflammatory neoplasm of unspecified breast

Code	Description
C50.A1	Malignant inflammatory neoplasm of right breast
C50.A2	Malignant inflammatory neoplasm of left breast
C50.011-C50.019	Malignant neoplasm of nipple and areola (code range)
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111-C50.119	Malignant neoplasm of central portion of female breast (code range)
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211-C50.219	Malignant neoplasm of upper-inner quadrant of female breast (code range)
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311-C50.319	Malignant neoplasm of lower-inner quadrant of female breast (code range)
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411-C50.419	Malignant neoplasm of upper-outer quadrant of female breast (code range)
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511-C50.519	Malignant neoplasm of lower-outer quadrant of female breast (code range)

Code	Description
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611-C50.619	Malignant neoplasm of axillary tail of female breast (code range)
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811-C50.819	Malignant neoplasm of overlapping sites of female breast (code range)
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911-C50.919	Malignant neoplasm of unspecified site of female breast (code range)
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C56.1-C56.3	Malignant neoplasm of ovary (code range)
C79.60	Secondary malignant neoplasm of unspecified ovary
C79.61-C79.63	Secondary malignant neoplasm of ovary (code range)
C79.81	Secondary malignant neoplasm of breast
C84.7A	Breast implant associated anaplastic large cell lymphoma (BIA-ALCL)
D05.00-D05.92	Carcinoma in situ of breast (code range)
D24.1-D24.9	Benign neoplasm of breast (code range)
D49.3	Neoplasm of unspecified behavior of breast

Code	Description
Z15.01	Genetic susceptibility to malignant neoplasm of breast
Z15.02	Genetic susceptibility to malignant neoplasm of ovary
Z15.05	Genetic susceptibility to malignant neoplasm of fallopian tube(s)
Z40.01	Encounter for prophylactic removal of breast
Z40.02	Encounter for prophylactic removal of ovary(s)
Z40.03	Encounter for prophylactic removal of fallopian tube(s)
Z42.1	Encounter for breast reconstruction following mastectomy
Z85.3	Personal history of malignant neoplasm of breast
Z90.11-Z90.13	Acquired absence of breast and nipple (code range)

REFERENCES

Agency for Healthcare Research and Quality [Internet]. Evidence reports: breast reconstruction after mastectomy. Last revised 2021 Jul 14 [accessed 2026 July 2] Available from: https://effectivehealthcare.ahrq.gov/products/breast-reconstruction-mastectomy/research

American Cancer Society [Internet]. Breast reconstruction after mastectomy. Cancer Reference Information. Last revised 2022 Sept 19 [accessed 2026 July 2]. Available from: https://www.cancer.org/cancer/types/breast-cancer/reconstruction-surgery.html

American Society of Plastic Surgeons [Internet]. Breast reconstruction following diagnosis and treatment for breast cancer. Archived practice parameter. 2004 Sep. [accessed 2026 July 02]. Available from: http://www.plasticsurgery.org/Documents/medical-professionals/health-policy/key-issues/BreastReconstructionFollowingDiagnosisandTreatmentforBreastCancer.pdf

American Society of Plastic Surgeons [Internet]. Breast reconstruction. 2026 [accessed 2026 July 02]. Available from: https://www.plasticsurgery.org/reconstructive-procedures/breast-reconstruction

Carbine NE, et al. Risk-reducing mastectomy for the prevention of primary breast cancer. Cochrane Database Syst Rev. Apr 05 2018;4(4).

Filipe MD, et al. Robotic nipple-sparring mastectomy complication rate compared to traditional nipple-sparing mastectomy: a systematic review and meta-analysis. J Robot Surg. 2022 Apr;16(2):265-272.

Griffin C, et al. Outcomes of women undergoing mastectomy for unilateral breast cancer who elect to undergo contralateral mastectomy for symmetry: a systematic review. Ann Surg Oncol. 2024;31:303-

315.

Kuruvilla AS, et al. Oncologic safety in autologous fat grafting after breast conservation therapy. Ann Plast Surg. 2023;90:106-110.

Mota BS, et al. Skin-sparing mastectomy for the treatment of breast cancer. Cochrane Database of Systematic Reviews 2023;3:CD010993.

National Cancer Institute [Internet]. Surgery to reduce the risk of breast cancer. 2025 Dec 02 [accessed 2026 July 02]. Available from: https://www.cancer.gov/types/breast/risk-reducing-surgery-fact-sheet

National Comprehensive Cancer Network [Internet]. Genetic/familial high-risk assessment: breast, ovarian, pancreatic, and prostrate. V.3.2026. 2025 Jul 10 [accessed 2026 Jul 24]. Available from: https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1419

National Comprehensive Cancer Network [Internet]. Breast cancer risk reduction. V.4.2026. 2026 Jun 12 [accessed 2026 July 02]. Available from: https://www.nccn.org/guidelines/guidelines-detail?category=2&id=1420

New York State Insurance Laws [Internet] § 3216, § 3221, and § 4303 (x) (1) [accessed 2026 Jul 02]. Available from: http://public.leginfo.state.ny.us/lawssrch.cgi?NVLWO:

New York State Department of Financial Services [Internet]. Insurance circular letter No.2. July 2016 Health insurance coverage for the prevention and treatment of breast cancer [accessed 2026 July 02]. Available from: https://www.dfs.ny.gov/industry_guidance/circular_letters/cl2016_02

Pietkowski AA, et al. Effect of total breast reconstruction with autologous fat transfer using an expansion device vs. implants on quality of life among patients with breast cancer, a randomized clinical trial. JAMA Surgery. 2023 May 1;158(5)456-464.

Regan JP. Breast reconstruction. National library of medicine: stat pearls. 23 July 2023. [accessed 2026 July 02]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK470317/

Schelletter M, et al. Complications of prosthetic breast reconstruction in prophylactic versus therapeutic mastectomy: a systematic review and meta-analysis. Plast Reconstr Surg Glob Open. 2025 Jun 19;13(6):e6904.

Tischkowitz M, et al. Management of individuals with germline variants in PALB2: a clinical practice resource of the American College of Medical Genetics and Genomics (ACMG). Genetics in Medicine. 2021;23:1416-1423.

Tung NM, et al. Management of hereditary breast cancer: American Society of Clinical Oncology, American Society for Radiation Oncology, and Society of Surgical Oncology Guideline. J Clin Oncol. 2020 Jun;38:2080-2106.

U.S. Department of Labor [Internet]. Women's Health and Cancer Rights Act. 2018 Sep. [accessed 2026 July 02]. Available from: https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/publications/your-rights-after-a-mastectomy.pdf

Wong SM, et al. Growing use of contralateral prophylactic mastectomy despite no improvement in long-term survival for invasive breast cancer. Ann Surg. 2017;265(3):581-589.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Breast Reconstruction Following Mastectomy (140.2) [accessed 2026 Jul 02]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 5/26

Revised:

Reviewed:

Date	Summary of Changes
9/1/2026	• New: Service was previously referenced on Cosmetic & Reconstructive Surgery policy 1370/20.000071.

MEDICAL POLICY

Medical Policy Title	**Bulking Agents for Treatment of Urinary or Fecal Incontinence**
Policy Number	**7.01.22**
Current Effective Date	**September 1, 2026**
Next Review Date	**March 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

Urinary Incontinence

I. Urethral bulking agents for the treatment of urinary incontinence may be considered **medically appropriate** if approved by the U.S. Food and Drug Administration (FDA) and meet the required criteria for the following indications:

   A. Collagen implants when the following criteria are met:

      1. **BOTH** of the following criteria:

         a. Stress incontinence due to urethral sphincter dysfunction; **and**

         b. Unresponsive to conservative therapy;

         AND

      2. **ONE** of the following indications:

         a. Patients with congenital sphincter weakness secondary to conditions such as myelomeningocele or epispadias;

         b. Patients with acquired sphincter weakness secondary to spinal cord lesion;

         c. Biological male patients following trauma, including prostatectomy and/or radiation; **or**

         d. Biological female patients without urethral hypermobility and with abdominal leak point pressure of 100 cm H_2O or less.

   B. Bulking agents when the following criteria are met:

      1. **ALL** of the following criteria:

         a. Treatment of stress incontinence due to intrinsic sphincter deficiency (ISD);

         b. Only in biological female patients; **and**

         c. Unresponsive to conservative therapy;

         AND

2. **ANY** of the following bulking agents, including but not limited to:
    a. Carbon-coated beads (Durasphere);
    b. Polyacrylamide hydrogel (Bulkamid);
    c. Spherical particles of calcium hydroxyapatite (Coaptite); **or**
    d. Polydimethylsiloxane (silicone elastomer) particles (Macroplastique).

II. Urethral bulking agents are considered **not medically necessary** in the treatment of other types of urinary incontinence including, but not limited to, the following:
    A. Urinary retention with overflow incontinence;
    B. Ectopic ureter;
    C. Neurogenic bladder dysfunction;
    D. Urinary fistulas;
    E. Psychogenic incontinence.

III. Additional Durasphere implants are considered **not medically necessary** when incontinence does not improve with five (5) separate injection sessions.

IV. Urethral bulking agents are considered **investigational** for the treatment of urinary stress incontinence including, but not limited to, **ANY** of the following:
    A. Polytetrafluoroethylene (Teflon);
    B. Autologous cellular therapy (e.g., myoblasts, fibroblasts, muscle-derived stem cells, adipose-derived stem cells);
    C. Microballoons (UroVive).

Fecal Incontinence

V. Perianal bulking agents to treat fecal incontinence (FI) are considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

7.01.10 Sacral Nerve Stimulation

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Use of Durasphere is restricted to prescription use by doctors trained in cystoscope use who have completed the appropriate implant training program.

DESCRIPTION

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Intrinsic Sphincter Deficiency

One physiologic cause of urinary incontinence is intrinsic sphincter deficiency (ISD). ISD describes a condition in which the urethral sphincter has been damaged by surgery, neurological disorders, or trauma. The result is sphincter incompetence and urinary leakage.

There are two types of ISD:

- Total ISD is characterized by constant involuntary dripping of urine from the urethra day and night without bladder distention, as determined by physical examination of the abdomen and measurement of residual urine.
- Partial sphincter deficiency, also known as stress incontinence, affects patients who may experience involuntary loss of urine when coughing, bending, lifting or performing any maneuver that increases transabdominal pressure.

Urethral Bulking Agents

Urethral bulking agents are substances that have been developed for use in the treatment of stress incontinence due to ISD. These substances are injected at the area of the bladder neck and proximal urethra. The increased bulk caused by these substances enhances urethral resistance to the outflow of urine, thus reducing urine leakage. Urethral bulking agents may be injected over a course of several treatments until the desired effect is achieved. The procedure for injecting urethral-bulking agents is performed either in the doctor's office or the outpatient department of a hospital.

Pyrolytic Carbon-Coated Beads (Durasphere)

Datasphere are indicated for use in the treatment of adult women with stress urinary incontinence due to ISD. Carbon beads do not require skin testing, as there is no associated antigenicity. Durasphere is injected sub-mucosal at the bladder neck in females. The final bulking result is derived from the combination of the carbon-coated beads and the body's own collagen.

Coaptite

Coaptite is an injectable implant composed of spherical particles of calcium hydroxyapatite. It is indicated for the treatment of stress urinary incontinence due to (ISD) in adult females.

Bulkamid

Bulkamid is a thick, permanent gel containing 2.5% cross-linked polyacrylamide and 97.5% apyrogenic water. It is injected into the wall of the urethra near the bladder to treat women who have stress urinary incontinence or stress predominant, mixed incontinence due to ISD.

Macroplastique

Macroplastique is an injectable soft-tissue urethral bulking agent for treating stress urinary incontinence primarily due to intrinsic sphincter deficiency. Macroplastique is made up of a water-soluble gel (polyvinylpyrrolidone) that is absorbed and removed from the body in urine; the synthetic, rubber-like, silicone elastomer implant material (cross-linked polydimethylsiloxane) is permanent and not absorbed by the body. The silicone elastomer causes the bulking effect around the urethra after

implantation.

Bulking agents injected into the anal canal have been proposed for treating fecal incontinence associated with internal anal sphincter (IAS) dysfunction. The bulking agent is injected into the submucosa of the anal canal to increase tissue bulk in the area, which narrows the opening of the anus. Current treatment options for fecal incontinence include conservative measures, e.g., dietary changes, pharmacotherapy, pelvic floor muscle exercises, sacral nerve stimulation, and surgical interventions to correct an underlying problem.

SUPPORTIVE LITERATURE

Urinary Incontinence

Clinical trials investigating the safety and efficacy of Durasphere have shown that they have improved the net health outcomes of patients in the short term by achieving dryness or significant improvements in the symptoms of incontinence and provided benefits comparable to alternative treatments such as surgery.

Braga et al (2022) conducted a systematic review, and meta-analysis on 11 articles to summarize the literature findings on the use of urethral bulking agents to manage recurrent stress urinary incontinence after failure of a mid-urethral sling. The overall cure and improvement rate ranged from 64% to 85% in the included studies, with a pooled value of 75%, compared with pooled failure and re-operation rates of 32% and 25%, respectively. A sub-group analysis was performed using bulking agents, bulkmamid and macroplastique. The pooled values of the cure and improvement rate were 84% and 80% for both of the bulking agents. While the study shows promise of using urethral bulking agents after failed mid-urethral sling, they suggest that further studies be completed.

Capobianco et al (2019) conducted a systematic review, and meta-analysis to evaluate the efficacy and the effectiveness, safety and tolerability of urethral bulking agents (UBAs) in women with mixed or stress urinary incontinence. Out of 42 full articles only 21 were selected. The most frequently administered bulking agents were Bulkmamid and macroplastique, followed by urolastic, Macroplastique Implantation System (MIS) and durasphere. The improvement rate was higher than 50 %, with an estimated 57 % after a follow-up of>1 year. The outcome cure/dryness ranged from 9.1% to 56.7 %. The treatment success rate, assessed with different tools, ranged from 32.7% to 93.3%. The pooled objective treatment success rate was 7.0 % and 46.0 % in patients receiving follow-up ≤12 and>12 months, retrospectively. There were several limitations based on quality, including the risk of selection bias. The study concluded that optimal injection technique has yet to be standardized. Overall, rates of complications that were associated with UBAs are low; however, long-term implications of permanent UBAs in the periurethral milieu are unknown.

Though autologous fat injections do not require FDA approval, results of clinical studies have shown poor health outcomes associated with reabsorption and fibrotic ingrowth.

Fecal Incontinence

Knowles et al (2023), conducted a multicenter, prospective, non-randomized study of 48 participants. The objective of the study was to examine the safety and efficacy of iltamiocel, an investigational

cellular therapy of autologous muscle-derived cells, as treatment for FI. Each participant was injected with a single dose of iltamiocel. No serious adverse effects and only one product-related adverse effect of inflammation at the injection site were reported. A ≥ 50% reduction in FI episodes was observed in 53.7% of participants, and 24.4% had complete restoration of continence. Symptom severity and quality of life improved with mean Cleveland Clinic Incontinence Score reduction (-2.9; 95% CI: −3.7, −2.1), and Fecal Incontinence Quality of Life increased (2.2; 95% CI:1.4, 2.9). No significant changes were detected in anorectal manometry measurements. Historically, episiotomy was significantly associated with treatment response in multivariate analysis. The administration of iltamiocel cellular therapy is safe. Iltamiocel shows promise for significantly improving fecal incontinence symptoms and quality of life.

Maeda et al (2013), in a Cochrane Review, determined the effectiveness of perianal injection of bulking agents for the treatment of fecal incontinence in adults. Five eligible randomized trials with a total of 382 patients were identified. Four of the trials were at an uncertain or high risk of bias. Most trials reported a short-term benefit from injections regardless of the material used, including placebo saline injection. One study demonstrated dextranomer in stabilized hyaluronic acid (NASHA Dx) to be more effective than sham injection, but with more adverse effects. Another study comparing silicone material (PTQ) to saline injections was too small to demonstrate a clinical benefit compared to the control injection of normal saline. A silicone biomaterial (PTQ) was shown to provide some advantages and was safer in treating fecal incontinence than carbon coated beads (Durasphere) in the short term. Similarly, there were short-term benefits from injections delivered under ultrasound guidance compared with digital guidance. No evidence on long-term outcomes was available, and further conclusions were not warranted from the available data. None of the studies reported patient evaluation of outcomes, and, thus, it is difficult to gauge whether the improvement in incontinence scores matched practical symptom improvements that mattered to the patients. The authors concluded that one large, randomized, controlled trial has shown that this form of treatment using dextranomer in stabilized hyaluronic acid (NASHA Dx) improves continence for a little over half of patients in the short term. However, the number of identified trials was limited, and most had methodological weaknesses.

PROFESSIONAL GUIDELINE(S)

Urinary Incontinence

American Urological Association (AUA) Guidelines (2017; amended 2023) for the Surgical Treatment of Female Stress Urinary Incontinence (SUI):

- "Physicians should not offer stem cell therapy for stress incontinent patients outside of investigative protocols." (Expert Opinion).
- Clinicians should counsel index patients considering surgery for SUI regarding the efficacy and safety of bulking agents (Strong recommendation; Evidence Level: Grade A).

American Urogynecologic Society 2024 Clinical Practice Statement in Urethral Bulking recommend the following:

- "Urethral bulking agents are indicated in cases of stress urinary incontinence (SUI), and that intrinsic sphincter deficiency is not predictive of patient outcomes" (Grade B evidence; strength [SOR]: strong recommendation).
- "Urethral bulking agents may be considered for initial management of SUI, however the grade of evidence and strength of the recommendation were weaker" (Grade C evidence; SOR: recommendation).

Fecal Incontinence

The American Society of Colon and Rectal Surgeons Clinical Practice Guidelines for the Management Fecal Incontinence (Bordeianou 2023) state that injection of biocompatible bulking agents into the anal canal is not routinely recommended for the treatment of FI.

American Gastroenterological Association 2017 Clinical Practice Update for Surgical Interventions and the Use of Device-Aided Therapy for the Treatment of Fecal Incontinence and Defecatory Disorders suggest the following:

- "Perianal bulking agents such as intra-anal injection of dextranomor may be considered when conservative measures and biofeedback therapy fail."

REGULATORY STATUS

Urinary Incontinence

Cross-linked collagen, carbon-coated beads (Durasphere), Coaptite, Bulkamid, and Macroplastique have been approved by the FDA, but only for the treatment of urinary stress incontinence due to ISD. Durasphere, Coaptite, Bulkamid, and Macroplastique are approved only for use in biologic females. Other synthetic urethral bulking agents do not have FDA approval.

The U.S. Food and Drug Administration (FDA) regulates [device] as medical devices. All [device] including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Feb 05]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Feb 05]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0963T (E/I)	Anoscopy with directed submucosal injection of bulking agent into anal canal (Effective 07/01/25)
0999T (E/I)	Autologous muscle cell therapy, harvesting of muscle progenitor cells, including ultrasound guidance, when performed (Effective 01/01/26)
1000T (E/I)	Autologous muscle cell therapy, administration of muscle progenitor cells into the urethral sphincter, including cystoscopy and post-void residual ultrasound, when performed (Effective 01/01/26)
1001T (E/I)	Autologous muscle cell therapy, injection of muscle progenitor cells into the external anal sphincter, including ultrasound guidance, when performed (Effective 01/01/26)
46999 (*E/I)	Unlisted procedure, anus (*E/I when used for Fecal incontinence ICD10 code range R15.0-R15.9)
51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck

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HCPCS Codes

Code	Description
L8603	Injectable bulking agent, collagen implant, urinary tract, per 2.5 ml syringe, includes shipping and necessary supplies
L8604 (E/I)	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, urinary tract, 1ml, includes shipping and necessary supplies
L8605 (E/I)	Injectable bulking agent, dextranomer/hyaluronic acid copolymer implant, anal canal, 1 ml, includes shipping and necessary supplies
L8606	Injectable bulking agent, synthetic implant, urinary tract, 1 ml syringe, includes shipping and necessary supplies

ICD10 Codes

Code	Description
N36.42-N36.43	Urethral functional and muscular disorders (code range)
N39.3	Stress incontinence (female) (male)
N39.41-N39.46	Other specified urinary incontinence (code range)
N39.498	Other specified urinary incontinence
R15.0-R15.9	Fecal incontinence (code range)

Code	Description
R32.0	Unspecified urinary incontinence

REFERENCES

American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin No. 155: Urinary Incontinence in Women. Obstet Gynecol. 2015 Nov;126(5):e66-81.

American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin No. 210: Fecal Incontinence. Obstet Gynecol. 2019 Apr;133(4):e260-273.

Barakat B, et al. Stem cell applications in regenerative medicine for stress urinary incontinence: A review of effectiveness based on clinical trials. Arab J Urol. 2020 Apr 17;18(3):194-205.

Bharucha AE, et al. Comparative effectiveness of biofeedback and injectable bulking agents for treatment of fecal incontinence: Design and methods. Contemp Clin Trials. 2021 Aug;107:106464.

Braga A, et al. Urethral bulking agents for the treatment of recurrent stress urinary incontinence: A systematic review and meta-analysis. Maturitas. 2022 Sep;163:28-37. doi: 10.1016/j.maturitas.2022.05.007.

Brosche T, et al. Seven-year efficacy and safety outcomes of Bulkamid for the treatment of stress urinary incontinence. Neurourol Urodyn. 2021 Jan;40(1):502-508.

Capobianco G, et al. Efficacy and effectiveness of bulking agents in the treatment of stress and mixed urinary incontinence: A systematic review and meta-analysis. Maturitas. 2020 Mar;133:13-31.

Elmelund M, et al. Patient characteristics that may influence the effect of urethral injection therapy for female stress urinary incontinence. J Urol. 2019 Jul;202(1):125-131.

Hartigan SM, et al. Which procedure for stress urinary incontinence? Injectable. Curr Opin Urol. 2020,30: 272-274.

Hong KD, et al. Midterm outcomes of injectable bulking agents for fecal incontinence: a systematic review and meta-analysis. Tech Coloproctol. 2017 Mar;21(3):203-210.

Itkonen Freitas AM, et al. Tension-free vaginal tape surgery versus polyacrylamide hydrogel injection for primary stress urinary incontinence: a randomized clinical trial. J Urol. 2020 Feb;203(2):372-378.

Kobashi KC, et al. Updates to surgical treatment of female stress urinary incontinence (SUI): AUA/SUFU Guideline (2023). J Urol. 2023 Jun;209(6):1091-1098.

Maeda Y, et al. Perianal injectable bulking agents as a treatment for faecal incontinence in adults. Cochrane Database Syst Rev. 2013 Feb 28;2:CD007959.

Matsuoka PK, et al. The efficacy and safety of urethral injection therapy for urinary incontinence in women: a systematic review. Clinics (Sao Paulo). 2016 Feb;71(2):94-100.

Muñoz-Duyos A, et al. Critical appraisal of international guidelines for the management of fecal

incontinence in adults: is it possible to define what to do in different clinical scenarios? Tech Coloproctol. 2022 Jan;26(1):1-17.

Pai A and Al-Singary W. Durability, safety and efficacy of polyacrylamide hydrogel (Bulkamid) in the management of stress and mixed urinary incontinence: three year follow up outcomes. Cent European J Urol. 2015;68(4):428-33.

Schmid FA, et al. Treatment of stress urinary incontinence with muscle stem cells and stem cell components: Chances, challenges and future prospects. Int J Mol Sci. 2021 Apr 12;22(8):3981.

Toia B, et al. Bulking for stress urinary incontinence in men: A systematic review. Neurourol Urodyn. 2019 Sep;38(7):1804-1811.

U.S. Food and Drug Administration [Internet]. Durasphere® injectable bulking agent. [updated 2016 Apr 06; accessed 2026 Feb 05]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P980053S016

U.S. Food and Drug Administration [Internet]. Summary of safety and effectiveness data for Bulkamid®. [updated 2020 Jan 28; accessed 2026 Feb 05]. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170023B.pdf

U.S. Food and Drug Administration [Internet]. Summary of safety and effectiveness data for Coaptite®. [updated 2005 Nov 10; accessed 2026 Feb 05]. Available from: http://www.accessdata.fda.gov/cdrh_docs/pdf4/p040047b.pdf

U.S. Food and Drug Administration [Internet]. Summary of safety and effectiveness data for Macroplastique®. [updated 2006 Oct 30; accessed 2026 Feb 05]. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf4/p040050b.pdf

Whooley J, et al. Stress urinary incontinence and pelvic organ prolapse: biologic graft materials revisited. Tissue Eng Part B Rev. 2020 Oct;26(5):475-483.

SEARCH TERMS

GAX, Macroplastique, Teflon, Uryx, Tegress, Solesta, Zuidex.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Incontinence Control Devices (NCD 230.10). [accessed 2026 Feb 05]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.

- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 5/26 **Revised**: **Reviewed**:	
Date	**Summary of Changes**
9/1/2026	• New: Service was previously referenced on Non-Covered Technology policy 1370/20.000444.

Policy/Procedure Name: Cablivi (caplacizumab-yhdp) **Control Number: 1350/20.000584**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Thrombotic thrombocytopenia purpura (TTP) is a rare, life-threatening hematologic disease characterized by thrombocytopenia, hemolytic anemia, and small clots forming in the smallest arteries that cause disturbances in the nervous system and other organs. Although the exact cause of TTP is unknown, this disease is thought to be generally associated with a deficiency in the ADAMTS13 enzyme, which is responsible for breaking down clotting protein von Willebrand factor. TPP can either be inherited, known as congenital TTP (cTTP, Upshaw-Schulman Syndrome), or acquired, known as immune-mediated TTP (aTTP or iTTP). Deficiency of ADAMTS13 appears to be caused by mutations of the ADAMTS13 gene in cTTP and by ADAMTS13 autoantibodies in aTTP.

aTTP typically presents as fatigue, dyspnea, petechiae, or other bleeding due to severe microangiopathic hemolytic anemia (MAHA) and thrombocytopenia in a previously healthy individual, although it may also present in patients with other autoimmune disorders, such as systemic lupus erythematosus (SLE). Not all patients' symptoms manifest as critical illness, with some presenting with minor complaints involving the nervous system (weakness/dizziness), gastrointestinal system (abdominal pain/nausea/vomiting), or easy bruising.

Plasma exchange is the standard of care for aTTP and prevents progression to neurologic deterioration, cardiac ischemia, irreversible renal failure, and death if left untreated. Prior to the widespread use of plasma exchange, the condition was associated with a 90% mortality rate, but with the treatment, an estimated 80% of patients recover. Glucocorticoids and rituximab further improve outcomes of plasma exchange and are generally administered concurrently and continued after discontinuation of plasma exchange.

In 2019, Sanofi's Cablivi was approved for the treatment of adult patients with aTTP, in combination with plasma exchange and immunosuppressive therapy. The efficacy of Cablivi to treat pediatric patients with aTTP was evaluated in a retrospective chart review study of 30 patients ranging in age from 2-18 years old. Results showed that 80% of patients achieved clinical remission, defined as achieving a normal platelet count and having LDH levels (a marker of red blood cell breakdown) less than 1.5 times the upper limit of normal for 30 days or more. In 2025, its label was expanded to include children 12 years of age and older.

Summary

Effective Date of Policy:	2/12/2026
Indications	Treatment of adult and pediatric patients 12 years of age and older with acquired thrombotic thrombocytopenic purpura (aTTP), in combination with plasma exchange and immunosuppressive therapy
ICD10 Diagnosis Codes	M31.1
HCPCS	C9047
Availability	11 mg single-dose vial of lyophilized powder
Duration	Initial: 1 month Continuation: up to 30 days

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy

1. The medication must be prescribed by, or in consultation with, a hematologist AND
2. The patient must be at least 12 years of age or older AND
3. Must have a diagnosis or suspected diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) AND
4. Must be used in combination with plasma exchange and immunosuppressive therapy (such as systemic corticosteroids or a rituximab-containing product)
5. If the above criteria are met, Cablivi will be approved for 1 month under the medical benefit for administration while the patient is receiving plasma exchange.

Continuation Criteria

Continued coverage post-plasma exchange, under the pharmacy benefit, will require the following:

- Documentation confirming a diagnosis of aTTP (i.e., suppressed ADAMTS13 activity levels, etc.) AND
- Documentation confirming the patient has not had more than 2 recurrences of aTTP while on therapy with Cablivi (a recurrence is defined as thrombocytopenia occurring after initial recovery of platelet count that requires re-initiation of daily plasma exchange) AND
- The date of last plasma exchange treatment AND
- The number of remaining doses (dosed once daily) needed to complete the post-plasma exchange treatment phase (maximum 30 days of treatment post-plasma exchange is allowed for the initial treatment course)
- Cablivi will be approved under the pharmacy benefit in accordance with the number of remaining doses required to complete the initial treatment course (up to 30 days postplasma exchange). For example, for a patient needing 24 doses to complete the initial treatment course will be approved for 24 days of treatment

Requests for additional therapy (after 30 days of treatment post-plasma exchange) will be approved for a maximum of 28 additional days if the provider submits the following:

- Documentation of remaining signs of persistent underlying disease (such as suppressed ADAMTS13 activity levels) AND
- Documentation confirming the patient has not had more than 2 recurrences of aTTP while on therapy with Cablivi (a recurrence is defined as thrombocytopenia occurring after initial recovery of platelet count that requires re-initiation of daily plasma exchange)

Considerations

- Cablivi should be discontinued if the patient experiences more than 2 recurrences of aTTP while on Cablivi
- Patient must have medical drug coverage administered by CDPHP for the initial dosing period during plasma exchange
- Patient must have pharmacy drug coverage administered by CDPHP for subsequent dosing after the plasma exchange period
- Prior authorization is obtained through the CDPHP pharmacy department.

References

		Updated	Accessed
1	Cabilivi [prescribing information]. Genzyme Corporation, a Sanofi Company. Cambridge, MA	12/2025	1/2026
2	FDA approves therapy for rare blood disorder in pediatric patients 12 years and older. US Food and Drug Administration. Available at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-therapy-rare-blood-disorder-pediatric-patients-12-years-and-older		1/2026
3	Thrombotic Thrombocytopenic Purpura. National Organization for Rare Disorders (NORD). Available at: https://rarediseases.org/rare-diseases/thrombotic-thrombocytopenic-purpura/	2/2025	1/2026
4	Zheng XL, Vesely SK, Cataland SR, et al. ISTH guidelines for treatment of thrombotic thrombocytopenic purpura. *J Thromb Haemost.* 2020;18(10):2496-2502. doi:10.1111/jth.15010	10/2020	1/2026

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application when administered under the medical benefit.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application when administered under the medical benefit.

Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program.

CDPHP Pharmacy Services 2/12/2026

New: 2/2026

Revised	Reviewed

Revision Date	Changes Made

This Pharmacy Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI), and Capital District Physicians' Healthcare Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

MEDICAL POLICY

Medical Policy Title	**Capsule Endoscopy**
Policy Number	**6.01.27**
Current Effective Date	**November 1, 2026**
Next Review Date	**October 2027**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Capsule endoscopy (CPT 91110, 91111) is considered **medically necessary** for **ANY** of the following indications:

A. To investigate suspected small bowel bleeding when conventional diagnostic workup failed to identify the source of bleeding (e.g., persistent or recurrent iron-deficiency anemia, positive fecal occult blood test, or visible bleeding);

B. For the initial diagnosis of suspected Crohn's disease (CD) when conventional diagnostic work-up failed to reveal evidence of disease, and there remains a strong clinical suspicion of CD (e.g., chronic diarrhea, abdominal pain, weight loss, fatigue, fever, anemia, elevated white blood cell (WBC) count, or elevated laboratory markers of inflammation);

C. For re-evaluation of members with an established diagnosis of Crohn's disease who remain symptomatic despite appropriate medical therapy;

D. Surveillance of the small bowel in members with a diagnosis of hereditary polyposis syndromes (i.e., familial adenomatosis polyposis [FAP] or Peutz-Jeghers syndrome);

E. For re-evaluation of members with an established diagnosis of celiac disease who remain symptomatic despite adherence to appropriate medical therapy;

F. Screening or surveillance of esophageal varices, in cirrhotic patients with significantly compromised liver function (e.g., Child-Pugh score of Class B or greater), where a standard upper endoscopy with sedation or anesthesia is contraindicated.

II. Capsule endoscopy is considered **investigational** for the evaluation or diagnosis of **ANY** other indication, including but not limited to:

A. Disease of the esophagus, other than as stated above;

B. Disease in the small bowel, other than as stated above;

C. Confirmation of lesions/pathology found by other diagnostic means;

D. Other GI diseases/conditions not presenting with GI bleeding (e.g., irritable bowel syndrome, portal hypertensive enteropathy, unexplained chronic abdominal pain);

E. Disease of the stomach (e.g., NaviCam, CPT 0651T);

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F. Disease of the large intestine/colon (e.g., detection of colonic polyps or colon cancer) (e.g., PillCam COLON2).

G. GI motility disorder (e.g., gastroparesis) (e.g., MotiliCap, Atmo Gas Capsule CPT 91112);

H. GI stricture(s) or obstruction (e.g., Pillcam Patency Capsule, CPT 91299);

I. Disease evaluation by magnetic capsule endoscopy (e.g., NaviCam, CPT 0651T);

J. Detection of GI blood (Pill Sense System, CPT 0977T).

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Capsule endoscopy (CE) must be performed under the supervision of a gastroenterologist with expertise in this technology and performed only when there is no suspected or confirmed gastrointestinal (GI) obstruction.

II. In the case of suspected small bowel bleeding, because of low lesion detection rate, a small bowel follow-through or enteroclysis is not necessarily required prior to CE. A small bowel follow-through may be beneficial in some cases, at the discretion of the clinician, prior to or after CE, in the detection of small bowel lesions and in their anatomical localization.

DESCRIPTION

Capsule endoscopy (CE), also known as wireless capsule endoscopy (WCE) or video capsule endoscopy, is a non-invasive diagnostic imaging device used to visualize segments of the esophagus, stomach, small bowel, and colon. The CE capsule is swallowed by the patient, propelled by peristalsis or magnetically-controlled through the gastrointestinal tract, and either dissolves (e.g., patency capsule) or is naturally excreted. As the capsule is propelled through the gastrointestinal (GI) tract, the capsule records and transmits data (e.g., images or electrical signals) for interpretation.

Small Bowel Capsule Endoscopy

The primary indications for capsule endoscopy including identifying the source of suspected small bowel bleeding when conventional diagnostic work-up failed to provide a definitive diagnosis; for the initial diagnosis of suspected Crohn's disease when conventional diagnostic work-up failed to provide a definitive diagnosis, to evaluate refractory celiac disease; and screen/surveillance of tumors in the small bowel in people diagnosed with polyposis genetic syndromes.

Colon Capsule Endoscopy (CCE)

Screening for colon cancer is suboptimal in the United States. To improve acceptability of screening, the colon capsule (PillCam Colon Capsule, Given Imaging) was developed as a non-invasive technique to explore the colon without intubation, sedation, and air insufflation. Bowel preparation is crucial

with CCE since it is not possible to clean the colon during the procedure and even the smallest amount of debris could interfere with identifying colonic polyps.

CCE is being investigated as a screening tool for colorectal polyps, including for individuals with an incomplete colonoscopy despite adequate bowel preparation. In such cases, full visualization of the colon is not technically achievable, limiting the ability to detect polyps and guide subsequent clinical decisions. Contributing factors to an incomplete colonoscopy include patient discomfort, diverticulosis, tortuosity, adhesions due to prior surgeries, angulation or fixation of bowel loops, ineffective sedation, and endoscopist and technician expertise.

Blood Detection Capsule

A novel device intended to be used for the detection of blood GI tract, the capsule features sensors that detect blood and wirelessly transmit data to an external receiver. The capsule makes its way through the gastrointestinal tract and is then passed naturally from the body. The reusable receiver collects and displays real-time information gathered by the capsule. The receiver interprets the data and displays a sensor output value. It plots these values on a chart using data acquisition and when completed displays a "blood detected" or "no blood detected" message. The software supports entering of the patient information, pairing of the receiver and capsule and data interpretation and display.

Esophageal Capsule

Capsule endoscopy is proposed as an option to visualize and detect mucosal disease of the esophagus (e.g., esophageal varices) and could triage patients for endoscopy if either the sensitivity or the specificity is high. Traditional endoscopy could then be performed on the appropriate group to determine false-positives or false-negatives, having spared the group with a high positive predictive value an endoscopy procedure.

A novel diagnostic ingestible capsule sponge device, the Cytosponge Cell Collection Device, is being investigated as a diagnostic tool for a wide range of upper GI conditions. The endoscopic cell collection device consists of a compressed spherical sponge inside a capsule, which is attached to a suture. The capsule is swallowed and dissolves in the stomach releasing the self-expanding sponge that collects cells from the outer layer of the esophageal tissue. The sponge is removed using the attached suture and the esophageal surface cells undergo cytological and histological analysis.

Magnetically Controlled Capsule Endoscopy

Magnetically controlled capsule endoscopy, also referred to as magnetically assisted capsule endoscopy (MACE), is being investigated for visualization of the stomach and duodenum to evaluate unexplained abdominal pain. The indication for use includes adults (≥22 years old) with a BMI less than 38. The system can be used in clinics and hospitals, including ER settings. This non-invasive system consists of a single-use ingestible capsule and magnet linked to a physician-operated console. The capsule contains a camera that wirelessly captures images of the desired anatomy. The console allows the operator to control the motion and direction of the capsule, ensuring visualization of the entire stomach. The capsule's camera captures images and transmits the images to a data recorder for interpretation. The procedure does not require sedation and has a procedural time of

approximately 15 to 20 minutes. The capsule leaves the body in 24 hours on average but may take as long as two (2) weeks. The device is contraindicated for use in patients with gastrointestinal obstruction, stenosis, fistula, or those with dysphagia. Other contraindications include patients with cardiac pacemakers or other implantable electronic medical devices as well as pregnant women, those less than 22 years of age, and those with a body mass index of 38 or greater.

Motility Capsule

The motility capsule is an alternative to gastric scintigraphy, which is considered the reference standard for diagnosing gastroparesis. The American Gastroenterological Association (AGA) defines gastroparesis as delayed gastric emptying of the stomach, possibly due to issues with the stomach muscles, nerves, or brain and spinal cord nerves. Gastroparesis is not a mechanical block in the stomach. Symptoms of gastroparesis are often nonspecific and may mimic other gastrointestinal tract disorders. Gastroparesis can be caused by many conditions, with most common causes including idiopathic, diabetic, or postsurgical. During wireless GI motility monitoring, the individual swallows a small capsule that contains sensors to measure gastrointestinal transit times and assess GI motility disorders.

Patency Capsule

The patency capsule (e.g., Pillcam Patency Capsule) is a dissolvable capsule developed to verify adequate patency of the gastrointestinal tract prior to administration of the wireless CE in patients with known or suspected strictures. Once the patient ingests the patency capsule, it is propelled through the GI tract by normal peristalsis. If the patency capsule is excreted structurally whole, then this indicates patency of the patient's GI tract, and a PillCam capsule can be administered.

SUPPORTIVE LITERATURE

Small Bowel Capsule Endoscopy

Suspected Small Bowel Bleeding

For individuals who have suspected small bowel bleeding (previously referred to as obscure gastrointestinal [GI] bleeding) who receive wireless capsule endoscopy (CE), the evidence includes numerous case series and a randomized controlled trial (RCT). The evidence has demonstrated that CE can identify a bleeding source in a substantial number of patients who cannot be diagnosed by other methods, with a low incidence of adverse events. Because there are few other options for diagnosing obscure small bowel bleeding in patients with negative upper and lower endoscopy, this technique likely improves health outcomes by directing specific treatment when a bleeding source is identified. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

A small randomized controlled trial (RCT) compared CE with mesenteric angiography in patients with acute melena or hematochezia (Leung 2012). While CE had a higher diagnostic yield (DY), secondary outcomes such as transfusion, hospitalization, and mortality did not differ significantly between groups. A large number of uncontrolled studies have evaluated the use of CE in the evaluation of patients with suspected small bowel bleeding. These studies have consistently reported that a

substantial proportion of patients receive a definitive diagnosis following this test when there are few other diagnostic options.

A meta-analysis of 24 studies estimated that the DY in this patient population was approximately half of the included patients and was higher in patients with documented iron-deficiency anemia (Koulaouzidis 2012). Capsule endoscopy appears to locate the source of bleeding at least as well as other diagnostic methods and direct treatment to the source of bleeding.

Crohn's Disease (CD)

The evidence is sufficient to determine that CE for suspected and established diagnosis of CD results in an improvement in the net health outcome.

The Selecting Therapeutic Targets in Inflammatory Bowel Disease (STRIDE) initiative began in 2015, with an updated STRIDE-II published by Turner et al (2021). STRIDE-II encompasses evidence- and consensus-based recommendations for treat-to-target strategies in adults and children with inflammatory bowel disease (IBD). Consensus recommends endoscopic and transmural assessment of healing by sigmoidoscopy or colonoscopy; however, when not feasible, alternatives can include CE. The authors acknowledge that transmural healing in Crohn's disease is becoming an important adjuvant assessment of the depth of treatment response; however, more research is needed to determine the incremental gain derived from the goal and whether the gain is worth the therapy-related risks and costs.

Choi et al (2017) conducted a meta-analysis comparing CE with various modalities for diagnosing CD. The analysis consisted of 24 trials (RCT, nonrandomized, and diagnostic accuracy studies) with suspected or established CD. In the pooled analysis, in patients with suspected CD, the sensitivity of CE ranged from 89.6% to 92.0% and the specificity was 100%.

Kopylov et al (2017) published a systematic review of studies evaluating the use of CE for CD. Reviewers included prospective studies comparing CE with magnetic resonance enterography (MRE) and/or small bowel (SB) contrast ultrasound in patients who had suspected or established CD. In the pooled analyses of the 11 studies that included patients with established CD, the diagnostic yield of CE for detection of active small bowel CD was similar to that of MRE and to ultrasound. The outcomes were similar for the subgroups of suspected versus established CD and adult versus pediatric patients. CE was superior to MRE for proximal SB CD. The summary of results demonstrate that all have similar DY for the detection of SB CD; none of the modalities can be considered superior over the others and their utilization should be tailored to the specific clinical situations. CE is the preferred modality for detection of proximal small bowel involvement.

Bruining et al (2020) reported results from the multicenter, prospective BLINK trial comparing the diagnostic accuracy of CE compared to ileocolonoscopy (IC) and/or MRE in patients with established CD. The per-protocol analysis included 99/158 enrolled subjects with 16 patients tested by all 3 modalities. The reference standard was defined as the presence or absence of inflammation as designated by the modality-specific scoring system at prospective interpretation by expert central readers. Overall sensitivity for active enteric inflammation (CE vs MRE and/or IC) was 94% vs 100% (p=0.125) and specificity was 74% vs 22% (p=0.001). Sensitivity of CE was superior to MRE for

enteric inflammation in the proximal small bowel (97% vs 71%, p=0.021), and similar to MRE and/or IC in the terminal ileum and colon (p=0.500-0.625). There were seven serious adverse advents of which three were related to the CE device. Several limitations to this study are noted. The authors concluded that this study demonstrates the powerful potential of panenteric CE to provide accurate Crohn's disease assessments and panenteric CE should be considered for utilization in non-structuring Crohn's disease evaluations.

Elosua et al (2022) evaluated the therapeutic impact of CE in patients with established CD in a retrospective, single-center study. Therapeutic impact was defined as change in CD-related treatment recommended based on CE results. A total of 305 patients with established CD underwent a small bowel capsule endoscopy (SBCE) between January 2008 and December 2019. From the 432 procedures performed, 87.5% were conclusive. Active disease was present in 63 patients; 41.6% mild inflammation and 21.9% moderate-to-severe activity. Disease activity demonstrated by CE results was correlated with therapeutic changes. A change of management was guided by SBCE in 51.3% of procedures. Mucosal healing assessed via CE was the only independent factor that predicted therapy de-escalation. Study limitations include the retrospective study design and limited heterogeneity due a limited group of research gastroenterologists.

Celiac Disease

For a suspected diagnosis of celiac disease, the clinical validity of wireless CE for diagnosing celiac disease has not been established and its diagnostic performance is currently insufficient to replace standard modalities or to effectively triage patients to other diagnostic approaches. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

A meta-analysis by El-Matary et al (2009) compared the diagnostic performance of CE with a reference standard of duodenal biopsy. The pooled analysis of 3 studies showed a sensitivity of 83% and a specificity of 98%. Rokkas and Niv (2012) conducted a meta-analysis to compare the diagnostic performance of CE with biopsy, summarizing 6 studies (N=166 subjects). The overall pooled sensitivity was 89%, and the specificity was 95%. Capsule endoscopy detected involvement of intestines beyond the duodenum; however, the clinical significance of detecting the extent of celiac disease is uncertain. Given the less than 90% sensitivity of CE for celiac disease, it does not appear to be an adequate alternative method of making an initial diagnosis.

Kurien et al (2013) conducted a non-randomized study of 62 patients with an equivocal diagnosis of celiac disease and 69 patients with confirmed celiac disease who were unresponsive to standard treatment were evaluated with CE. Results were combined with human leukocyte antigen typing and response to gluten challenge, with the final diagnosis made by three expert physicians who received the information from all three sources. The main outcome was the increase in diagnostic yield after CE combined with the other tests. The diagnostic yield was greatest in cases with antibody-negative villous atrophy where a diagnosis of celiac disease was made in 9 of 32 patients (28%). In eight of the 69 nonresponsive celiac disease patients (12%), CE identified 2 cases of enteropathy-associated lymphoma, 4 type 1 refractory disease cases, 1 fibroepithelial polyp, and 1 case of ulcerative jejunitis. This study was limited by the small sample size and use of other tests in conjunction with CE to ascertain a final diagnosis.

Shapiro and Niv (2025) conducted a systematic review and meta-analysis to assess the diagnostic yield of video capsule endoscopy (VCE) in patients with CD. Analyzing data from 22 studies involving 1,585 patients, the authors found that VCE identified pathognomonic features of CD (e.g., villous atrophy, scalloping, mosaic patterns, fissuring, ulcers, and erosions) in approximately 60% of cases. The pooled effect size for any diagnostic pathology was 0.601, with higher yields observed in patients with refractory CD. VCE achieved complete small bowel visualization in over 96% of patients, which the authors concluded demonstrate its utility as a non-invasive, high-resolution imaging modality for evaluating mucosal abnormalities, especially when conventional endoscopy is inconclusive or incomplete. Study limitations include small sample sizes, unblinded studies, and high heterogeneity across studies. The authors concluded that their findings suggest that VCE offers a moderate diagnostic yield for celiac disease, with a possible role in early management and diagnosis of refractory celiac disease (RCD). Future studies should aim to standardize protocols and explore the effectiveness of VCE using artificial intelligence and machine learning to complement existing diagnostic methods.

Inherited Polyposis Syndromes

Small bowel capsule endoscopy (SBCE) can be used as a surveillance tool for small bowel polyps in patients with inherited polyposis syndromes. SBCE has been found to have a better diagnostic capability to reveal small bowel polyps, compared to barium follow-through, in patients with Peutz-Jeghers syndrome (Brown 2006; Iaquinto 2008; Urquhard 2014).

Lynch Syndrome

At present, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome and surveillance of the small bowel is not generally recommended as a routine intervention for patients with Lynch syndrome.

Saurin et al (2010) conducted a small prospective, blinded, comparative study of CE and computed tomography (CT) enteroclysis with 35 asymptomatic patients with Lynch syndrome. Small bowel neoplasms were diagnosed in three patients (8.6%). Capsule endoscopy identified all neoplasms, and CT enteroclysis raised suspicion of one neoplasm (adenocarcinoma) but missed the two others. The clinical usefulness of systematic small-bowel screening in these patients should be confirmed through large prospective studies.

Haanstra et al (2015) evaluated 200 patients with Lynch syndrome who underwent video CE to determine the prevalence of small-bowel neoplasia in asymptomatic patients with Lynch syndrome. Small bowel neoplasia was detected in the duodenum in two patients (1 adenocarcinoma, 1 adenoma). In another patient, a duodenal cancer was diagnosed 7 months after a negative video CE, which is considered a lesion missed by CE. All three neoplastic lesions were within reach of a conventional gastroduodenoscope.

Valdivia et al (2024) report that the role of small bowel (SB) cancer surveillance by CE in Lynch syndrome patients has been investigated, with contradicting results. The authors conducted a systematic review and meta-analysis to evaluate the diagnostic yield (DY) of CE as a screening tool in asymptomatic LS patients. Five studies, comprising 428 patients and 677 CE procedures, were

included for data extraction and statistical analysis. The estimated pooled DY for CE-identified pathological findings was 8% in the first screening round and 6% in the second. Limiting the analysis to histologically confirmed pathological findings, the pooled DY of second-round screening dropped to 0%. The included studies showed a significantly different prevalence of pathogenic variants in mismatch repair (path_MMR) genes, which underlie different cumulative incidences of extracolonic cancers. SB surveillance by CE with a 2-year interval in asymptomatic LS individuals does not appear to be an effective screening strategy. Confirmatory prospective studies in this context are needed, considering the different cumulative incidence of SB tumors according to underlying path_MMR defects. The authors concluded that, although the DY of CE is high in detecting small bowel lesions in LS, the low number of positive examinations eventually resulted in an even lower number of true-positive patients after histological confirmation, with a pooled yield proximate to 0%. SB surveillance by CE with a 2-year interval in asymptomatic LS individuals does not appear to be an effective screening strategy.

Blood Detection Capsule Endoscopy

Akiki et al (2024) reported findings from a prospective, open-label, single-arm comparative clinical trial to evaluate the safety and efficacy of the PillSense System, a novel ingestible capsule designed to rapidly detect upper gastrointestinal bleeding (UGIB). Physicians conducting the esophagogastroduodenoscopy (EGD) were blinded to the PillSense results. The study involved 126 adults with suspected UGIB who received the capsule followed by EGD within four hours. Compared with EGD results, the capsule correctly detected the presence of blood in 26 of 28 cases and the absence of blood in 87 of 96 cases. Sensitivity and specificity were 92.9% (P = .02) and 90.6% (P < .001), respectively. Among the 126 patients in the safety population, 23 (18.3%) experienced at least 1 AE. This industry sponsored study concluded that the novel blood-sensing capsule device provides highly accurate and rapid detection of UGIB. However, future studies are needed to identify and validate the performance of the PillSense system in a real-world clinical setting.

Colon Capsule Endoscopy

Colon capsule endoscopy (CCE) has been proposed as an alternative imaging modality to explore mucosa of the entire colon. CCE does not allow for biopsy or polyp removal; therefore, patients with lesions detected typically require subsequent colonoscopy for further evaluation and/or treatment. Studies looking at the efficacy of colon capsule endoscopy compared with standard colonoscopy have reached variable results. Most studies report sensitivities for detecting polyps ≥ 6 mm between 70 and 88 percent (range 39 to 88 percent), and specificities between 80 and 90 percent (range 64 to 93 percent) (Cave et al., 2024). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Given Imaging conducted an 884-patient, 16-site clinical trial that studied the accuracy and safety of PillCam COLON 2, compared to optical colonoscopy, in detecting adenomas 6 millimeters or larger. Results from this clinical trial demonstrated that the sensitivity for PillCam COLON was 88% and specificity was 82% in detecting adenomas at least 6 mm in size. The FDA based its clearance decision on an analysis of this clinical trial data, which used a more restrictive methodology for matching polyps. In this analysis, which was conducted on hyperplastic polyps and adenomas, the

positive percent agreement for PillCam COLON and optical colonoscopy was 69%, and negative percent agreement was 81% for polyps at least 6 millimeters in size. The wireless capsule had not been adequately studied in the large intestine. The colon was not well-visualized due to stool obscuring the colonic mucosa. Adequate visualization of the colon was also hampered by the colon's larger diameter which made it possible for the capsule camera to miss suspicious areas.

Eliakim et al (2006) conducted a prospective study to determine whether CE of the colon can provide similar detection rates of pathological colonic conditions, compared to conventional colonoscopy. Conventional colonoscopy detected more polyps compared to wireless CE: 70% were identified with the capsule and 16/20 (80%) were identified by conventional colonoscopy. In comparison with conventional colonoscopy, false-positive findings on PillCam Colon capsule examination were recorded in 15/45 cases (33%). Additional studies are needed, to evaluate the accuracy of PillCam Colon endoscopy in patient populations with different prevalence levels of colonic disease.

Parodi et al (2018) stated that CCE has been recognized as an alternative for colorectal cancer (CRC) screening in average-risk people; however, in first-degree relatives (FDRs) of patients with inherited predispositions to CRC have a much higher increased risk of developing CRC but compliance with colonoscopy screening by FDRs remains suboptimal. The researchers conducted a prospective study to assess the accuracy of CCE as a screening tool in FDRs of people with CRC. An optical colonoscopy (OC) with segmental unblinding was the reference standard. In this study, 177 FDRs underwent both CCE and optical colonoscopy (OC), with segmental unblinding of CCE findings used to validate results. CCE demonstrated a sensitivity of 91% for detecting polyps ≥ 6 mm, identifying 51 of 56 cases, and a specificity of 88%, correctly classifying 107 of 121 participants without lesions of this size. The positive predictive value (PPV) and negative predictive value (NPV) for polyps ≥ 6 mm were 78% and 95%, respectively. For polyps ≥ 10 mm, CCE achieved a sensitivity of 89% (24 of 27 cases) and a specificity of 95% (142 of 150 cases). Limitations to the present analysis include the study design and lack of analysis of FDRs' compliance with CCE screening. The authors concluded that the results showed both high technical feasibility and accuracy of CCE as a primary screening test for FDRs of patients with CRC, supporting its use for such an indication.

Kjolhede et al (2020) reported a systematic review and meta-analysis of the diagnostic accuracy of CE compared to colonoscopy with stratified results for polyps of any size, polyps ≥ 6 mm, and polyps ≥ 10 mm. Across analyzed patients in the 12 eligible studies, the indications for endoscopy included colorectal cancer screening or history of polyps or colorectal cancer (n=1200; 63.2%), positive fecal immunochemical test (n=493; 26%), first-degree relatives of patients with colorectal cancer (n=177; 9.3%), or unspecified (n=28; 1.5%). The rate of patients with an adequate bowel preparation ranged from 40% to 100%. The rates of complete CE transits ranged from 57% to 100%. The authors note that the relatively high rate of incomplete CE investigations limits the utility of CE in the colorectal cancer setting. All but one study was assessed to have a high risk of bias and applicability concerns for the reference standard.

Cash et al (2021) evaluated the diagnostic characteristics of CE using subsequently performed colonoscopy as the reference standard. Randomizing patients to colon CE or computed tomography (CT) colonography followed by optical colonoscopy. Data from 286 patients revealed that the proportion of enrollees with any polyp 6 mm or larger confirmed by subsequent blinded optical

colonoscopy was 31.6% for colon CE versus 8.6% for CT colonography. The sensitivity and specificity of colon CE for polyps 6 mm or larger was 79.2% and 96.3%, respectively, while that of CT colonography was 26.8% and 98.9%. For polyps 10 mm or larger, the sensitivity and specificity of colon CE was 85.7% and 98.2% compared with 50% and 99.1% for CT colonography. The authors concluded that colon CE should be considered comparable or superior to CT colonography as a screening test; however, neither test was as effective as optical colonoscopy.

Lei et al (2025) conducted a systematic review and meta-analysis evaluating follow-up endoscopy rates (FERs) as a measure of effectiveness in colon capsule endoscopy (CCE). Analyzing data from 19 studies involving 2,850 patients, the study found that 42% of individuals undergoing CCE required a follow-up endoscopic or radiologic investigation, which is significantly higher than FERs for colonoscopy (10–15%) and CT colonography (25%). Reinvestigation was more frequent with the newer CCE2 capsules, likely due to improved diagnostic performance Despite applying meta-regression and subgroup analyses, substantial heterogeneity was observed across study results, largely attributable to multiple confounding variables. The authors concluded that further research is needed to reduce CCE FERs, which is essential for improving patient outcomes and ensuring CCE becomes a viable and widely adopted service in clinical practice.

Colon Capsule Endoscopy (CCE) Following Incomplete Optical Colonoscopy

Hussey et al. (2018) state that CCE is a new, noninvasive technique for exploring the large intestine, with recent studies demonstrating good correlation between OC and CCE in detecting both significant and non-significant large bowel pathology. The researchers conducted an observational, prospective, single-center study to assess the efficacy of same-day CCE following incomplete OC in an unselected patient cohort. Patients (n=50) with an incomplete OC for reasons other than obstruction or inadequate bowel preparation were recruited. CCE was performed using the second-generation PillCam colon capsule (Medtronic/Given Imaging, Yokneam, Israel) after a minimum one-hour recovery period following OC. Although only 76% (n=38) of CCEs were complete, full colonic views were obtained in 84% (n=42) of cases. OC findings prior to CCE were normal in 76% (n=38), diverticular disease in 24% (n=12) and polyps which were removed in 12% (n=6). CCE findings were normal in 26% (n=13), polyps 38% (n=19), inflammation 22% (n=11), diverticular disease 25% (n=12), angiodysplasia 3% (n=1), and cancer 3% (n=1). Among patients with polyps (n=19), seven (36%) were deemed to have significant polyps requiring referral for polypectomy. Of these, four patients had a polyp > 6 mm and three patients had ≥ 3 polyps. Subsequent histology of the referred polyps (n=14) revealed tubulovillous adenoma with low-grade dysplasia in 57% of cases (n=8), tubulovillous adenoma with high-grade dysplasia in 7% (n=1), sessile-serrated adenoma in 14% (n=2) and hyperplastic polyps in 21% (n=3). Significant small bowel findings were identified in three cases, including Crohn's disease and a neuroendocrine tumor. A major adverse event occurred in one patient due to capsule retention which required surgical resection. The authors acknowledged several study limitations; however, they concluded that same-day CCE following incomplete OC is a safe and feasible alternative for assessing unexplored segments of the colon in selected patients.

Baltes et al (2018) conducted a prospective multicenter observational study in Germany to evaluate the ability of PillCamColon2 to visualize colonic segments missed during incomplete optical colonoscopy (OC) and to assess the DY. Data from 74 patients were analyzed (51% in group A; 49%

in group B). Reasons for referral to colonoscopy were CRC screening (22%), anemia (15%), hematochezia (15%), irregular stool (12%), abdominal pain (12%), B symptoms (7%), colitis (5%) and other reasons (12%). Bowel cleansing was adequate in 67% of cases, and CCE could visualize colonic segments missed by incomplete colonoscopy in 90% of patients under protocol A and 97% of patients under protocol B (p = 0.35). Significant polyps, including adenocarcinoma, were detected in 24% of cases. Detection rates for all polyps and significant polyps per patient were similar in both protocols. Polyps were found predominantly in the right colon (86%) in segments that were not reached by optical colonoscopy. Extracolonic findings (e.g., reflux esophagitis, suspected Barrett esophagus, upper GI-bleeding, gastric polyps, gastric erosions) were identified in eight patients. PillCamColon2 capsule was retained in the ileum of one patient without symptoms. The authors report that the second-generation CCE using low-volume bowel preparations is useful, well tolerated, and capable of detecting additional relevant lesions. Although the risk of capsule retention is low, comparable to that of small bowel capsule endoscopy, it must still be considered. Future studies should focus on improving colon cleansing and the completeness of CCE following incomplete OC.

Esophageal Capsule

Capsule endoscopy has been used to diagnose portal hypertensive enteropathy (PHE) particularly in patients with portal hypertension and suspected small-bowel bleeding or anemia. Based on the outcomes of small studies comparing the Pill Cam ESO to upper endoscopy in patients with portal hypertension and esophageal varices, the PillCam ESO represents an accurate, non-invasive alternative to EGD for the detection of esophageal varices and portal hypertensive gastropathy (Eisen 2006; Lapalus 2006; Penna 2008; Lu 2009). While further studies are required to validate these initial findings, the use of wireless CE for those patients with significantly compromised liver function, who cannot tolerate sedation or anesthesia, appears reasonable.

Barrett Esophagus

Capsule endoscopy is being investigated as a diagnostic screening technique for esophageal conditions (e.g., Barrett esophagus); however, the clinical validity of wireless CE for monitoring esophageal disorders has not been established. Other available modalities are superior to CE for monitoring esophageal disorders. The diagnostic characteristics of CE are inadequate to substitute for other modalities or to triage patients to other modalities.

The Cytosponge cell collection device (Medtronic), an ingestible capsule containing a 'sponge on a string,' is being investigated as a minimally invasive method of sampling surface esophageal cells in patients who require screening or surveillance of esophageal pathologies such as Barrett's Esophagus (BE). However, current evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Eliakim et al (2004) conducted a feasibility case series study to compare the PillCam ESO to conventional upper endoscopy in patients with suspected disorders of the esophagus (n= 17 patients). The negative predictive value for any esophageal disorder was 100%, while the positive predictive value was 92% (sensitivity 100%, specificity 80%). The authors stated that further, large-scale studies are necessary to fully assess this diagnostic tool.

Eliakim et al (2005) conducted a larger, multi-center study of 106 patients with either GERD or Barrett's esophagus. The authors reported esophageal abnormalities in 66/106 patients, providing a sensitivity of 92% and specificity of 95%.

Lin et al (2007) conducted a prospective, multi-center, blinded study to evaluate the accuracy of esophageal capsule endoscopy (ECE) in diagnosing Barrett's esophagus. Of the 96 subjects enrolled, 90 (94%) completed the study, including 66 screening and 24 surveillance patients. ECE demonstrated a sensitivity of 67% and a specificity of 84% for identifying Barrett's esophagus, correctly diagnosing 14 of 21 biopsy-confirmed cases. Among screening patients, the positive predictive value was 22%, and the negative predictive value was 98%. Sensitivity was similar for both short- and long-segment Barrett's esophagus. The authors concluded that ECE has only moderate sensitivity and specificity for detecting Barrett's esophagus, and while not suitable as a primary screening tool in its current form, ECE may be considered for patients unwilling to undergo esophagogastroduodenoscopy (EGD).

Iqbal et al (2018) conducted a systematic review to analyze the efficacy and safety of a minimally invasive cell sampling device (Cytosponge) in the diagnosis of esophageal pathology. A total of 13 studies were include in the review, with six studies observing the efficacy of the Cytosponge in diagnosis Barrett's esophagus (BE) undergoing EGD and three in diagnosing eosinophilic esophagitis (EoE). The pooled sensitivity and specificity of diagnosing BE through the sponge devices were 81 and 91%, respectively. The pooled sensitivity and specificity of detecting EoE was calculated at 76.3% and 98.8%, respectively. Although published studies have good quality and showed promising results, the major limitation is that the majority were performed by a single group of authors. The authors concluded that given the current favorable results, the product should be independently verified to avoid the potential biases and conflicts inherent to the current literature.

Xu et al (2019) conducted a pilot study, SUGAR, to explore the feasibility of combining serological testing with Cytosponge technology to screen for upper gastrointestinal adenocarcinoma risk. Blood samples from 56 patients with Barrett's esophagus and 202 non-Barrett controls who previously took part in a trial assessing the accuracy of the Cytosponge for Barrett's esophagus were assessed for serum pepsinogen (PG) 1 and 2, gastrin-17, trefoil factor 3 (TFF3) and Helicobacter pylori infection.

The researchers found that low serum PG1 levels were significantly associated with gastric symptoms but not with Barrett's esophagus, suggesting its potential utility in identifying patients at risk for gastric pathology. Patients without a diagnosis of Barrett's esophagus had significantly lower serum values for PG1 levels (100.7 vs 292.0 ng/mL), PG2 (6.0 vs 13.9 ng/mL) and G17 (4.8 vs 13.4 ng/mL) than those with Barrett's metaplasia ($p<0.001$). Patients with Barrett's esophagus did not show pathologically altered serum PGs. Although serum trefoil factor 3 (TFF3) has been reported as a stable marker for gastric atrophy, assessment of TFF3 did not add further value to that of PG1. Prospective validation is needed to assess if the combination of a serum markers for gastric pathology with the minimally invasive Cytosponge test for Barrett's esophagus could be a potentially complimentary strategy to identify patients at risk for upper gastrointestinal adenocarcinoma.

Fitzgerald et al (2020) conducted the Barrett's Esophagus Screening Trial 3 (BEST3) study to investigate whether offering the Cytosponge-trefoil factor 3 (TFF3) to patients on medication for

gastro-esophageal reflux would increase the detection of Barrett's esophagus compared with standard management. This multicenter, pragmatic, RTC was real-world implementation of the Cytosponge-TFF3, conducted in 109 socio-demographically diverse general practice clinics in England. Randomization occurred at both the general practice clinic level (cluster randomization) and at the individual patient level, and the results for each type of randomization were analyzed separately before being combined. Participants received either standard management for gastroesophageal reflux (usual care group), in which endoscopy was performed only if deemed necessary by the general practitioner, or usual care plus an offer of the Cytosponge–TFF3 procedure, followed by endoscopy if TFF3-positive cells were identified (intervention group). The primary outcome was the diagnosis of Barrett's esophagus at 12 months after enrollment, expressed as a rate per 1000 person-years, in all participants in the intervention group (regardless of whether they had accepted the offer of the Cytosponge-TFF3 procedure) compared with all participants in the usual care group. Based on the number who had an endoscopy following a Cytosponge-TFF3 procedure but did not have Barrett's esophagus or cancer (n=90), and on the number who successfully swallowed the Cytosponge-TFF3 but did not have Barrett's esophagus or cancer (n=1523), the researchers estimated the specificity of the Cytosponge-TFF3 procedure to detect Barrett's esophagus, dysplasia or cancer to be 94%. The authors concluded that offering Cytosponge–TFF3 testing to patients with gastroesophageal reflux improves detection of Barrett's esophagus.

Tan et al (2025) conducted the DELTA study to evaluate the real-world implementation of capsule sponge testing combined with biomarker risk stratification for surveillance of Barrett's esophagus. This prospective, multicenter UK study involved patients with non-dysplastic Barrett's esophagus who underwent both capsule-sponge testing and endoscopy. Among the 910 patients in the cohort, 138 (15%) were classified as high risk, 283 (31%) as moderate risk, and 489 (54%) as low risk according to the capsule-sponge risk stratification score. The high-risk group demonstrated a 37.7% positive predictive value for dysplasia or worse, with the highest risk observed in those with both atypia and abnormal p53 expression. In contrast, the low-risk group had a 0.4% prevalence of high-grade dysplasia or cancer and a 97.8% negative predictive value, suggesting that these patients could be safely monitored using capsule-sponge testing alone. The authors concluded that the capsule sponge risk stratification classifier enables clinicians to triage high-risk patients for earlier endoscopy while safely deferring invasive procedures for low-risk individuals.

Magnetic Capsule Endoscopy (CE)

Studies evaluating the diagnostic characteristics of magnetic CE as compared to conventional gastroscopy in the target population have generally demonstrated similar accuracy, sensitivity, and specificity, with increases in patient preference and an acceptable safety profile with the magnetic CE approach. However, the diagnostic characteristics of magnetic CE are inadequate to substitute for other modalities or to triage patients to other modalities based on the current literature. Direct evidence of improved outcomes or a strong chain of evidence to improved outcomes is lacking. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Denzer et al (2015) prospectively evaluated a magnetically guided gastric capsule compared to conventional gastroscopy in 189 patients with upper abdominal complaints (e.g., upper abdominal

pain and/or anemia) from two French centers. In this first large study to evaluate magnetically guided capsule gastroscopy in patients with upper abdominal symptoms, the authors concluded that this technique was feasible in practice and clearly preferred by patients; however, further studies are needed to define its role in the clinical setting (e.g., as a filter test to stratify patients to undergo conventional gastroscopy or some other role). This non-US study reported a low sensitivity and provided an limited discussion of the types of upper abdominal complaints experienced by enrolled patients. No discussion in terms of the severity and duration of the complaints, as well as prior testing and treatment was undertaken, which makes determination of the appropriate place in therapy for magnetic CE in patients with unexplained upper abdominal complaints difficult.

Liao et al (2016) evaluated the accuracy of magnetically controlled CE as compared with conventional gastroscopy in 350 patients with upper abdominal complaints in a prospective, multicenter, blinded comparison study conducted in China. Overall, with conventional gastroscopy as the gold standard, magnetic CE detected gastric focal lesions in the entire stomach with 90.4% sensitivity, 94.7% specificity, and 93.4% accuracy. Similar sensitivity and specificity results were observed with magnetic CE as compared to conventional gastroscopy when detecting focal lesions in the upper or lower stomach specifically. No lesions of significance were missed by magnetic CE. Only five patients reported an adverse event, with the majority of these events considered to be related to gastric preparation. The authors concluded that magnetic CE detects upper abdominal focal lesions with comparable accuracy to conventional gastroscopy and is a promising alternative for screening for gastric diseases.

Meltzer et al (2023) conducted the first pilot study of magnetically controlled capsule endoscopy (MCCE) in the United States. The primary objective was to demonstrate that MCCE could visualize the major anatomic regions of the stomach in symptomatic patients before an EGD. In this prospective, single-arm, single-center, comparative study, included symptomatic adult patients (N=40) who were referred for an EGD as part of a standard evaluation. Participants received MCCE before the EGD. MCCE videos were reviewed by 2 independent physicians and compared with subsequent EGD. Patients were followed for 30 days for safety outcomes and satisfaction. Of the 40 study patients, MCCE detected each of the 6 preidentified major gastric anatomic landmarks with a greater than 95% rate of visualization. Although every capsule was able to visualize the lower esophagus, the Z-line was only visible between 78% and 85% of cases. Thirty-five patients received a follow-up EGD, and no high-risk lesions were missed with MCCE. The study is limited by the small sample size, low number of pathologic lesions, and unblinded physician interpreting results. The authors concluded that future studies need to further establish the accuracy of MCCE compared with EGD for low-risk symptomatic patients.

Motility Capsule Endoscopy

Studies assessing the utility of motility capsule testing for suspected gastric motor disorders have been limited by study design and small sample sizes. Larger, well-designed studies are needed.

Stein et al (2013) conducted a systematic review for the Agency for Healthcare Research and Quality (AHRQ). Of the 12 studies included, seven studies evaluated the diagnosis of gastric emptying delay. The strength of evidence in available studies on the ingestible capsule for assessing colonic transit

times was found to be low overall. No studies were identified that compared the SmartPill to colonic scintigraphy. Accuracy of the ingestible capsule in diagnosing slow-transit constipation was similar to tests using radiopaque markers. A moderate correlation between colonic transit times with the ingestible capsule and tests with radiopaque markers was shown in five studies (range, 0.69-0.71). The authors concluded that although the overall strength of evidence is low, data were relatively consistent and suggested that this modality is no less sensitive than conventional testing. The evidence is insufficient to determine whether use of the wireless motility capsule will improve outcomes of care.

Lee et al (2019) and Hasler et al (2019) reported findings on two large, prospective, multicenter trials that compared WMC testing with gastric emptying scintigraphy (GES) in patients with gastroparesis symptoms. Both studies found that WMC detected delayed gastric emptying more often than GES, due to WMC's capability of profiling the entire gastrointestinal tract in patients. However, the studies were limited by practice standards, participant population, and lack of correlation of physiological results with symptoms and/or management outcomes. Additional clinical studies are needed, to further investigate and compare GES versus WMC testing in patients with gastroparesis symptoms.

Sangnes et al (2020) conducted a small prospective, single center, cohort study to compare the diagnostic reliability of WMC with scintigraphy in individuals with diabetic gastroparesis, with the objective of assessing diagnostic reliability. Although the researchers reportedly found a strong correlation between WMC and 4-hour GES, the study was limited by its small study size (n = 66) and a patient cohort that may have been more severely affected by their disease.

Kuo et al (2025) conducted a multicenter, comparative, prospective cohort study to compare and evaluate the performance characteristics of the Atmo Capsule and the SmartPill Capsule (discontinued reference standard WMC) for measurement of gastric emptying time (GET) and colonic transit time (CTT) in patients with confirmed or suspected disordered gastrointestinal transit. A total of 213 participants aged 22 years or older were enrolled, each meeting at least one of the following criteria: a history of delayed GET from a prior study within the past two years and/or symptoms suggestive of gastroparesis; functional constipation per Rome IV criteria; or constipation-predominant irritable bowel syndrome per Rome IV criteria. Measurements of GET and CTT using the Atmo and SmartPill capsules were strongly correlated, with observed biases within 10% of the delayed transit margin. Delayed GET (68/177) and delayed CTT (56/147) were each identified in 38% of participants, with 84% agreement between the devices for both delayed GET (sensitivity 68%, specificity 91%) and delayed CTT (sensitivity 83%, specificity 85%). No serious adverse device effects were reported. A noted limitation of the study was the lack of diversity in the participant cohort. Additionally, due to the limited number of cases with rapid transit, the study could not assess diagnostic agreement between the devices for identifying rapid transit times. The authors concluded that this comparative prospective study demonstrated that the Atmo Capsule provides reliable measurements of GET and CTT, correlating well with the SmartPill Capsule. With the discontinuation of the SmartPill, these findings suggest that the Atmo Capsule may serve as a clinically useful and viable alternative for evaluating gastrointestinal transit.

Patency Capsule

The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. The overall balance of harm and benefit of using the patency capsule cannot be determined from the existing studies.

Delvaux et al (2005) evaluated the usefulness of this system in 22 patients with suspected intestinal stenosis who were also undergoing CE. The authors stated that the current technical development of the patency capsule limits its use in clinical practice, as it did not detect stenoses undiagnosed by computed tomography (CT) or small bowel follow-through. They also stated that the start of dissolution at 40 hours after ingestion was too slow to prevent episodes of intestinal occlusion. The authors noted that patients with Crohn's disease are most likely to be at risk of blockage of progression of the capsule and should benefit from a CT investigation before CE. They noted that a careful interview eliciting the patient's medical history and symptoms remains the most useful indicator with regard to suspicion of an intestinal stenosis.

Signorelli et al (2006) evaluated 32 patients. The 26 patients who excreted the patency capsule intact, without experiencing abdominal pain, were deemed eligible for the CE procedure, which was performed uneventfully in the 25 who agreed to undergo the examination. The authors stated that the patency capsule "is an effective method for the assessment of small bowel patency before CE. However, the real incidence of complications such as the development of severe abdominal pain and small bowel obstruction needs to be ascertained before the patency test can be recommended as the standard method to evaluate patients at risk of developing capsule retention." There is a lack of data defining the safety and role of the patency capsule. Conventional evaluations remain the gold standard for ruling out any known or suspected gastrointestinal obstruction, strictures, and fistulas, prior to CE.

Kim et al (2025) conducted a systematic review and meta-analysis to evaluate the diagnostic accuracy of patency capsule (PC) and cross-sectional imaging (CSI) in predicting capsule retention (CR) during small bowel capsule endoscopy (SBCE), particularly in patients with suspected small bowel stenosis. A total of 23 studies involving 3,273 patients were included: 17 studies assessed PC (n = 3,051), four assessed CSI (n = 140), and two evaluated both PC and CSI (n = 82). The pooled sensitivity and specificity of CSI for predicting CR were 54% and 88%, respectively. In comparison, PC demonstrated a pooled sensitivity of 75% and specificity of 94%. PC showed significantly higher specificity ($p = 0.05$) and a lower pooled false-negative rate than CSI ($p = 0.001$).

PROFESSIONAL GUIDELINE(S)

Small Bowel Capsule Endoscopy

In 2017, the American Gastroenterological Association's (AGA) issued a clinical practice guideline on the use of video capsule endoscopy (Enns 2017).

- CE is recommended for patients presenting with clinical features consistent with Crohn's disease (CD), and negative ileocolonoscopy and imaging studies; for patients with CD and clinical features unexplained by ileocolonoscopy or imaging studies; in patients with polyposis syndromes, in suspected small-bowel recurrence of CD; for patients with celiac disease and unexplained symptoms despite treatment and appropriate investigations, and repeated

obscure bleeding.

- AGA recommends against CE for patients with suspected celiac disease.

The 2017 American Society for Gastrointestinal Endoscopy (ASGE) clinical guideline on the role of endoscopy in the management of suspected small-bowel bleeding suggest video CE as the initial test for patients with overt or occult small-bowel bleeding.

Refractory celiac disease management guidelines, issued by the American Gastroenterological Association's (AGA) (Green et al 2022) recommend:

- Perform small bowel imaging with capsule endoscopy and computed tomography or magnetic resonance enterography to exclude enteropathy-associated T-cell lymphoma and ulcerative jejunoileitis at initial diagnosis of type 2 refractory celiac disease (RCD2).
- Repeat imaging should be obtained in patients with RCD2 who are clinically worsening due to the increased risk of lymphoma. The presence of strictures, inflammation, erosions, ulcers, or mass lesions on capsule endoscopy or cross-sectional imaging should prompt further evaluation with small bowel enteroscopy to secure a pathologic diagnosis.

Celiac disease diagnosis and management by capsule endoscopy is not addressed in the 2023 American College of Gastroenterology (ACG) guideline update (Rubio-Tapia et al., 2023).

In 2023, the European Society of Gastrointestinal Endoscopy (ESGE) issued guideline recommendations on small-bowel capsule endoscopy and device-assisted enteroscopy for diagnosis and treatment of small-bowel disorders (Pennazio 2023).

- Recommend: small-bowel capsule endoscopy as the first-line examination, before consideration of other endoscopic and radiological diagnostic tests for suspected small-bowel bleeding. (Strong recommendation, moderate quality evidence)
- Does not recommend: routine second-look endoscopy prior to small-bowel capsule endoscopy in patients with suspected small-bowel bleeding or iron-deficiency anemia. (Strong recommendation, low quality evidence)
- Recommend: the performance of small-bowel capsule endoscopy as a first-line examination in patients with iron-deficiency anemia when small bowel evaluation is indicated. (Strong recommendation, high quality evidence)
- Recommend: small-bowel capsule endoscopy in patients with suspected CD and negative ileo-colonoscopy findings as the initial diagnostic modality for investigating the small bowel, in the absence of obstructive symptoms or known bowel stenosis. (Strong recommendation, high quality evidence)
- Recommend: in patients with established CD, the use of a patency capsule before small-bowel capsule endoscopy to decrease the capsule retention rate. (Strong recommendation, moderate quality evidence).

<u>Polyposis Syndromes</u>

In 2020, the American Society for Gastrointestinal Endoscopy (ASGE) guideline on the role of endoscopy in familial adenomatous polyposis syndromes recommends screening sigmoidoscopy or colonoscopy in suspected FAP (Yang 2020). However, the ASGE acknowledges that with the advent of CE, it has become the preferred imaging modality, because false-negative rates in contrast studies are up to 42% for polyps > 10 mm in FAP patients. When compared with magnetic resonance enterography (MRE), CE is also more sensitive for detecting smaller polyps. The 2 tests performed equally for detecting polyps >15 mm, although MRE was more reliable for determining the location and size of polyps. MRE also has the advantage of imaging outside the GI tract, including detecting desmoid tumors.

In 2022, the US Multi-Society Task Force on Colorectal Cancer (USMSTF) recommended that individuals diagnosed with Peutz-Jeghers syndrome undergo a baseline small bowel surveillance, using video CE or MRE, performed between ages 8-10 years or earlier if the patient is symptomatic (Boland et al 2022). If no polyps are found at the initial examination, surveillance should resume at age 18. (Strong recommendation, low quality of evidence).

Lynch Syndrome

The 2019 European Society of Gastrointestinal Endoscopy (ESGE) guideline on endoscopic management of Lynch syndrome and of familial risk of colorectal cancer does not address the use of capsule endoscopy (van Leerdam 2019).

Colon Capsule Endoscopy

In 2020, the European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastrointestinal and Abdominal Radiology (ESGAR) issued updated best practice guidelines for imaging alternatives to colonoscopy: CT colonography (CTC) and colon capsule endoscopy (CCE) specific to patients undergoing screening or with suspicion of colorectal neoplasm (Spada et al., 2020). Consensus recommendations include:

- For previously incomplete colonoscopy: CCE may be considered (weak recommendation, low quality evidence).
- For patients with symptoms suggestive of colorectal cancer, but a colonoscopy is contraindicated or not possible:
    - for patients with alarm symptoms: due to a lack of evidence, CCE is not recommended in this situation (very low-quality evidence).
    - for patients without alarm symptoms: CCE may be considered (weak recommendation, low quality evidence).
- For colorectal cancer screening: CCE is not suggested as a first-line screening test (weak recommendation, low quality evidence).
- There is insufficient evidence to recommend CCE for:
    - following curative-intent resection of colorectal cancer,
    - surveillance after polypectomy,

The 2021 American College of Gastroenterology (ACG) clinical guidelines for colorectal cancer screening suggest consideration of the colon capsule for screening [conditional recommendation; very low quality] (Shaukat et al., 2021).

The 2021 U.S. Preventive Services Task Force (USPSTF) final recommendation statement for colorectal cancer screening specifically indicates that USPSTF recommendation does not include capsule endoscopy for colorectal cancer screening due to limited available evidence on these tests and because other effective tests (i.e., the recommended screening strategies) are available.

The 2025 National Comprehensive Cancer Network (NCCN version 2.2025) clinical practice guidelines for colorectal cancer screening do not include capsule endoscopy as an image-based colorectal cancer screening modality. However, NCCN footnotes state, "for patients who have had incomplete colonoscopy, consider CE as alternative exam for completing the screening."

GI Bleed Detection Capsule Endoscopy

There are currently no recommendations from professional medical societies supporting the use of GI bleed detection capsule endoscopy for any clinical indication.

Esophageal Capsule

The 2019 American Society for Gastrointestinal Endoscopy (ASGE) guidelines on screening and surveillance of Barrett's esophagus (BE) acknowledge the significant potential of emerging screening technologies beyond standard upper endoscopy. These include esophageal capsule endoscopy, Cytosponge (Medtronic), tethered capsule endomicroscopy, and electronic nose devices. However, the ASGE panel ultimately endorsed screening for BE in at-risk populations based on the available evidence regarding BE prevalence in specific groups.

The 2022 clinical practice update from the American Gastroenterological Association (AGA) on new technologies for BE screening and surveillance reaffirmed that upper endoscopy with biopsies remains the gold standard for diagnosing BE (Muthusamy, 2022). Nonetheless, the AGA issued best practice advice supporting the consideration of nonendoscopic cell-collection devices—such as Cytosponge (Medtronic GI Solutions), EsoCheck (Lucid Diagnostics), and EsophaCap (Capnostics)—as screening options for BE. While all three devices have demonstrated excellent tolerability, safety, and sensitivity for BE diagnosis, the AGA emphasized the need for further data to validate patient selection criteria and determine the optimal settings for their use in the United States.

The 2023 European Society of Gastrointestinal Endoscopy (ESGE) guidelines on the diagnosis and management of Barrett esophagus (BE) recommends that a swallowable non-endoscopic cell collection device (e.g., Cytosponge) can be used as an alternative to endoscopy for case finding of Barrett's esophagus (strong recommendation, high quality evidence) (Weusten et al., 2023). The recommendation was based on findings from observational case-controlled studies and one randomized controlled trial.

Magnetic Capsule Endoscopy (CE)

There are currently no recommendations from professional medical societies supporting the use of magnetic capsule endoscopy for any clinical indication.

Motility Capsule Endoscopy

In 2021, the United European Gastroenterology (UEG) and European Society for Neurogastroenterology and Motility (ESNM) consensus on gastroparesis did not endorse the statement that wireless motility capsule (WMC) assessment is a valid test of diagnosing gastroparesis [Grade B recommendation] (Schol 2021). Noting the pitfall with WMC is that it is an indigestible solid and, therefore, it empties from the stomach in response to phase 3 migrating motor complexes rather than with the test meal.

The 2022 American Gastroenterological Association (AGA) expert review clinical practice update on management of medically refractory gastroparesis reiterated the EUG/ESNM consensus concern that because the WMC, an inanimate object, identifies the phase III activity front of the migrating motor complex rather than overall gastric emptying, a meal-based test provides better physiological assessment of gastric emptying and is thus recommended as the first-line test of gastric emptying over the WMC (Lacy 2022).

The American College of Gastroenterology (ACG) updated clinical guidelines on gastroparesis recommends scintigraphy gastric emptying (SGE) as the standard test for the evaluation of gastroparesis in patients with upper GI symptoms (strong recommendation, moderate level of evidence) (Camilleri 2022). The ACG reports that research supports WMC testing as an alternative test to SGE for the evaluation of gastroparesis in patients with upper GI symptoms and made a conditional recommendation (low quality of evidence) that WMC testing may be an alternative to the SGE assessment.

Patency Capsule

The 2017 American Gastroenterological Association (AGA) clinical practice guidelines for the use of video CE states "In patients with known or suspected strictures of the small bowel, we suggest a patency capsule before CE to minimize risk of retention. (GRADE: Conditional recommendation, very low-quality evidence for efficacy, low-quality evidence for safety)." (Enns 2017).

The 2023 European Society of Gastrointestinal Endoscopy (ESGE) guideline on small-bowel capsule endoscopy and device-assisted enteroscopy for diagnosis and treatment of small-bowel disorders recommends, in patients with established Crohn's disease, the use of a patency capsule before small-bowel capsule endoscopy to decrease the capsule retention rate (Pennazio 2023). (Strong recommendation, moderate quality evidence).

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates capsule endoscopy systems as medical devices. All capsule endoscopy systems including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Sep 17].

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most

serious type of recalls. on our website by the date that the FDA posts the information on our website. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls [accessed 2025 Sep 17].

The FDA has cleared several capsule endoscopy devices, including but not limited to devices that visualize small bowel mucosa (e.g., PillCam SB2 and SB3), esophageal mucosa (e.g., PillCam ESO), the colon (e.g., PillCam COLON), and the stomach (e.g., NaviCam Stomach Capsule System). In addition, the FDA has cleared capsules for other diagnostic purposes, such as verifying GI patency (e.g., PillCam Patency Capsule), measuring gastrointestinal transit time (e.g., Atmo Gas Capsule), and detecting the presence of blood in the GI tract (e.g., PillSense System).

Small Bowel Capsule Endoscopy

The Given Diagnostic Imaging System, PillCam SB, received initial Section 510(k) marketing clearance from the FDA on August 1, 2001. The FDA cleared the device for use along with, not as a replacement for, other endoscopic and radiologic evaluations of the small bowel. On July 2, 2003, the FDA approved the PillCam SB as a first-line tool in the detection of abnormalities of the small bowel, removing the adjunctive tool qualifier. On October 29, 2003, the FDA announced that it had expanded its approved indications for the use of wireless CE, PillCam SB, to include visualization of the small bowel and detection of abnormalities in symptomatic children aged 10 to 18 years. This approval was based on data from a small trial where the wireless CE was able to diagnose or definitively exclude a bleeding source, small bowel polyps or Crohn's disease in 29 out of 30 children. In September 2009, the FDA expanded its approval of the PillCam SB for use in children aged two years and up.

The Olympus Capsule Endoscope System received Section 510(k) marketing clearance from the FDA in September 2007, as equivalent in intended use, method of operation, material, and design to the predicate device (PillCam SB). It is used for visualization of the small intestine mucosa. FDA approval was based upon a study of 51 patients with OGIB who swallowed both the PillCam SB and the Endocapsule, 40 minutes apart and in randomized order. The devices were similar, in terms of the detection of normal versus abnormal small intestine mucosa and in their diagnostic capability (Cave et al., 2008).

Ingestible Esophageal Capsule

The PillCam ESO (Given Imaging) was approved by the FDA in November 2004 as a non-invasive alternative to endoscopy, to diagnose and evaluate diseases of the esophagus. Direct imaging of the small bowel with an endoscope is limited, and, thus, wireless CE of the small bowel occupies a unique diagnostic niche. In contrast, esophageal endoscopy, which also offers the opportunity for biopsy, is a routinely performed procedure. Therefore, assessment of CE of the esophagus requires comparison of its diagnostic performance to the gold standard of conventional endoscopy. One proposed indication for the capsule camera is detection of Barrett's esophagus, considered a premalignant condition associated with gastroesophageal reflux disease (GERD). Conventional endoscopy is often recommended in patients with longstanding symptoms of GERD, or in those requiring pharmacologic therapy to control GERD symptoms, to rule out Barrett's esophagus. This is a high-volume indication for conventional upper endoscopy, given the high prevalence of GERD.

Colon Capsule Endoscopy

Given Imaging received FDA Section 510(k) clearance (Class II) for the PillCam COLON 2 in February 2014. The clearance is intended for use in patients who had an incomplete traditional colonoscopy and still require a better review of the passageway.

Patency Capsule

The FDA approved the Agile patency capsule in May 2006 as an accessory to the Pill Cam video capsule, intended to verify adequate patency of the gastrointestinal tract prior to administration of the Pill Cam video capsule in patients with known or suspected strictures. Medtronic replaced the Agile Patency System with an updated product, PillCam Patency Capsule, which was FDA cleared in 2018.

Motility Capsule Endoscopy

In 2006, the ingestible capsule (SmartPill GI Monitoring System) was FDA-cleared through the Section 510(k) process for the evaluation of delayed gastric emptying. In 2009, the FDA expanded the use of the SmartPill to determine colonic transit time for the evaluation of chronic constipation and to differentiate between slow and normal transit constipation. The SmartPill motility capsule was discontinued in June 2023.

The Atmo Gas Capsule (Atmo Biosciences, Ltd) received FDA premarket approval in June 2025. The capsule measures whole gut and regional gut (stomach, small bowel, and colon) transit times for the evaluation of patients with suspected gastroparesis, and it not for use in pediatric patients.

Magnetic Capsule Endoscopy (CE)

The FDA approved a novel magnetically maneuvered CE system, NaviCam (AnX Robotica, Inc.) in May 2020. The device is contraindicated for use in patients with gastrointestinal obstruction, stenosis, fistula, or those with dysphagia. Other contraindications include patients with cardiac pacemakers or other implantable electronic medical devices as well as pregnant women, those less than 22 years of age, and those with a body mass index of 38 or greater.

Blood Detection Capsule Endoscopy

In February 2023, the FDA approved a novel ingestible GI blood detection capsule, PillSense System (EnteraSense) intended to be used as an adjunct, not a standalone diagnostic device, for clinical decision making. The device is a single-use ingestible capsule uses spectrophotometry (light absorption technology) to detect blood in the upper gastrointestinal tract as wirelessly transmits data to an external receiver.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational

- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
91110	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus through ileum, with interpretation and report
91111	Gastrointestinal tract imaging, intraluminal (e.g., capsule endoscopy), esophagus with interpretation and report
91112 (E/I)	Gastrointestinal transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report
91113 (E/I)	Gastrointestinal tract imaging, intraluminal colon (e.g., capsule endoscopy), with interpretation and report
91299 (*E/I)	Unlisted diagnostic gastroenterology procedure *E/I when billed as use of patency capsule and blood detection capsule
0651T (E/I)	Magnetically controlled capsule endoscopy, esophagus through stomach, including intraprocedural positioning of capsule, with interpretation and report
0977T (E/I)	Upper gastrointestinal blood detection, sensor capsule, with interpretation and report (Effective 07/01/25)

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

Akiki K, et al. A novel blood-sensing capsule for rapid detection of upper GI bleeding: a prospective clinical trial. Gastrointest Endosc. 2024 May;99(5):721-720. Epub 2023 Dec 6. PMID: 38065512

ASGE Standards of Practice Committee, et al.; ASGE Standards of Practice Committee Chair. ASGE guideline on screening and surveillance of Barrett's esophagus. Gastrointest Endosc. 2019 Sep;90(3):335-359.e2.

ASGE Standards of Practice Committee, et al. Guideline: The role of endoscopy in inflammatory bowel

disease. Gastrointestinal Endoscopy. 2015 May 22;81(5):1101-1121.E13.

ASGE Standards of Practice Committee, et al. Guideline: The role of endoscopy in the management of suspected small-bowel bleeding. Gastrointestinal Endoscopy. 2017 Jan;85(1):22-31.

Baltes P, et al. PillCamColon2 after incomplete colonoscopy - a prospective multicenter study. World J Gastroenterol. 2018 Aug 21;24(31):3556-3566.

Boland RC, et al. Clinical practice guidelines. Diagnosis and management of cancer risk in the gastrointestinal hamartomatous polyposis syndromes: recommendations from the US multi-society task force (USMSTF) on colorectal cancer. Gastroenterol. 2022;162:2063-2085.

Brito HP, et al. Video capsule endoscopy vs double-balloon enteroscopy in the diagnosis of small bowel bleeding: a systematic review and meta-analysis. World J Gastrointest Endosc. 2018 Dec 16;10(12):400-421.

Brodersen JB, et al. Artificial Intelligence-assisted analysis of pan-enteric capsule endoscopy in patients with suspected Crohn's disease: a study on diagnostic performance. J Crohns Colitis. 2024;18(1):75-81.

Bruining DH, et al. BLINK study group. Panenteric capsule endoscopy versus ileocolonoscopy plus magnetic resonance enterography in Crohn's disease: a multicentre, prospective study. BMJ Open Gastroenterol. 2020 Jun;7(1):e000365.

Camilleri M, et al. ACG Clinical Guideline: Gastroparesis. Am J Gastroenterol. 2022 Aug;117(8):1197-1220.

Casciani E, et al. MR enterography versus capsule endoscopy in paediatric patients with suspected Crohn’s disease. Eur Radiol. 2011 Apr;21(4):823-31.

Cash BD, et al. Multicentre, prospective, randomised study comparing the diagnostic yield of colon capsule endoscopy versus CT colonography in a screening population (the TOPAZ study). Gut 2021;70(11):2115-2122.

Cave D, et al. A Multicenter randomized comparison of the endocapsule and the PillCam SB. Gastrointest Endosc. 2008; Sep;68(3):487-94.

Choi M, Lim S, Choi MG, et al. Effectiveness of capsule endoscopy compared with other diagnostic modalities in patients with small bowel Crohn’s disease: a meta-analysis. Gut Liver. 2017 Jan 15;11(1):62-72. PMID 27728963.

De Franchis R, et al. Esophageal capsule endoscopy (PillCam ESO) is comparable to traditional endoscopy for detection of esophageal varices- an international multicenter trial. Gastrointest Endosc. 2007;65(5):AB107.

Delvaux M, et al. Esophageal capsule endoscopy in patients with suspected esophageal disease: double blinded comparison with esophagogastroduodenoscopy and assessment of interobserver variability. Endoscopy. 2008 Jan;40(1):16-22.

Denzer UW, et al. Magnetically guided capsule versus conventional gastroscopy for upper abdominal

complaints: a prospective blinded study. J Clin Gastroenterol. 2015 Feb; 49(2): 101-107.

Dionisio PM, et al. Capsule endoscopy has a significant higher diagnostic yield in patients with suspected and established small-bowel Crohn's disease: a met-analysis. Am J Gastroenterol. 2010 Jun;105(6):1240-8.

Eliakim R, et al. Evaluation of the Pill Cam Colon capsule in the detection of colonic pathology: results of the first multicenter, prospective, comparative study. Endoscopy. 2006 Oct;38(10):963-70.

Eliakim R, et al. Prospective multicenter performance evaluation of the second-generation colon capsule compared with colonoscopy. Endoscopy. 2009 Dec;41(12):1026-31.

El-Matary W, et al. Diagnostic characteristics of given video capsule endoscopy in diagnosis of celiac disease: A meta-analysis. J Laparoendosc Adv Surg Tech A. 2009 Apr 30 [Epub ahead of print].

Elosua A, et al. Does capsule endoscopy impact clinical management in established Crohn's disease?. Dig Liver Dis. 2022 Jan;54(1):118-124.

Enns RA, et al. Clinical Practice Guidelines for the Use of Video Capsule Endoscopy. Gastroenterology. 2017 Feb;152(3):497-514.

Ferretti F, et al. Effectiveness of capsule endoscopy and double-balloon enteroscopy in suspected complicated celiac disease. Clin Gastroenterol Hepatol. 2020;20:941-949.

Fitzgerald RC, et al.; BEST3 Trial team. Cytosponge-trefoil factor 3 versus usual care to identify Barrett's oesophagus in a primary care setting: a multicentre, pragmatic, randomised controlled trial. Lancet. 2020 Aug 1;396(10247):333-344.

Fritscher-Ravens A, et al. The feasibility of wireless capsule endoscopy in detecting small intestinal pathology in children under the age of 8 years: a multicentre European study. Gut. 2009 Nov;58(11):1467-72.

Galmiche JP, et al. Screening for esophagitis and Barrett's esophagus with wireless esophageal capsule endoscopy: a multicenter prospective trial in patients with reflux symptoms. Am J Gastroenterol. 2008 Mar;103(3):538-45.

Gerson LB, et al. ACG clinical guideline: Diagnosis and Management of Small Bowel Bleeding. Am J Gastroenterol. 2015 Sep;110(9):1265-1287.

Green PHR, et al. AGA clinical practice update on management of refractory celiac disease: expert review. Gastroenterol. 2022 Nov;163(5):1461-1469.

González-Suárez B, et al. Colon capsule endoscopy versus CT colonography in FIT-positive colorectal cancer screening subjects: a prospective randomised trial-the VICOCA study. BMC Med. 2020 Sep 18;18(1):255.

Gostout C. Capsule endoscopy clinical update: American Society for Gastrointestinal Endoscopy. 2002 Oct;10(2):1-4.

Gupta A, et al. A prospective study of MT enterography versus capsule endoscopy for the surveillance of adult patients with Peutz-Jeghers syndrome. AJR Am J Roentgenol. 2010 Jul;195(1):108-16.

Guturu P, et al. Capsule endoscopy with PillCAM ESO for detecting esophageal varices: a meta-analysis. Minerva Gastroenterol Dietol 2011. Mar;57(1):1-11.

Hartmann D, et al. A prospective two-center study comparing wireless capsule endoscopy with intraoperative enteroscopy in patients with obscure GI bleeding. Gastrointest Endosc. 2025 Jun;61(7):826-832.

Haanstra JF, et al. Prevalence of small-bowel neoplasia in Lynch syndrome assessed by video capsule endoscopy. Gut. 2015 Oct; 64(10): 1578-83.

Hasler WL, et al. Influence of gastric emptying and gut transit testing on clinical management decisions in suspected gastroparesis. Clinical and Translational Gastroenterology. 2019;10:e00084.

Hussey M, et al. Same-day colon capsule endoscopy is a viable means to assess unexplored colonic segments after incomplete colonoscopy in selected patients. United European Gastroenterol J. 2018 Dec;6(10):1556-1562.

Iqbal U, et al. Safety and efficacy of a minimally invasive cell sampling device ('Cytosponge') in the diagnosis of esophageal pathology: a systematic review. European J Gastroenterol & Hepatol. 2018;30(11):1261-1269.

Kjolhede T, et al. Diagnostic accuracy of capsule endoscopy compared with colonoscopy for polyp detection: systematic review and meta-analyses. Endoscop.y 2021 Jul;53(7):713-721.

Kim YE, et al. Patency capsule and cross-sectional imaging for predicting capsule endoscopy retention: a systematic review and meta-analysis. Dig Dis Sci. 2025 Feb;70(2):761-773.

Kopylov U, et al. Diagnostic yield of capsule endoscopy versus magnetic resonance enterography and small bowel contrast ultrasound in the evaluation of small bowel Crohn's disease: Systematic review and meta-analysis. Dig Liver Dis. 2017 Aug; 49(8): 854-863.

Koulaouzidis A, et al. Diagnostic yield of small-bowel capsule endoscopy in patients with iron-deficiency anemia: a systematic review. Gastrointest Endosc. 2012 Nov;76(5):983-92.

Kuo B, et al. The assessment of gastrointestinal transit by the Atmo capsule: a comparison with the SmartPill capsule. Clin Gastroenterol Hepatol. 2025 Aug;23(9):1633-1641.e8.

Kurien M, et al. Capsule endoscopy in adult celiac disease: a potential role in equivocal cases of celiac disease?. Gastrointest Endosc. 2013 Feb 2013; 77(2): 227-32.

Lacy BE, et al. AGA clinical practice update on management of medically refractory gastroparesis: expert review. Clin Gastroenterol Hepatol. 2022 Mar;20(3):491-500. Epub 2021 Oct 29.

Lai LH, et al. Long-term follow-up of patients with obscure gastrointestinal bleeding after negative capsule endoscopy. Am J Gastroenterol. 2006 Jun;101(6):1224-8.

Lai H-S, Wang X-K, Cai J-Q, et al. Standing-type magnetically guided capsule endoscopy versus gastroscopy for gastric examination: multicenter blinded comparative trial. Dig Endosc. 2020;32(4):557-564.

Lee AA, et al. Validation of diagnostic and performance characteristics of the wireless motility capsule

in patients with suspected gastroparesis. Clinical Gastroenterology and Hepatology. 2019;17:1770–1779.

Lei II, et al. Follow-up endoscopy rates as an indicator of effectiveness in colon capsule endoscopy: a systematic review and meta-analysis. BMJ Open Gastroenterol. 2025 May 11;12(1):e001800.

Leighton J, et al. Quality indicators for capsule endoscopy and deep enteroscopy. Am J of Gastroent. 2022 Nov;117(11):1780-1796.

Liao Z, et al. Accuracy of magnetically controlled capsule endoscopy, compared with conventional gastroscopy, in detection of gastric diseases. Clin Gastroenterol Hepatol. 2016 Sep; 14(9): 266-1273.e1.

Lichtenstein GR, et al. ACG clinical guidelines: Management of Crohn's disease in adults. Am J Gastroenterol. 2018 Mar; 113:481–517. Epub 2018 Mar 27.

Lin OS, et al. Blinded comparison of esophageal capsule endoscopy versus conventional endoscopy for a diagnosis of Barrett's esophagus in patients with chronic gastroesophageal reflux. Gastrointest Endosc. 2007 Apr;65(4):577-83.

Lu Y, et al. Meta-analysis of capsule endoscopy in patients diagnosed or suspected with esophageal varices. World J Gastroenterol. 2009 Mar 14;15(10):1254-8.

Meltzer AC, et al. Magnetically controlled capsule for assessment of the gastric mucosa in symptomatic patients: a prospective, single-arm, single-center, comparative study. iGIE. 2023;2(2):139-147.

Muthusamy VR, et al. AGA clinical practice update on new technology and innovation for surveillance and screening in Barrett's esophagus: expert review. Clin Gastroenterol Hepatol. 2022 Dec;20(12):2696-2706.e1.

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology. Colorectal cancer screening. v2.2025 – June 24, 2025 [accessed 2025 Sep 9]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/colorectal_screening.pdf

Nemeth A, et al. Video capsule endoscopy in pediatric patients with Crohn's disease: a single-center experience of 180 procedures. Therap Adv Gastroenterol. 2018 Mar 4;11:1756284818758929.

Parodi A, et al. Colon capsule endoscopy to screen for colorectal neoplasia in those with family histories of colorectal cancer. Gastrointest Endosc. 2018 Mar;87(3):695-704.

Pennazio M, et al. Small-bowel capsule endoscopy and device-assisted endoscopy for diagnosis and treatment of small-bowel disorders: European Society of Gastrointestinal Endoscopy (ESGE) guideline – update 2022. Endoscopy. 2023 Jan;55(1):58-95. Epub 2022 Nov 24. PMID: 36423618.

Postgate A, et al. Feasibility of video capsule endoscopy in the management of children with Peutz-Jeghers syndrome: a blinded comparison with barium enterography for the detection of small bowel polyps. J Pediatr Gastreoenterol Nutr. 2009 Oct;49(4):417-23.

Rubio-Tapia A, et al. American College of Gastroenterology guidelines update: diagnosis and

management of celiac disease. Am J of Gastroenterol. 2023 Jan;118(1):59-76.

Rokkas T, et al. A meta-analysis evaluating the accuracy of colon capsule endoscopy in detecting colon polyps. Gastrointest Endosc. 2010 Apr;71(4):792-8.

Sangnes DA, et al. Wireless motility capsule compared with scintigraphy in the assessment of diabetic gastroparesis. Neurogastroenterol & Motility. 2020 Apr;32(4)e13771.

Saurin JC, et al. Small-bowel capsule endoscopy diagnoses early and advanced neoplasms in asymptomatic patients with Lynch syndrome. Endoscopy. 2010 Dec; 42(12): 1057-62.

Schelde-Olesen B, et al. Colon CApsule endoscopy compared to conventional COlonoscopy in patients with colonic DIverticulitis: the study protocol for a randomised controlled superiority trial (CACODI trial). BMJ Open. 2023;13:e073575.

Schol J, et al. United European Gastroenterology (UEG) and European Society for Neurogastroenterology and Motility (ESNM) consensus on gastroparesis. United European Gastroenterol J. 2021 April;9(3):287-306.

Sharma P, et al. The diagnostic accuracy of esophageal capsule endoscopy in patients with gastroesophageal reflux disease and Barrett's esophagus: a blinded, prospective study. Am J Gastroenterol. 2008 Mar;103(3):525-32.

Shahaeen NJ, et al. Diagnosis and management of barrett's esophagus: an updated ACG guideline. Am J Gastroenterol. 2022;117:559-587.

Shapiro M, Niv Y. Diagnostic yield of video capsule endoscopy (VCE) in celiac disease (CD): a systematic review and meta-analysis. J Clin Gastroenterol. 2025 Aug 1;59(7):598-606.

Shaukat A, et al. ACG clinical guidelines: colorectal cancer screening 2021. Am J Gastroenterol 2021 Mar 01; 116(3): 458-479.

Singh K, et al. Diagnostic yield of capsule endoscopy for small bowel arteriovenous malformations in patients with hereditary hemorrhagic telangiectasia: a systematic review and meta-analysis. Endosc Int Open. 2019 Feb;7(2):E282-E289.

Shapiro M, Niv Y. Diagnostic yield of video capsule endoscopy (VCE) in Celiac Disease (CD): a systematic review and meta-analysis. J Clin Gastroenterol. 2025 Aug 1;59(7):598-606.

Spada C, et al. Imaging alternatives to colonoscopy: CT colonography and colon capsule. European Society of Gastrointestinal Endoscopy (ESGE) and European Society of Gastrointestinal and Abdominal Radiology (ESGAR) Guideline - Update 2020. Endoscopy. 2020 Dec;52(12):1127-1141. Epub 2020 Oct 26. PMID: 33105507.

Stein E, et al. Wireless motility capsule versus other diagnostic technologies for evaluating gastroparesis and constipation: A comparative effectiveness review. 2013 May; AHRQ Publication No. 13-EHC060-EF.

Tan WK, et al.; DELTA consortium. Biomarker risk stratification with capsule sponge in the surveillance of Barrett's oesophagus: prospective evaluation of UK real-world implementation. Lancet.

2025 Jul 19;406(10500):271-282. Erratum in: Lancet. 2025 Jul 19;406(10500):234.

Turner D, et al. STRIDE-II: An update on the selecting therapeutic targets in inflammatory bowel disease (STRIDE) initiative of the international organization for the study of IBD (IOIBD): Determining therapeutic goals for treat-to-target strategies in IBD. Gastroenterol. 2021 April:160(5):1570-1583.

Urquhart P, et al. Capsule endoscopy versus magnetic resonance enterography for the detection of small bowel polyps in Peutz-Jeghers syndrome. Fam Cancer. Jun 2014; 13(2): 249-55.

U.S. Preventative Services Task Force (USPSTF) [Internet]. Colorectal cancer: screening. Final recommendation statement. 2021 May 18 [accessed 2025 Sep 9]. Available from: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/colorectal-cancer-screening

Valdivia PC, et al. Indications, detection, completion, and retention rates of capsule endoscopy in two decades of use: a systematic review and meta-analysis. Diagnostics. 2022 Apr;12(5)1105.

Valdivia PC, et al. Surveillance of the small-bowel by capsule endoscopy in Lynch syndrome - A systematic review with meta-analysis. Dig Liver Dis. 2024 Apr;56(4):601-606. Epub 2023 Aug 8.

van Leerdam ME, et al. Endoscopic management of Lynch syndrome and of familial risk of colorectal cancer: European Society of Gastrointestinal Endoscopy (ESGE) Guideline. Endoscopy. 2019 Nov;51(11):1082-1093. Epub 2019 Oct 9.

Weusten BLAM, et al. Diagnosis and management of Barrett esophagus: European Society of Gastrointestinal Endoscopy (ESGE) guideline. Endoscopy. 2023 Dec;55(12):1124-1146. Epub 2023 Oct 9. PMID: 37813356.

Weusten BLAM, et al. Endoscopic management of gastrointestinal motility disorders – part 1: European Society of Gastrointestinal Endoscopy (ESGE) guideline. Endoscopy. 2020 Jun;52(6):498–515. Epub 2020 May 6.

Xu Y, et al. Feasibility of combined screening for upper gastrointestinal adenocarcinoma risk by serology and Cytosponge testing: the SUGAR study. J Clin Pathol. 2019 Dec;72(12):825-829.

Yang, et al. American Society for Gastrointestinal Endoscopy guideline on the role of endoscopy in familial adenomatous polyposis syndromes. Gastrointestin Endosc. 2020;90:963982.e2.

Zammit SC & Sidhu R. Capsule endoscopy – Recent developments and future directions. Expert Review of Gastroenterology & Hepatology. 2021 Vol 15;2: 127-137.

Zammitt SC, et al. Small bowel capsule endoscopy in refractory celiac disease: a luxury or a necessity? Ann Gastroenterol. 2021;34(2):188-195.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Colon Capsule Endoscopy (CCE) (LCD L38571) [accessed 2025 Sep 9]

Billing and Coding: Colon Capsule Endoscopy (CCE) (A58294) [accessed 2025 Sep 9]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 7/26 **Revised**: **Reviewed**:	
Date	**Summary of Changes**
11/1/2026	• New

MEDICAL POLICY

Medical Policy Title	**Cardiac Rehabilitation**
Policy Number	**8.01.14**
Current Effective Date	**August 1, 2026**
Next Review Date	**October 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Monitored Phase I and Phase II cardiac rehabilitation (CR) programs are considered **medically appropriate** for **ANY** of the following indications:

   A. Acute myocardial infarction (MI) within the preceding 12 months;

   B. Percutaneous coronary intervention (i.e., percutaneous transluminal coronary angioplasty (PTCA), atherectomy, stenting) within the preceding 12 months;

   C. Coronary bypass surgery within the preceding 12 months;

   D. Heart transplantation within the preceding 12 months;

   E. Class II or higher congestive heart failure;

   F. Stable angina pectoris;

   G. Valvular disease.

II. Additional CR services are considered **medically appropriate** if the individual has another qualifying cardiac event, including **ANY** of the following:

   A. Another documented MI or extension of initial infarction;

   B. Another cardiovascular surgery or percutaneous intervention;

   C. New, clinically significant coronary lesions documented by cardiac catheterization.

III. Phase III maintenance programs are considered **not medically necessary**. (Please refer to Policy Guideline IV).

IV. Intensive cardiac rehabilitation (ICR), is considered **investigational** for **ALL** indications, including but not limited to, the following programs:

   A. The Ornish Program for Reversing Heart Disease;

   B. The Pritikin Program;

   C. The Benson-Henry Institute Cardiac Wellness Program.

RELATED POLICIES

Corporate Medical Policy

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

11.01.03 Experimental or Investigational Services

Inpatient Physical Rehabilitation: Acute, Subacute & Skilled 1370/20.000204

POLICY GUIDELINE(S)

I. Cardiac rehabilitation for pediatric patients will be reviewed based on clinical indicators, including, but not limited to the patient's diagnosis (e.g., congenital anomalies, valvular disorders), recent surgical procedures (e.g., cardiac transplant, valvular replacement, or repair), and acceptance into a pediatric cardiac rehabilitation program.

II. Monitored Phase II cardiac rehabilitation programs must be recommended by the patient's cardiologist or primary care physician and rendered by a provider whose cardiac rehabilitation program has been approved by:

   A. the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR), if the program is rendered at an outpatient free-standing facility or in the practitioner's office; or

   B. the AACVPR, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), or the American Osteopathic Association (AOA), if the program is rendered at a hospital-based facility.

III. Due to the increased risk of experiencing a cardiac event (e.g., ventricular arrhythmia, infarction), Phase II CR programs must include physician supervision and continuous electrocardiographic monitoring during exercise.

IV. Phase III maintenance programs consist of activities that preserve the patient's present level of function and prevent regression of that function. Maintenance begins when the therapeutic goals of a treatment plan have been achieved or when no additional functional progress is apparent or expected to occur.

DESCRIPTION

Cardiac rehabilitation services are comprehensive, long-term programs involving medical evaluation, prescribed exercise, cardiac risk factor modification, education, and counseling. These programs are designed to limit the physiologic and psychological effects of cardiac illness, reduce the risk for sudden death or re-infarction, control cardiac symptoms, stabilize or reverse the atherosclerotic process, and enhance the psychosocial and vocational status of selected patients.

A CR program should be initiated as soon as medically indicated following a cardiac event. Examples of cardiac events are acute MI, coronary artery bypass graft, percutaneous transluminal coronary angioplasty (PTCA), heart valve surgery, heart transplantation, stable angina pectoris, or compensated heart failure.

CR consists of three phases, or levels, of service:

I. Phase I, or inpatient CR: a program that delivers preventive and rehabilitative services to hospitalized patients following an index cardiovascular disease (CVD) event.

II. Phase II, or early outpatient CR: a physician-supervised outpatient program that includes electrocardiographic monitoring during exercise and is intended to improve cardiac function and exercise tolerance. Programs are hospital, physician's office- or clinic-based and must meet federal and state regulatory and licensing requirements; and

III. Phase III, or long-term outpatient CR: a supervised or non-supervised maintenance program.

CR program providers are subject to state and federal licensing requirements. Due to the advances in the diagnosis and treatment of cardiac disease, there is a shift of CVD from an acutely fatal event to a chronic disease. There is a growing need for medical services to aid patients in improving their quality of life, lessen symptoms, increase functional capacity, and decrease disability. Formal CR programs meet this need for select cardiac patients and improve their net health outcomes by decreasing the incidence of cardiac death.

Intensive Cardiac Rehabilitation

According to the Centers for Medicare and Medicaid Services (CMS), ICR refers to a physician-supervised program that furnishes CR services more frequently, and often in a more rigorous manner. As required by §1861(eee)(4)(A) of the U.S. Social Security Act (the "Act"), an ICR program must demonstrate, through peer-reviewed, published research, that it accomplished one or more of the following for its patients:

I. Positively affected the progression of coronary heart disease (CHD);

II. Reduced the need for coronary bypass surgery; or

III. Reduced the need for percutaneous coronary interventions.

The ICR program must also demonstrate, through peer-reviewed, published research, that it accomplished a statistically significant reduction in five (5) or more of the following levels for patients, measured from before CR services to after CR services:

I. Low-density lipoprotein;

II. Triglycerides;

III. Body mass index;

IV. Systolic blood pressure;

V. Diastolic blood pressure; and

VI. the need for cholesterol, blood pressure, and diabetes medications.

ICR program sessions are limited to 72 one-hour sessions, up to six sessions per day, over a period of up to 18 weeks. There is no standard definition of an ICR program and, thus, specific programs are reviewed individually.

SUPPORTIVE LITERATURE

Sumner et al (2017) published a systematic review of controlled observational studies evaluating CR in patients diagnosed with acute MI. CR interventions consisted of structured, multi-component programs that included exercise and at least one of the following: education, information, health behavior change, and psychological or social support. Usual care interventions, generally supervised medical interventions, were the control conditions. Ten studies met reviewers' eligibility criteria. In a meta-analysis of five studies reporting all-cause mortality (an unadjusted outcome), there was a significantly lower risk of death in the group that received CR (odds ratio, 0.25; 95% CI, 0.16 to 0.40). Three studies that reported an adjusted analysis of all-cause mortality also found a significant benefit from CR (odds ratio, 0.47; 95% CI, 0.38 to 0.59). Similarly, a meta-analysis of three studies reporting cardiac-related mortality (an unadjusted analysis) found a significant benefit from CR (odds ratio, 0.21; 95% CI, 0.12 to 0.37). Only one study reported an adjusted analysis of cardiac-related mortality, so data could not be pooled.

Nilsson et al (2018) investigated the effect of a 12-week CR program with a high-intensity interval exercise component using participant VO2peak as a measure of improved exercise capacity. Increased exercise capacity has been shown to improve survival among persons with CHD. The objective of the study was to assess whether this addition to a CR program yielded improved long-term results. A total of 133 coronary patients participated in this prospective cohort study and were evaluated at baseline, at the end of the 12-week program, and again at a 15-month follow-up. Additional test measurements included a cardiopulmonary exercise test, body mass index, blood pressure tests, and a quality of life questionnaire. Of the 133 patients, 86 patients had complete information for the 15-month follow-up. Mean VO2peak improved from a baseline of 31.9 mL/kg/min to 35.9 mL/kg/min ($p<0.001$) at the end of the 12-week program, and to 36.8 mL/kg/min (CI not reported) at 15-month follow-up. Most of the 86 patients reported maintaining an exercise routine. Study limitations included the small sample size, a relatively low-risk male population at baseline, and lack of information on the qualifying event for CR. The authors concluded that the CR program intervention potentially fostered consistent and beneficial exercise habits, as demonstrated by improved VO2peak.

The benefits of formal CR programs outweigh those of informal exercise programs or the lack of a rehabilitative program. Through clinical trials, supervised/formal CR programs have been proven to improve the health outcomes of select cardiac patients.

Intensive Cardiac Rehabilitation

Ornish et al (1990) conducted a randomized, controlled trial (RCT), called the Lifestyle Heart Trial, comparing a version of the Ornish Program for Reversing Heart Disease with usual care. Initial results were reported in 1990, and five-year results in 1998. Twenty (71%) of 28 patients in the intervention group and 15 (75%) of 20 in the control group completed the five-year follow-up. The intervention and control groups did not differ significantly in the number of MI events (2 versus 4), CABGs (2 versus 5), or deaths (2 versus 1). However, compared with the control group, the intervention group had significantly fewer percutaneous transluminal coronary angioplasties (8 versus 14, $p<0.050$) and cardiac hospitalizations (23 versus 44, $p<0.001$). The trial had a small sample size for a cardiac trial (N=48), and only 35 patients were available for the five-year follow-up.

Lakhani et al. (2023) conducted a prospective, nonrandomized study that compared intensive cardiac rehabilitation with the Pritikin Program and traditional outpatient cardiac rehabilitation. The primary outcomes of interest were change in diet quality and quality of life from baseline to visit 24. There was a significant improvement in diet quality but not in quality of life between the Pritikin Program and traditional cardiac rehabilitation groups. Body mass index was also improved in patients who received intensive rehabilitation. Limitations of the study include a short follow-up, lack of data for cardiovascular outcomes, and nonrandomization.

Racette et al (2022) published seven-year outcomes from the first institution to implement the Pritikin Program. Retrospective data for 1,507 patients who received the intensive cardiac rehabilitation program and 456 patients who received traditional cardiac rehabilitation were compared. Outcomes of interest (e.g., anthropometric measures, dietary patterns, 6-minute walk distance [6MWD], grip strength, and HRQoL) all improved with the Pritikin Program. Significant benefit of the Pritikin Program compared to traditional cardiac rehabilitation were noted for change in body weight ($p<.0001$), body mass index ($p<.0001$), waist circumference ($p<.0001$), and diet quality as measured by the Rate Your Plate score ($p<.0001$). There was no difference in 6MWD or grip strength between groups. Cardiovascular outcomes, including rehospitalization or mortality, were not assessed and there was no follow up on the patients who did not complete the program.

No RCTs have evaluated the Pritikin Program or the Benson-Henry Institute Cardiac Wellness Program, in comparison to usual care or to standard CR; therefore, conclusions cannot be drawn for these programs regarding their impact on health outcomes.

PROFESSIONAL GUIDELINE(S)

The American College of Cardiology (ACC), American Heart Association (AHA), American College of Emergency Physicians (ACEP), National Association of EMS Physicians (NAEMSP) and Society for Cardiovascular Angiography and Interventions (SCAI) published guideline for the management of patients with acute coronary syndromes (Rao 2025). Their recommendations regarding cardiac rehabilitation state:

- "Patients with ACS should be referred to an outpatient CR program prior to hospital discharge to reduce death, myocardial infarction, hospital readmissions, and improve functional status and quality of life (Class 1; LOE A)."
- "In patients with ACS, a home-based CR program is a reasonable alternative to a center-based CR program to improve functional status and QOL (Class IIa; LOE BR)."

The AHA and the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) published a scientific statement addressing the core components of CR and secondary prevention programs (Brown 2024). The core components included patient assessment before beginning the program, nutritional counseling, weight management and body composition, blood pressure management, lipid management, diabetes management, tobacco cessation, psychosocial management, aerobic exercise training, strength training, physical activity counseling, and program quality. Programs that only offered supervised exercise training were not considered cardiac rehabilitation.

The AHA and ACC published a scientific statement regarding the supervised exercise training for chronic heart failure with preserved ejection fraction (Sachdev 2023). Their findings include the following:

- "Current guidelines also include a Class 1 recommendation (Level of Evidence A) for exercise training in patients with HF."
- "To the best of our knowledge, only 4 trials of home-based exercise training for patients with chronic HF have been published. All reported improved exercise capacity and quality-of-life metrics. However, because of the short duration (3–6 months) and small number of exercising subjects (n=67) included, the safety and efficacy of these training regimens remain unproven."

The AHA, ACC, and the Heart Failure Society of America (HFSA) published clinical practice guidelines for the management of heart failure (Heidenreich 2022). They recommend:

- "A cardiac rehabilitation program for patients with HF usually includes a medical evaluation, education regarding the importance of medical adherence, dietary recommendations, psychosocial support, and an exercise training and physical activity counseling program. Patients with HF on optimal [goal directed medical therapy] GDMT, who are in stable medical condition and are able to participate in an exercise program, are candidates for an exercise rehabilitation program."
- "For patients with HF who are able to participate, exercise training (or regular physical activity) is recommended to improve functional status, exercise performance, and QOL."
- "In patients with HF, a cardiac rehabilitation program can be useful to improve functional capacity, exercise tolerance, and health related QOL."

REGULATORY STATUS

Not Applicable

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
93797	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)

Code	Description
93798	Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)

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HCPCS Codes

Code	Description
G0422 (E/I)	Intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session
G0423 (E/I)	Intensive cardiac rehabilitation; with or without continuous ECG monitoring; without exercise, per session
S9472	Cardiac rehabilitation program, non-physician provider, per diem

ICD10 Codes

Code	Description
A52.03	Syphilitic endocarditis
I01.1	Acute rheumatic endocarditis
I02.0	Rheumatic chorea with heart involvement
I05.0-I09.9	Chronic rheumatic heart diseases (code range)
I20.1	Angina pectoris with documented spasm
I20.8-I20.9	Other or unspecified forms of angina pectoris (code range)
I21.01-I21.3	ST elevation (STEMI) myocardial infarction (code range)
I21.4	Non-ST elevation (NSTEMI) myocardial infarction
I21.9	Acute myocardial infarction, unspecified
I21.A1-I21.A9	Other type of myocardial infarction (code range)
I22.0-I22.9	Subsequent ST (STEMI) or non-ST (NSTEMI) elevation myocardial infarction (code range)
I25.10-I25.9	Chronic ischemic heart disease (code range)

Code	Description
I34.0-I34.9	Nonrheumatic mitral valve disorders (code range)
I35.0-I35.9	Nonrheumatic aortic valve disorders (code range)
I36.0-I36.9	Nonrheumatic tricuspid valve disorders (code range)
I37.0-I37.9	Nonrheumatic pulmonary valve disorders (code range)
I50.1-I50.9	Heart failure (code range)
Q23.2	Congenital mitral stenosis
Z94.1	Heart transplant status
Z94.3	Heart and lungs transplant status
Z95.1	Presence of aortocoronary bypass graft
Z95.2	Presence of prosthetic heart valve
Z95.5	Presence of coronary angioplasty implant and graft
Z95.812	Presence of fully implantable artificial heart
Z98.61	Coronary angioplasty status

Revenue Codes

Code	Description
943	Cardiac rehabilitation

REFERENCES

Bjarnason-Wehrens B, et al. Exercise-based cardiac rehabilitation in patients with reduced left ventricular ejection fraction: The Cardiac Rehabilitation Outcome Study in Heart Failure (CROS-HF): A systematic review and meta-analysis. Eur J Prev Cardiol 2020 Jun;27(9):929-952.

Brown TM, et al; on behalf of the American Heart Association Exercise, Cardiac Rehabilitation and Secondary Prevention Committee of the Council on Clinical Cardiology; Council on Cardiovascular and Stroke Nursing; Council on Lifestyle and Cardiometabolic Health; and Council on Quality of Care and Outcomes Research. Core components of cardiac rehabilitation programs: 2024 update: a scientific statement from the American Heart Association and the American Association of Cardiovascular and Pulmonary Rehabilitation. Circulation. 2024;150:e328–e347.

Chacón MM, et al. Effects of supervised cardiac rehabilitation programs on quality of life among myocardial infarction patients: a systematic review and meta-analysis. J Cardiovasc Dev Dis 2021 Nov;8(12):166.

Heidenreich PA, et al. 2022 AHA/ACC/HFSA Guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines. J Am Coll Cardiol 2022 May;79(17):e263-e421. Erratum in: J Am Coll Cardiol 2023 Apr;81(15):1551.

Lakhani F, et al. Prospective study of the impact of outpatient intensive cardiac rehabilitation on diet quality, health-related quality of life, and cardiovascular health indices. Am J Cardiol 2023 Apr;192:60-66.

Long L, et al. Exercise based rehabilitation for heart failure. Cochrane Database Syst Rev 2019 Jan 29;1:CD003331.

Molloy CD, et al. Exercise-based cardiac rehabilitation for adults with heart failure - 2023 Cochrane systematic review and meta-analysis. Eur J Heart Fail 2023 Dec;25(12):2263-2273.

Nielsen KM, et al. Exercise-based cardiac rehabilitation for adult patients with an implantable cardioverter defibrillator. Cochrane Database Syst Rev 2019 Feb 12;2:CD011828.

Nilsson BB, Lunde P, Grogaard HK, et al. Long-term results of high-intensity exercise-based cardiac rehabilitation in revascularized patients for symptomatic coronary artery disease. Am J Cardiol Jan 1 2018;121(1):21-26.

Ornish D, et al. Can lifestyle changes reverse coronary heart disease? The Lifestyle Heart Trial. Lancet 1990 Jul 21;336(8708):129-33.

Ornish D, et al. Intensive lifestyle changes for reversal of coronary heart disease. JAMA 1998 Dec 16;280(23):2001-7.

Racette SB, et al. Benefits of the first Pritikin outpatient intensive cardiac rehabilitation program. J Cardiopulm Rehabil Prev 2022 Nov;42(6):449-455.

Rao SV, et al. 2025 ACC/AHA/ACEP/NAEMSP/SCAI Guideline for the management of patients with acute coronary syndromes: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2025;151:e771–e862.

Sachdev V, et al; American Heart Association Heart Failure and Transplantation Committee of the Council on Clinical Cardiology; Council on Arteriosclerosis, Thrombosis and Vascular Biology; and American College of Cardiology. Supervised exercise training for chronic heart failure with preserved ejection fraction: A scientific statement from the American Heart Association and American College of Cardiology. Circulation 2023 Apr;147(16):e699-e715.

Snoek, JA, et al. Effectiveness of home-based mobile cardiac rehabilitation as alternative strategy for nonparticipation in clinic-based cardiac rehabilitation among elderly patients in Europe, a randomized clinical trial. JAMA Cardiology 2020 Nov;6(4):463-468.

Social Security Act [Internet]. Title XVIII of the Social Security Act §1861(eee)(4)(A). 2025 Aug 28 [accessed Sep 12]. Available from: https://www.govinfo.gov/content/pkg/COMPS-8768/pdf/COMPS-8768.pdf

Sumner J, et al. The effectiveness of modern cardiac rehabilitation: A systematic review of recent observational studies in non-attenders versus attenders. PLoS One 2017;12(5):e0177658.

Thomas RJ, et al. AACVPR/ACC/AHA 2010 update: performance measures on cardiac rehabilitation for referral to cardiac rehabilitation/secondary prevention services. J Cardiopulmon Rehabil Prev 2010;30:279-88.

Thomas RJ, et al. 2018 ACC/AHA clinical performance and quality measures for cardiac rehabilitation: A report of the American College of Cardiology/American Heart Association Task Force on Performance Measures. J Am Coll Cardiol 2018 Apr 24;71(16):1814-1837.

SEARCH TERMS

Cardiac rehabilitation, Cardiac therapy, Heart therapy.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Cardiac Rehabilitation Programs for Chronic Heart Failure (NCD 20.10.1) [accessed 2025 Sep 12]

Intensive Cardiac Rehabilitation (ICR) Programs (NCD 20.31) [accessed 2025 Sep 12]

Benson-Henry Institute Cardiac Wellness Program (NCD 20.31.3) [accessed 2025 Sep 12]

Ornish Program for Reversing Heart Disease (NCD 20.31.2) [accessed 2025 Sep 12]

The Pritikin Program (NCD 20.31.1) [accessed 2025 Sep 12]

Additional information, regarding Cardiac and Intensive Cardiac Rehabilitation Programs, can be found in the Medicare Claims Processing Manual, Section 140. Available from: Medicare Claims Processing Manual [accessed 2025 Sep 12]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 07/89 **Revised**: 06/90, 12/91, 07/93, 04/96, 03/97, 03/98, 03/99, 09/99, 09/00, 09/03, 04/04, 12/04, 10/05, 05/06, 04/07, 03/08, 03/09, 01/10, 03/10, 03/11, 03/12, 05/14, 03/19, 11/19, 03/20, 3/21, 7/21, 1/22, 7/26 **Reviewed**: 04/92, 04/94, 05/95, 09/02, 05/03, 03/13, 03/14, 03/15, 03/16, 03/17, 03/18, 3/23, 3/24, 3/25, 3/26	
Date	**Summary of Changes**
8/1/2026	• Transitioned Cardiac/Intensive Cardiac Rehabilitation policy, 1370/20.000069 to Lifetime HealthCare Companies policy template and criteria.
5/1/2022* *No change to effective date for this update	• Clarified exclusion for intensive cardiac rehabilitation for Select Plan/HARP.
5/1/2022	• Removed intensive cardiac rehabilitation criteria from the Position Statement and added to the Medicare Advantage section. Added intensive cardiac rehabilitation to the Exclusions section to apply to Commercial LOB.
8/1/2021	• Removed visit limit of 72 visits from Position Statement. • Added limits for cardiac rehab and intensive cardiac rehab to the Medicare Advantage section. • Removed exclusion for services rendered at other than an approved facility, health spa, or gym.
7/1/2021	• Removed statement regarding location of services from the Position Statement section. • Removed S9472 from the list of Exclusions.
7/1/2020	• Clinical indications for cardiac rehabilitation/intensive cardiac rehabilitation programs are made the same. • Section in policy addressing cardiac rehabilitation/intensive cardiac rehabilitation program component requirements was expanded upon to better align with language in Medicare Benefit Policy Manual.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

1/1/2020	• Increased allowable sessions for cardiac rehabilitation from 36 to 72 in the Policy Considerations section. • Added section on intensive cardiac rehabilitation to Policy Considerations section and removed from the Medicare Advantage section as it now applies to all LOB. • Removed references to intensive cardiac rehabilitation from the Exclusions section. • Removed statement from Medicare Advantage section that 72 sessions of cardiac rehabilitation would be allowed as it was added to the Policy Considerations section to apply to all LOB.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Sickle Cell Disease

Sickle cell disease (SCD) refers to a group of inherited blood disorders that are caused by a mutation in the β-globin gene, causing abnormal hemoglobin properties. The mutant hemoglobin is susceptible to continuous polymerization with other hemoglobin molecules in hypoxic environments. As the mutated hemoglobin (HbS) polymerizes, the red blood cell becomes deformed; rigid and inflexible in a "sickle" shape which leads to vaso-occlusion and hemolysis severely affecting blood flow in these patients. Incidence of sickle cell disease is estimated at 300,000 to 400,000 live births throughout the world. It is estimated that 100,000 people are living with SCD in the United States. [1]

Hallmark manifestations of SCD include recurrent vaso-occlusive events or crises (VOEs or VOCs) which can lead to acute pain crises. Vaso-occlusive crises can lead to episodes of severe pain from decreased blood flow in microcapillaries and can include blood vessel blockage that can lead to tissue ischemia of the bone and bone marrow. These can lead to an increase in hospitalizations, and underlying medication complications such as severe infections, acute chest syndromes (ACS), acute splenic sequestration crisis, priapism, and stroke. There are several subtypes of SCD that exist that are determined by specific mutations in each hemoglobin gene. Severe SCD genotypes are listed as: βS/βS, βS/β0, and βS/β+. However, the available treatments that have been created thus far are independent of these subtypes.

America Society of Hematology guidelines recommend treating SCD based on need of complication. Guidelines exist for sickle cell disease with cardiopulmonary and kidney disease, transfusion support, cerebrovascular disease, management of acute and chronic pain, and stem cell transplantation.

Historically, Hydroxyurea has been the mainstay of treatment in SCD. This medication increases red blood cell fetal hemoglobin to reduce the amount of "sickled" cells being produced. Other available and FDA approved treatments for SCD include Endari (L-glutamine), Adakveo (crizanlizumab), and Oxybryta (voxelotor). Other interventions include hematopoietic stem cell transplantation (HSCT) which has shown to be curative in some individuals but depends on patient specific factors and compatible donor availability. Blood transfusions, and packed red blood cells may help as adjunctive therapy in unblocking blood vessels by delivering oxygen to the body. Stem cell gene therapy interventions are emerging for SCD and may offer a curative treatment for its complications.

Beta Thalassemia

Thalassemias are inherited hemoglobinopathies in which impaired production of one type of globin chain; either alpha or beta, causes an imbalance in the ratio between those chains. These chains precipitate and cause significant cellular damage, thus causing issues with red blood cell maturation and leads to ineffective erythropoiesis, hemolytic anemia, iron overload, and ensuing complications. Specifically in beta-thalassemia, this impaired production is caused by mutations in the hemoglobin beta globin gene. There are more than 350 beta-thalassemia mutations currently known, and while distinction of the various phenotypes of thalassemia is mostly based on clinical parameters, genotype-phenotype associations are commonly established. There are four different phenotypes in beta-thalassemia: Major, intermedia, trait/minor, and silent carriers. However, in terms of treatment, individuals with beta thalassemia are classified as either being transfusion dependent (TDT) or non-transfusion dependent (NTDT).

Transfusion dependent individuals are those patients that require regular, life-long transfusions to mitigate severe anemia and extramedullary hematopoiesis. This classification does not include those patients who only periodically require transfusions for anemia, but they may become fully transfusion dependent over time. Non-transfusion dependent individuals do not require regular transfusions.

Whichever the category a patient falls into, the management of beta thalassemia mainly involves treating the anemia if it is severe enough to cause symptoms, reducing ineffective erythropoiesis, preventing excess iron stores from forming, and treating the complications of such iron overload if it occurs. Both TDT and NTDT are fluid categories based on clinical parameters, and a patient can switch from one group to the other over the course of their lives. As such, these designations should primarily represent a patient's current clinical status.

If iron overload occurs from the frequent transfusions, it can cause organ toxicity and potentially mortality. In this case, it may be necessary to use iron chelation therapy to remove excess iron from the body. Currently, there are three iron chelating agents on the market for iron overload: deferasirox, deferiprone, and deferoxamine. No single agent is considered the "gold standard," and long-term randomized, prospective studies for this comparison are lacking. However, all three are approved for the treatment of iron overload in transfusion-

dependent thalassemia, and the choice of agent is largely dependent on preference of the prescriber and patient, patient age, comorbidities, and side effect profile.

Potentially curative treatment for beta-thalassemia was hemopoietic stem cell transplant from an HLA-matched donor as well as betibeglogene autotemcel (beti-cel) gene therapy. Beti-cel is a promising type of curative treatment for those with beta-thalassemia, and it is used to introduce new genes or edit existing genes in hematopoietic stem cells to reduce the frequency of blood transfusions. Betibeglogene autotemcel has yielded results in five studies, two phase 1/2 trials, 2 phase 3 trials (of which 89% of participants achieved transfusion dependence), and one long-term follow up cohort study of trial participants.

Casgevy (Exagamglogene autotemcel)
Casgevy *(exagamglogene autotemcel)* is an autologous genome edited hematopoietic stem cell-based gene therapy approved for use in patients 12 years and older with sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs) and transfusion-dependent β-thalassemia (TDT). Casgevy uses clustered regularly interspaced palindromic repeats (CRISPR)/CRISPR-associated protein 9 (Cas9)–based gene editing. This technology allows for targeted manipulation of specific genes. In the case of SCD, Casgevy targets the BCL11A gene to reduce its expression and ultimately increase fetal hemoglobin (HbF) and γ-globin production. Elevated levels of fetal hemoglobin (HbF) have been associated with improved morbidity and mortality in patients with SCD and TDT. Typically, infants and neonates are asymptomatic due to elevated fetal hemoglobin levels and begin to show symptoms after HbF synthesis declines within the first year of life.[7-9] In TDT, the increase in γ-globin alleviates the imbalance between α-globin and non-α-globin chains resulting in improved erythropoiesis and hemoglobin levels and ultimately transfusion independence.

SCD Clinical Study Experience
In a single phase I/II/III trial of exa-cel (CLIMB-121 trial) there were 35 participants with only 17 participants having had 12 months of follow up for the primary study outcome. Of those 17 participants, 16 (94.1%) were free of severe VOEs/VOCs during that time. The clinical trial for exa-cel has defined severe VOCs as:

- Acute pain that requires a visit to a medical facility and administration of pain medications (opioids, or IV NSAIDs) or RBC transfusions
- ACS, as indicated by presence of new pulmonary infiltrate associated with pneumonia-like symptoms, pain, or fever
- Priapism lasting more than two hours
- Splenic sequestration

The Institute for Clinical and Economic Review (ICER) reviewed Exa-Cel as part of a review titled, "Gene Therapies for Sickle Cell Disease." In both trials for lovo-cel and exa-cel, there were serious adverse events observed. These serious adverse effects are attributed to the myeloablative conditioning however were not infrequent and both therapies require chemotherapy before receiving them. ICER noted that uncertainly still remains about the long-term degree of risk of gene therapies in the real word. Exa-cel has its own concerns, with the small number of patients treated, short median follow-up time in CLIMB-121, and that CRISPR therapy is even newer than lentiviral gene therapy. **ICER noted that in those with severe SCD, compared with standard of care, treatment with exa-cel may be comparable, result in incremental net benefit, or result in substantial net benefit (rating C++, comparable or better).**

TDT Clinical Study Experience
This study was an ongoing ((NCT03655678) at least 24 months after treatment) open-label, multi-center, single-arm trial evaluating exa-cel in those with transfusion-defendant beta-thalassemia. For those treated, after 24 months, those subjects were encouraged to enroll in a follow-up trial, for a 15 year follow up (NCT04208529). Eligibility for this study included a history of requiring at least 100 mL/kg/year or 10 units/year of RBC transfusions in the two years prior to enrollment. At the time of the interim analysis, 59 subjects were enrolled in the trial, of which 88% (n-52) received therapy and formed the full analysis set (FAS). From the FAS population, 67% had adequate follow-up to allow for primary efficacy endpoint analysis (primary efficacy set or PES). The primary outcome was the proportion of patients achieving transfusion independence for 12 consecutive months (**TI12**), defined as maintaining weighted average Hb ≥ 9 g/dL without RBC transfusions for at least 12 consecutive months any time within the first 24 months after infusion, evaluated starting 60 days after the last RBC transfusion for post-transplant support or TDT disease management. The TI12 responder rate was 32/35 (91.4%, 98.3% one-sided CI: 75.7%, 100%). All patients who achieved TI12 remained transfusion-independent, with a median (min, max) duration of transfusion-independence of 20.8 (13.3, 45.1) months and normal mean weighted average total Hb levels (mean [SD] 13.1 [1.4] g/dL). The median (min, max) time to last RBC transfusion for patients who achieved TI12 was 30 (11, 91) days following infusion. Three patients did not achieve TI12. These patients had reductions in annualized RBC transfusion volume requirements of 79.8%, 83.9%, and 97.9%, and reductions in annualized transfusion frequency of 78.6%, 67.4%, and 94.6%, respectively, compared to baseline requirements.

Summary	
Effective Date of Policy	7/14/2026
Indications	Sickle Cell Disease (D57), transfusion-dependent β-thalassemia (TDT) (D56.1)
Availability	See FDA Prescribing Information
HCPCS Code	J3392
Duration	Authorization will be for 6 months to allow sufficient time for administration

Required Criteria for Initial Approval		
All of the following conditions for the requested indication must be met in order to approve therapy		
Indication	**Inclusion Criteria**	**Recommended Dosing**

Treatment of patients aged 2 years and older with sickle cell disease (SCD) with recurrent vaso-occlusive crises (VOCs)
(FDA Approved)
	• Enrollee is ≥ 2 years of age
	• Therapy is requested by a hematologist or prescriber with expertise in the management of Sickle Cell Disease
	• Must have documentation of all of the following:
	  ○ Patient has a confirmed diagnosis of sickle-cell disease with one of the following βS/βS or βS/β0 or βS/β+ genotype. Additional genotypes will be considered on a case-by-case basis based on disease severity AND
	  ○ History of at least 2 severe vaso-occlusive events or crises (VOCs/VOEs) per year over the last 2 years. Severe VOC/VOE is defined as at least ONE of the following:
	  ▪ Acute pain episode that requires a visit to a medical facility and administration of pain medications (opioids or IV NSAIDs) or RBC transfusions OR
	  ▪ Acute chest syndrome (ACS), as indicated by presence of new pulmonary infiltrate associated with pneumonia-like symptoms, pain, or fever OR
	  ▪ Hepatic sequestration OR
	  ▪ Priapism lasting more than 2 hours and leading to a medical-facility visit
	• Must have experienced ONE of the following pertaining to hydroxyurea (1, 2, or 3):
	  ○ 1. A therapeutic failure (ex. continued frequent and/or severe VOCs or ongoing, frequent transfusion requirements) to a ≥ 6 consecutive month trial of hydroxyurea at maximum tolerated dosing. Adherence will be assessed based on:
	  ▪ Pharmacy refill history. If the patient does not have pharmacy benefits through this health plan, a recent pharmacy profile will be requested. Progress notes documenting usage of sample medication may also be requested OR
	  ○ 2. A contraindication to hydroxyurea defined as a hypersensitivity to hydroxyurea or any component of the formulation OR
	  ○ 3. Experienced two hematologic toxicity reactions with hydroxyurea that resulted in discontinuation of therapy
	  ▪ Hematologic toxicity with hydroxyurea is defined by neutrophil, platelet, hemoglobin and/or reticulocyte count abnormalities concurrent with hydroxyurea use suggestive of hematologic toxicity. After the first hematologic toxicity, hydroxyurea therapy should be stopped and can be restarted with a dose reduction upon hematologic recovery. If a second hematologic toxicity is experienced, treatment should be discontinued
	• Must have Karnofsky performance status of ≥ 80% for patients ≥ 16 years of age or Lansky performance status of ≥ 80% for patients < 16 years of age
	• Must be used as a single agent therapy (not applicable to myeloablative conditioning therapy)
	• Enrollee has been screened and found negative for active infections of the following: hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus 1 &2 (HIV-1/HIV-2) in accordance with clinical guidelines prior to collection
		• The minimum recommended dose of Casgevy is 3 × 10^6 CD34+ cells/kg and will be approved as a one-time dose
		• Please refer to Casgevy FDA-approve prescribing information for complete dosage and administration instructions
		• Casgevy is for autologous use only

	of cells (documentation of laboratory results taken within the past 3 months is required • Enrollee will not receive concomitant therapy with any of the following: o Iron chelators for 7-days prior to mobilization and 6 months post-treatment (3-months post-treatment for non-myelosuppressive iron chelators) AND o Disease-modifying agents (e.g., voxelotor, crizanlizumab, L- glutamine) for at least 8-weeks prior to mobilization AND o Hydroxyurea for at least 2 months prior to mobilization • Enrollee must be eligible to undergo hematopoietic stem cell transplant (HSCT) • Prescriber must attest that the patient will not be re-started on hydroxyurea or other disease modifying therapies for SCD after receipt of Casgevy	
Treatment of patients aged 2 years and older with transfusion-dependent β-thalassemia (TDT) **(FDA Approved)**	• Enrollee is ≥ 2 years of age • Therapy is prescribed by a hematologist or provider who specializes in management of beta thalassemia • Enrollee has documented diagnosis of Transfusion Dependent Beta Thalassemia with genetic confirmation of the following: o Non-β0/β0 genotype (i.e., β0/β+, βE/β0, and β+/β+) OR o β0/β0 genotype (other examples include: β0/β+(IVS-I-110) and β+(IVS-I-110)/β+(IVS-I-110)) • Clinical documentation supports the enrollee has had the following in the previous two years (one of the below two options): o Receipt of ≥ 10 transfusions of packed red blood cells (pRBC) per year OR o Receipt of ≥ 100 mL/kg/year of pRBC per year • Must have a Karnofsky performance status of ≥ 80% for subjects ≥ 16 years of age or a Lansky performance status of ≥ 80% for subjects < 16 years of age • Patient must be eligible to undergo hematopoietic stem cell transplant (HSCT) • Enrollee has been assessed for an HLA-matched sibling donor Hematopoietic Stem Cell Transplant (HSCT) and determined not to be a candidate based on match • Physician attests that enrollee is fit to receive Casgevy therapy, including therapy for myeloablative conditioning • Patient has been screened and found negative for active infections of the following: hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus 1 & 2 (HIV-1/HIV-2) in accordance with clinical guidelines prior to collection of cells (documentation of laboratory results taken within the past 3 months is required) • Enrollee will not receive concomitant therapy with any of the following: o Iron chelators for 7-days prior to mobilization and 6 months post-treatment (3-months post-treatment for non-myelosuppressive iron chelators) AND o Disease-modifying agents (e.g., voxelotor, crizanlizumab, L- glutamine) for at least 8-weeks prior to mobilization AND o Hydroxyurea for at least 2 months prior to mobilization	• See FDA Prescribing Information
Exclusion Criteria		
Sickle Cell Disease Therapy will not be approved if any of the below criteria are met: • An accessible and willing 10/10 human leukocyte antigen (HLA)-matched related donor • Prior receipt of allogeneic or autologous HSCT • Prior treatment with gene therapy/editing product		

- Clinically significant and active bacterial, viral, fungal, or parasitic infection
- History of untreated Moyamoya disease or presence of Moyamoya disease
- Advanced liver disease, defined as any of the following:
    - Alanine transaminase (ALT) > 3 × the upper limit of normal (ULN) or direct bilirubin value > 2.5 × ULN
    - Baseline prothrombin time (PT) (international normalized ratio [INR]) > 1.5 × ULN
    - History of cirrhosis or any evidence of bridging fibrosis, or active hepatitis
- Baseline estimated glomerular filtration rate < 60 mL/min/1.73 m2 (documentation of laboratory results taken within the past 3 months is required)
- Any contraindications to the use of plerixafor during the mobilization of hematopoietic stem cells and any contraindications to the use of busulfan and any other medicinal products required during the myeloablative conditioning, including hypersensitivity to the active substances or to any of the excipients.
- Any prior or current malignancy or myeloproliferative disorder or a significant immunodeficiency disorder.
- History of familial cancer syndrome

Transfusion-dependent β-Thalassemia
Therapy will not be approved if any of the below criteria are met:

- An accessible and willing 10/10 human leukocyte antigen (HLA)-matched related donor
- Prior receipt of allogeneic or autologous HSCT
- Prior treatment with gene therapy/editing product
- Significant and active bacterial, viral, fungal, or parasitic infection
- α-thalassemia and > 1 alpha chain deletion, or alpha multiplications
- White blood cell (WBC) count < 3×10^9/L or platelet count < 50×10^9/L not related to hypersplenism (documentation of laboratory results taken within the past 3 months is required)
    - NOTE: If patient has a white blood cell count less than $3 \text{ X } 10^9$/L, and/or platelet count less than $100 \text{ X } 10^9$/L, then documentation of hypersplenism (i.e., ultrasound) is required
- Any prior or current malignancy or myeloproliferative disorder or a significant immunodeficiency disorder
- A cardiac T2* < 10 ms by MRI or left ventricular ejection fraction (LVEF) < 45% by echocardiogram
- Baseline estimated glomerular filtration rate < 60 mL/min/1.73 m2 (documentation of laboratory results taken within the past 3 months is required)
- Any contraindications to the use of plerixafor or granulocyte colony stimulating factor (G-CSF) during the mobilization of hematopoietic stem cells and any contraindications to the use of busulfan and any other medicinal products required during the myeloablative conditioning, including hypersensitivity to the active substances or to any of the excipients.
- Advanced liver disease, defined as any of the following:
    - Aspartate transaminase (AST), alanine transaminase (ALT) > 3 x the upper limit of normal (ULN), or direct bilirubin value > 2.5 x the ULN
    - Baseline prothrombin time (International Normalized Ratio; INR) > 1.5 x ULN
    - History of cirrhosis or any evidence of bridging fibrosis, or active hepatitis on previous liver biopsy.
    - Liver iron content (LIC) ≥ 15 mg/g on R2* MRI of liver

Continuation Criteria

- Not applicable
- If approved, therapy will only be approved for one lifetime administration

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department
- Casgevy (exagamglogene autotemcel) is considered not medically necessary when the above criteria are not met.
- Casgevy (exagamglogene autotemcel) is considered not medically necessary for all other indications.
- Physician acknowledges that CDPHP will request documentation, not more frequently than biannually, of follow-up patient assessments including but not limited to:
    - Sickle Cell disease: occurrence of VOE's/VOC's, laboratory findings, and other hematologic clinical events

- Transfusion-dependent β-Thalassemia: occurrence of RBC transfusion events, laboratory findings, and other hematologic clinical events

References

		Accessed
1	Hassell KL. Population Estimates of Sickle Cell Disease in the U.S. American Journal of Preventive Medicine. 2010;38(4):S512-S521.	Oct 2023
2	Kato GJ, Piel FB, Reid CD, et al. Sickle cell disease. Nat Rev Dis Primers. 2018;4:18010	Oct 2023
3	A Safety and Efficacy Study Evaluating CTX001 in Subjects With Severe Sickle Cell Disease. ClinicalTrials.gov identifier: NCT03745287. Updated October 31, 2024. https://clinicaltrials.gov/study/NCT03745287	Oct 2023
4	Institute for Clinical and Economic Review (ICER). ICER Sickle Cell Disease Final Policy Recommendations. August 2023. Available at: https://icer.org/wp-content/uploads/2023/08/ICER_Sickle-Cell-Disease_Final-Policy-Recommendations.pdf.	Nov 2023
5	Institute for Clinical and Economic Review (ICER). ICER Sickle Cell Disease Final Report. Published August 21, 2023. Available at: https://icer.org/wp-content/uploads/2023/08/ICER_SCD_Final_Report_FOR_PUBLICATION_082123.pdf	Nov 2023
6	Casgevy prescribing information, Vertex Pharmaceuticals Incorporated, Boston, MA 02210. Revised 9/2025	Oct 2025
7	Casgevy (exagamglogene autotemcel) clinical trial (NCT03655678). Available at: https://clinicaltrials.gov/study/NCT03655678?cond=NCT03655678&rank=1	Feb 2024
8	Frangoul H, et al. CRISPR-Cas9 Gene Editing for Sickle Cell Disease and β-Thalassemia. N Engl J Med 2021;384:252-60.	Feb 2024
9	2021 Guidelines for the Management of Transfusion Dependent Thalassaemia (TDT). 4th Edition (Version 2.0). June 25, 2021. Available at: https://issuu.com/internationalthalassaemiafederation/docs/final_guideline_4th	Feb 2024
10	Policies and Billing Guidance for Practitioner Administered Drugs. New York Medicaid. Available at: https://www.health.ny.gov/health_care/medicaid/program/practitioner_administered/ffs_practitioner_administer.htm	11/2025

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE CHOICES: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Effective January 1st, 2026, Casgevy and Lyfgenia will be reimbursed by the NYS Medicaid fee-for-service (FFS) program for Managed Medicaid/HARP members. The prior authorization process for these medications will remain unchanged. The Plan will continue to review these medications for medical necessity.

CDPHP Pharmacy Services 7/14/2026

New: 12/2023

Revised	Reviewed
2/2024, 2/2026, 5/2026, 7/2026	2/2025

Revision Date	Changes Made
2/2024	Changed title to include FDA Brand Name (Casgevy) Added FDA approved indication of Transfusion-dependent Beta-thalassemia, including Inclusion and Exclusion Criteria
12/2025	Updated authorization duration to 6 months to allow adequate time for administration Updated age range from 12-35 to at least 12 years of age Added Karnofsky performance status or Lansky performance status Added not receiving concomitant therapy Updated language regarding Medicaid applicability Updated exclusion criteria
2/2026	Clarified genetic variants of beta thalassemia
5/2026	Removed criteria for being followed for 24 months at certified center Updated genotypes for sickle cell disease Removed baseline hemoglobin and physician attestation of fitness for β-thalassemia Added HCPCS Code
7/2026	Added must be screened and negative for Hep B, C, and HIV Updated age

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BEHAVIORAL HEALTH
RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: **CHILDREN AND FAMILY TREATMENT AND SUPPORT SERVICES (CFTSS)**

POLICY EFFECTIVE DATE:	***Refer to specific program sections below.***
Policy Control #:	1370/20.000498
Next Annual Review:	12/2026

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

Other Licensed Practitioner (OLP): 90791, H0004, H2011, 90882
Community Psychiatric Support and Treatment (CPST): H0036
Psychosocial Rehabilitation (PSR): H2017
Family Peer Support Services (FPSS): H0038
Youth Peer Support and Training (YPSS): H0038
Crisis Intervention (CI), including Crisis Residential Services: H2011, S9484, S9485,

DESCRIPTION

Children and Family Treatment and Support Services (CFTSS) consist of services for children (under 21 years of age) include the following:

Other Licensed Practitioner (OLP)
Services provided by a non-physician behavioral health practitioner (NP-LBHP) in the community in order to effectively engage children and youth.

Activities include:

- Recommending treatment that also considers trauma-informed, cultural variables and nuances,
- Individual, family, and/or group outpatient psychotherapy and behavioral health assessment, evaluation, and testing consistent with the American Medical Association (AMA) definitions of the covered Current Procedural Terminology (CPT) codes and other activities within the scope of all applicable state laws and their professional license.

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Crisis Intervention (CI)
Services provided to a member identified as experiencing an acute psychological/emotional change which results in a marked increase in personal distress and which exceeds the abilities and the resources of those involved (e.g. collateral, provider, community member) to effectively resolve it.

Crisis Intervention services are provided to the member who is experiencing a psychiatric or substance use crisis, and his/her family/caregiver, and are designed to:
- Interrupt and/or ameliorate the crisis experience
- Include an assessment that is culturally and linguistically sensitive
- Result in immediate crisis resolution and de-escalation

Community Psychiatric Support and Treatment (CPST)
Goal-directed supports and solution-focused interventions intended to address challenges associated with a behavioral health need and to achieve identified goals or objectives as set forth in the enrollee's treatment plan.

Designed to provide community-based services to children and families who may have difficulty engaging in formal office settings, but can benefit from community based rehabilitation services.

Services may include one or more of the following:
- Rehabilitative psychoeducation
- Intensive interventions
- Strength based treatment planning
- Rehabilitative supports
- Crisis avoidance
- Intermediate term crisis management

Psychosocial Rehabilitation (PSR)
Services designed to work with children and their families to implement interventions outlined in a treatment plan to compensate for or eliminate functional deficits and interpersonal and/or environmental barriers associated with a child/youth's behavioral health needs.

Family Peer Support Services (FPSS)
Formal and informal activities and supports provided to families caring for/raising a child/youth who is experiencing social, emotional, medical, developmental, substance use, and/or behavioral challenges in their home, school, placement, and/or community. Services provide a structured, strength-based relationship between a family peer advocate (FPA) and the parent/family member/caregiver for the benefit if the child/youth.

Youth Peer Support and Training (YPST)
Formal and informal services and supports provided to youth, who are experiencing social, emotional, medical, developmental, substance use, and/or behavioral challenges in their home, school, placement, and/or community. Services provide the training and support necessary to ensure engagement and active participation of the youth in the treatment planning process and with the ongoing implementation and reinforcement of skills.

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Note: Child is an individual under 21 years of age. Reference to family is broadly defined, and includes families created through birth, foster care, adoption, or self-created unit.

RELATED POLICIES/DOCUMENTS

N/A

POSITION STATEMENT

CDPHP does not provide coverage for the ambulatory mental health programs identified above except for Select Plan as described below.

POLICY CONSIDERATIONS

FOR SELECT PLAN AND CHILD HEALTH PLUS

Benefits are provided for the following ambulatory mental health programs for an enrollee under 21 years of age unless otherwise specified when criteria outlined below are met.

Other Licensed Practitioner (OLP)
Note: Benefits for Non-SSI children are effective 1/1/19. Benefits for SSI children are effective 7/1/19. Benefits for Child Health Plus children are effective 1/1/23.

OLP does not require a DSM diagnosis in order for services to be delivered.

Service is delivered by a non-physician licensed behavioral health practitioner (NP-LBHP) who is licensed in New York state, operating within the scope of practice defined in state law and in any setting permissible under state law practice. NP-LBHP include:

- Licensed psychoanalyst
- Licensed clinical social worker (LCSW)
- Licensed marriage and family therapist
- Licensed mental health counselor
- Licensed master social worker under the supervision/direction of a LCSW, licensed psychologist, or psychiatrist.

Practitioner must operate within a child-serving agency that is licensed, certified, designated and/or approved by New York State OCFS, OMH, OASAS or DOH, or its designee, in setting permissible by that designation.

Treatment services must be part of a treatment plan including goals and activities necessary to correct or ameliorate conditions discovered during the initial assessment.

Medically necessary services that are best delivered in a school setting by a community provider need to be detailed in the treatment plan.

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Admission Criteria
One of the following criteria is met:

- Treatment to correct or ameliorate condition(s) found through an early and periodic screening, diagnostic and treatment (EPSDT) screening; *or*
- Treatment addressing the prevention, diagnosis, and/or treatment of health impairments; the ability to achieve age-appropriate growth and development, and the ability to attain, maintain, or regain functional capacity.

Continued Stay Criteria

- Enrollee is making some progress, but has not fully achieved established service goals and there is an expectation that if the enrollee continues, there will be improvement; *or*
- All of the following:
  - Continuation of service is needed to prevent the loss of functional skills already achieved;
  - Continues to meet admission criteria;
  - Enrollee and/or family/caregiver(s) continue to be engaged in services;
  - Alternative service(s) would not meet enrollee's needs;
  - Treatment plan has been updated to establish or modify ongoing goals.

Discharge Criteria
Meets one of the following:

- Enrollee no longer meets continued stay criteria; *or*
- Enrollee has successfully reached individual/family established service goals for discharge; *or*
- Enrollee or parent/caregiver(s) withdraws consent for services; *or*
- Enrollee is not making progress on established service goals, nor is there expectation of any progress with continued provision of services; *or*
- Enrollee is no longer engaged in the service, despite multiple attempts on the part of the provider to apply reasonable engagement strategies; *or*
- Enrollee and/or family/caregiver(s) no longer needs service as s/he is obtaining a similar benefit through other services and resources.

Limits/Exclusions

- Educationally necessary services provided by a school employee must be included in the individualized education plan (IEP) and are not reimbursed by CDPHP or Medicaid fee for service (FFS).
- Services rendered while a resident of an institution for mental disease are part of the institutional service and not otherwise reimbursable.
- Visits to intermediate care facilities for enrollee with mental retardation are not covered.
- Visits to nursing facilities are allowed for licensed professionals other than social workers if a preadmission screening and resident review (PASRR) indicates it is medically necessary treatment. Social worker visits are included in the nursing facility visit and may not be billed separately.

Crisis Intervention
Note: Benefits effective 1/1/20. Crisis Residential Services effective 12/1/20. Benefits for Child Health

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Plus children are effective 1/1/23.

Crisis services cannot be denied based upon substance use.

Admission Criteria
All of the following criteria are met:

- Experiencing acute psychological/emotional change which results in a marked increase in personal distress and which exceeds the abilities and the resources of those involved (e.g. collateral, provider, community member) to effectively resolve it; *and*
- Demonstrates at least one of the following:
- Suicidal/assaultive/destructive ideas, threats, plans or actions that represent a risk to self or others; *or*
- Impairment in mood/thought/behavior disruptive to home. School, or the community; *or*
- Behavior escalating to the extent that a higher intensity of services will likely be required *and*
- Intervention is necessary to further evaluate, resolve, and/or stabilize to previous level of functioning; *and*
- Service is recommended by any of the following licensed practitioners of the healing arts operating within the scope of their practice of their state license:
  - Psychiatrist
  - Physician
  - Licensed psychoanalyst
  - Registered professional nurse
  - Nurse practitioner
  - Clinical nurse specialist
  - Licensed clinical social worker (LCSW)
  - Licensed marriage and family therapist
  - Licensed mental health counselor
  - Licensed psychologist

Discharge Criteria
Meets one of the following:

- No longer meets admission criteria (demonstrates symptom reduction, stabilization, and restoration, or developing the coping mechanisms to pre-crisis levels of functioning) and/or meets criteria for another level of care, either more or less intensive; *or*
- Enrollee or parent/caregiver(s) withdraw consent for services.

Limitations/Exclusions

- The following activities are excluded:
  - Financial management
  - Supportive housing
  - Supportive employment services
  - Basic skills acquisition services that are habilitative in nature
- Services may not be primarily educational, vocational, recreational, or custodial (i.e., for the purpose of assisting with the activities of daily living; for maintaining the enrollee's or anyone else's safety; and could be provided by persons without professional skills/training)
- Does not include services, supplies or procedures performed in a non-conventional setting including:

resorts, spas, therapeutic programs, and camps.

Crisis Residential Services for Children

- Services provided at Crisis Residence programs are one component of a comprehensive continuum of crisis services, intended to help avert extended emergency room visits and inpatient hospitalizations.
- Children must be in crisis or at risk of being in crisis (psychiatric distress) to be admitted
- For admission to a Children's Crisis Residence, a mental health diagnosis is not required
- Children cannot be at imminent risk of self-harm or harm to others
- There are three Crisis Residence Programs available to youth under 21 years of age:
  - Children's Crisis Residences – available to youth up to age 21
  - Intensive Crisis Residence Programs and Residential Crisis Support Programs (see Ambulatory Mental Health Programs, 1370/20.000488 for more information) – available for youth ages 18 and older

- Service components for Children's Crisis Residence include:
  - Comprehensive Intake Assessment including:
    - Mental Health assessment
    - Risk assessment and crisis planning
    - Health screening for physical conditions
  - Service Planning
  - Care Coordination
  - Individual and family counseling including:
    - Alleviating psychiatric symptoms, maintaining stabilization and preventing escalation of mental health symptoms including providing a relief or break for the child/youth
    - Consulting with psychiatric prescribers and urgent psychopharmacology intervention including medication monitoring and medication management and training, as needed
    - Resolving conflict, de-escalating and monitoring of high-risk behavior, including providing one-to-one monitoring and behavior supports
    - Family Support

Community Psychiatric Support and Treatment (CPST)

Note: Benefits for Non-SSI children are effective 1/1/19. Benefits for SSI children are effective 7/1/19. Benefits for Child Health Plus children are effective 1/1/23.

Service components include:

- Rehabilitative psychoeducation
- Intensive interventions
- Strengths based treatment planning
- Rehabilitative supports
- Crisis avoidance
- Intermediate term crisis management

Treatment services must be part of the treatment plan including goals and activities necessary to correct or ameliorate conditions covered during the initial assessment visits.

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Admission Criteria

All of the following criteria are met:

- Enrollee has a behavioral health diagnosis that demonstrates symptoms consistent or corresponding with the DMS; *or* is at risk of development of a behavioral health diagnosis; *and*
- Enrollee is expected to achieve skill restoration in one of the following areas:
  - Participation in community activities and/or positive peer support networks;
  - Personal relationships;
  - Personal safety and/or self-regulation;
  - Independences/productivity;
  - Daily living skills;
  - Symptom management;
  - Copies strategies and effective functioning in the home, school, social or work environment; *and*
- Enrollee is likely to benefit from and respond to the service to prevent the onset or worsening of symptoms; *and*
- Service is recommended by any of the following licensed practitioners of the healing arts operating within the scope of their practice of their state license:
  - Licensed master social worker
  - Licensed clinical social worker
  - Licensed mental health counselor
  - Licensed creative arts therapist
  - Licensed marriage and family therapist
  - Licensed psychoanalyst
  - Physician assistant
  - Psychiatrist
  - Physician
  - Registered professional nurse
  - Nurse practitioner

Continued Stay Criteria

All of the following criteria are met:

- Enrollee continues to meet admission criteria; *and*
- Enrollee shows evidence of engagement toward resolution of symptoms but has not fully reached established service plan goals and there is an expectation that if the service continues, the enrollee will continue to improve; *and*
- Enrollee does not require an alternate and/or higher, more intensive level of care or treatment; *and*
- Enrollee is at risk of losing skills gain if the service is not continued; *and*
- Treatment planning includes family/caregiver(s) and/or other support systems, unless not clinically indicated or relevant.

Discharge Criteria

Meets one of the following:

- Enrollee no longer meets admission criteria and/or meets criteria for another level of care, either more or less intensive; *or*
- Enrollee has successfully met the specific goals outlined in the treatment plan for discharge; *or*
- Enrollee or parent/caregiver(s) withdraws consent for services; *or*

- Enrollee is not making progress on established service goals, nor is there expectation of any progress with continued provision of services; *or*
- Enrollee is no longer engaged in the service, despite multiple attempts by the provider to apply reasonable engagement strategies; *or*
- Enrollee and/or family/caregiver(s) no longer needs service as s/he is obtaining a similar benefit through other services and resources.

Limitations/Exclusions

- Enrollee with a developmental disability diagnosis without a co-occurring behavioral health condition is not eligible for this service.

Psychosocial Rehabilitation (PSR)

Note: Benefits for Non-SSI children are effective 1/1/19. Benefits for SSI children are effective 7/1/19. Benefits for Child Health Plus children are effective 1/1/23.

Treatment services must be a part of a treatment plan including goals and activities necessary to correct or ameliorate conditions discovered during the initial assessment visit

Admission Criteria

All of the following criteria are met:

- Enrollee has a behavioral health diagnosis that demonstrates symptoms consistent or corresponding with the DMS; *and*
- Enrollee is likely to benefit from and respond to the service to prevent the onset or the worsening of symptoms; *and*
- Service is needed to meet rehabilitative goals by restoring, rehabilitating, and/or supporting enrollee's functional level to facilitate integration of the enrollee as participant of his/her community and family; *and*
- Service is recommended by any of the following licensed practitioners of the healing arts operating within the scope of their practice of their state license:
  - Licensed master social worker
  - Licensed clinical social worker
  - Licensed mental health counselor
  - Licensed creative arts therapist
  - Licensed marriage and family therapist
  - Licensed psychoanalyst
  - Licensed psychologist
  - Physician assistant
  - Psychiatrist
  - Physician
  - Registered professional nurse
  - Nurse practitioner

Continued Stay Criteria

All of the following criteria are met:

- Enrollee continues to meet admission criteria; *and*

- Enrollee shows evidence of engagement toward resolution of symptoms but has not fully reached established service plan goals and there is an expectation that if the service continues, the enrollee will continue to improve; *and*
- Enrollee does not require an alternate and/or higher, more intensive level of care or treatment; *and*
- Enrollee is at risk of losing skills gain if the service is not continued; *and*
- Treatment planning includes family/caregiver(s) and/or other support systems, unless not clinically indicated or relevant.

Discharge Criteria
Meets one of the following:
- Enrollee no longer meets admission criteria and/or meets criteria for another level of care, either more or less intensive; *or*
- Enrollee has successfully met the specific goals outlined in the treatment plan for discharge; *or*
- Enrollee or parent/caregiver(s) withdraws consent for services; *or*
- Enrollee is not making progress on established service goals, nor is there expectation of any progress with continued provision of services; *or*
- Enrollee is no longer engaged in the service, despite multiple attempts on the part of the provider to apply reasonable engagement strategies; *or*
- Enrollee and/or family/caregiver(s) no longer needs service as s/he is obtaining a similar benefit through other services and resources.

Limitations/Exclusions
- Enrollee with a developmental disability diagnosis without a co-occurring behavioral health condition is not eligible for this service

Family Peer Support Services (FPSS)
Note: Benefits effective 7/1/19. Benefits for Child Health Plus children are effective 1/1/23.

Treatment services must be part of the treatment plan including goals and activities necessary to correct or ameliorate conditions covered during the initial assessment visits.

Admission Criteria
All of the following criteria are met:
- Enrollee has a behavioral health diagnosis that demonstrates symptoms consistent or corresponding with the DMS; *or* displays demonstrated evidence of skill(s) lost or undeveloped as a result of the impact of his/her physical health diagnosis; *and*
- Enrollee is likely to benefit from and respond to the service to prevent the onset or the worsening of symptoms; *and*
- Enrollee's family is available, receptive to and demonstrates need for improvement in the following areas such as, but not limited to:
  - Strengthening the family unit
  - Building skills within the family for the benefit of the enrollee
  - Promoting empowerment within the family
  - Strengthening overall supports in the enrollee's environment

  and

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- Service is recommended by any of the following licensed practitioners of the healing arts operating within the scope of their practice of their State license:
  - Licensed master social worker
  - Licensed clinical social worker
  - Licensed mental health counselor
  - Licensed creative arts therapist
  - Licensed marriage and family therapist
  - Licensed psychoanalyst
  - Licensed psychologist
  - Physician assistant
  - Psychiatrist
  - Physician
  - Registered professional nurse
  - Nurse practitioner

Continued Stay Criteria

All of the following criteria are met:

- Enrollee continues to meet admission criteria; *and*
- Enrollee is making progress but has not fully reached established service goals and there is a reasonable expectation that continued services will increase the enrollee meeting service goals; *and*
- Family/caregiver(s) participation in treatment is adequate to meaningfully contribute to the enrollee's progress in achieving service goals; *and*
- Additional psychoeducation or training to assist the family/caregiver understanding the enrollee's progress and treatment or to care for the enrollee would contribute to the enrollee's progress; *and*
- Enrollee does not require an alternate and/or higher, more intensive level of care or treatment; *and*
- Enrollee is at risk of losing skills gain if the service is not continued; *and*
- Treatment planning includes family/caregiver(s) and/or other support systems, unless not clinically indicated or relevant.

Discharge Criteria

Meets one of the following:

- Enrollee and/or family/caregiver no longer meets admission criteria; *or*
- Enrollee has successfully met the specific goals outlined in the treatment plan for discharge; *or*
- Family withdraws consent for services; *or*
- Enrollee and/or family is not making progress on established service goals, nor is there expectation of any progress with continued provision of services; *or*
- Enrollee and/or family is no longer engaged in the service, despite multiple attempts on the part of the provider to apply reasonable engagement strategies; *or*
- Family/caregiver(s) no longer needs service as s/he is obtaining a similar benefit through other services and resources.

Limitations/Exclusions

- Enrollee with a developmental disability diagnosis without a co-occurring behavioral health condition is not eligible for this service

- The following activities are excluded from FPSS:
  - 12-step programs run by peers.
  - General outreach and education including participation in health fairs, and other activities designed to increase the number of individuals served or the number of services received by individuals accessing services; community education services, such as health presentations to community groups, PTAs, etc.
  - Contacts that are not medically necessary.
  - Time spent doing, attending, or participating in recreational activities.
  - Services provided to teach academic subjects or as a substitute for educational personnel such as, but not limited to, a teacher, teacher's aide, or an academic tutor.
  - Time spent attending school (e.g., during a day treatment program).
  - Habilitative services for the child/youth to acquire self-help, socialization, and adaptive skills necessary to reside successfully in community setting.
  - Childcare services or services provided as a substitute for the parent or other individuals responsible for providing care and supervision.
  - Respite care.
  - Transportation for the enrollee or family. Services provided in the car are considered transportation and time may not be billed under rehabilitation.
  - Services not identified on the enrollee's authorized treatment plan.
  - Services not in compliance with the service manual and not in compliance with State Medicaid standards.
  - Services provided to children, spouse, parents, or siblings of the enrollee under treatment or others in the enrollee's life to address problems not directly related to the enrollee's issues and not listed on the enrollee's treatment plan.
  - Any intervention or contact not documented or consistent with the approved treatment/recovery plan goals, objectives, and approved services will not be reimbursed.

Youth Peer Support and Training
Note: Benefits effective 1/1/20. Benefits for Child Health Plus children are effective 1/1/23.

Treatment services must be part of the treatment plan including goals and activities necessary to correct or ameliorate conditions covered during the initial assessment visits.

Admission Criteria
All of the following criteria are met:
- Enrollee has a behavioral health diagnosis that demonstrates symptoms consistent or corresponding with the DMS; *or* displays demonstrated evidence of skill(s) lost or undeveloped as a result of the impact of his/her physical health diagnosis; *and*
- Enrollee requires involvement of a youth peer advocate to implement the intervention(s) outlined in the treatment plan; *and*
- Enrollee demonstrates a need for improvement in the following areas such as, but not limited to:
  - Enhancing enrollee's ability to effectively manage comprehensive health needs
  - Maintaining recovery
  - Strengthening resiliency, self-advocacy
  - Self-efficacy and empowerment

  - Developing competency to utilize resources and supports in the community
  - Transition into adulthood or participate in treatment

  and
- Enrollee is involved in the admission process and helps determine service goals; *and*
- Enrollee is available and receptive to receiving this service; *and*
- Service is recommended by any of the following licensed practitioners of the healing arts operating within the scope of their practice of their state license:
  - Licensed master social worker
  - Licensed clinical social worker
  - Licensed mental health counselor
  - Licensed creative arts therapist
  - Licensed marriage and family therapist
  - Licensed psychoanalyst
  - Licensed psychologist
  - Physician assistant
  - Psychiatrist
  - Physician
  - Registered professional nurse
  - Nurse practitioner

Continued Stay Criteria

All of the following criteria are met:
- Enrollee continues to meet admission criteria; *and*
- Enrollee shows evidence of engagement toward resolution of symptoms but has not fully reached established service goals and there is expectation that if the service continues, the enrollee will continue to improve; *and*
- Enrollee does not require an alternate and/or higher, more intensive level of care or treatment; *and*
- Enrollee is at risk of losing skills gain if the service is not continued; *and*
- Treatment planning includes family/caregiver(s) and/or other support systems, unless not clinically indicated.

Discharge Criteria

Meets one of the following:
- Enrollee and/or family/caregiver no longer meets admission criteria; *or*
- Enrollee has successfully met the specific goals outlined in the treatment plan for discharge; *or*
- Enrollee or parent/caregiver withdraws consent for services; *or*
- Enrollee is not making progress on established service goals, nor is there expectation of any progress with continued provision of services; *or*
- Enrollee is no longer engaged in the service, despite multiple attempts on the part of the provider to apply reasonable engagement strategies; *or*
- Enrollee no longer needs service as s/he is obtaining a similar benefit through other services and resources.

Limitations/Exclusions

- Enrollee with a developmental disability diagnosis without a co-occurring behavioral health condition

is not eligible for this service.

- The following activities are excluded from YPSS:
  - 12-step programs run by peers.
  - General outreach and education including participation in health fairs, and other activities designed to increase the number of individuals served or the number of services received by individuals accessing services; community education services, such as health presentations to community groups, PTAs, etc.
  - Contacts that are not medically necessary.
  - Time spent doing, attending, or participating in recreational activities.
  - Services provided to teach academic subjects or as a substitute for educational personnel such as, but not limited to, a teacher, teacher's aide, or an academic tutor.
  - Time spent attending school (e.g., during a day treatment program).
  - Habilitative services for the child/youth to acquire self-help, socialization, and adaptive skills necessary to reside successfully in community setting.
  - Childcare services or services provided as a substitute for the parent or other individuals responsible for providing care and supervision.
  - Respite care.
  - Transportation for the enrollee or family. Services provided in the car are considered transportation and time may not be billed under rehabilitation.
  - Services not identified on the enrollee's authorized treatment plan.
  - Services not in compliance with the service manual and not in compliance with State Medicaid standards.
  - Services provided to children, spouse, parents, or siblings of the enrollee under treatment or others in the enrollee's life to address problems not directly related to the enrollee's issues and not listed on the enrollee's treatment plan.
  - Any intervention or contact not documented or consistent with the approved treatment/recovery plan goals, objectives, and approved services will not be reimbursed.

Considerations for Telehealth

- Every OMH-designated CFTSS provider must obtain OMH approval pursuant to Part 596 to provide Telehealth Services.
- CFTSS are designed to be delivered in the natural environment, specifically the home and community-based settings. Therefore, providers should prioritize in-person service delivery.
- Telehealth must not replace in-person program requirements.
- Telehealth may be used to supplement in-person services, to optimize engagement (e.g., for screening so that the individual can learn about choices in services), to temporarily provide care in circumstances where in-person engagement is not possible (e.g., risk of infection), or to engage others in the individual's care, such as for family therapy sessions, collateral contacts, etc.
- Where services are provided using telehealth, audio-visual modalities are strongly encouraged, unless an individual does not have access to audio-visual technology (in which case, provider should assist individual in obtaining audio-visual technology, or training or otherwise helping them become comfortable using audio-visual technology).
- See NYS OMH April 2023 Telehealth Services Guidance for OMH Providers

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EXCLUSIONS

Rehabilitative services do not include the following:

- Educational, vocational and job training services
- Room and board
- Habilitation services
- Services to inmates in public institutions as defined by 42 CFR 435.1010
- Recreational and social activities
- Services that must be covered elsewhere in the state Medicaid plan

Audio-only telehealth services to conduct Other Licensed Practitioner (OLP) evaluations for children/youth for the sole purpose of informing eligibility for alternative programming is excluded from coverage

OLP Crisis Off-site is restricted to in-person services only, and cannot be delivered via telehealth

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted above in the policy, effective 1/1/23.
MEDICARE ADVANTAGE:	Medicare does not provide coverage for the ambulatory mental health supports identified above.
SELECT PLAN/HARP:	HARP does not provide coverage for the ambulatory mental health supports identified above.

SOURCES

1. Children's Health and Behavioral Health Services Transformatoin – Medicaid State Plan Children and Family Treatment and Support Services Provider Manual for Children's Behavioral Health Early and Periodic Screening and Diagnostic Treatment (EPSDT) Services (https://www.health.ny.gov/health_care/medicaid/redesign/behavioral_health/children/docs/updated_spa_manual.pdf)
2. Crisis Intervention Benefit: Children's Crisis Residence Program Benefit and Billing Guidance, October 2020
3. NYS OMH Telehealth Services Guidance for OMH Providers (https://omh.ny.gov/omhweb/guidance/telehealth-guidance.pdf)

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: CHILDREN AND FAMILY TREATMENT AND SUPPORT SERVICES (CFTSS)

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Date 1/6/25

CDPHP Behavioral Health

POLICY APPROVAL DATES

New: 01/19

Revised: 01/20, 01/21, 12/22, 8/23

Reviewed: 10/21, 12/23, 12/24, 4/26

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CDPHP Universal Benefits,® Inc.
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POLICY NAME: CHILDREN AND FAMILY TREATMENT AND SUPPORT SERVICES (CFTSS)

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
8/1/2023	Updated Policy Name from "Ambulatory Mental Health Programs for Children" to "Children and Family Treatment and Support Services". Removed H2013 from Crisis Intervention Services (Crisis Residential Services removed from CFTSS, and is standalone OMH SPA benefit). Added Considerations for Telehealth section. Updated Source documents.
1/1/2023	Benefit added for CHP plans.
12/1/2020	Addition of Crisis Residential Services description, coverage criteria, and code H2013.
1/1/2020	Reference to age limit of 14-21 as being criteria for coverage for programs is removed. As of 1/1/20, NYS is prohibiting plans from conducting utilization review on mental health services for individuals under age 21.

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Policy/Procedure Name: Chimeric Antigen Receptor T-Cell (CAR-T) Therapy **Control Number:** 1350/20.000503

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

The spontaneous regression of certain cancers (e.g., renal cell carcinoma and melanoma) supports the idea that a patient's immune system can delay tumor progression and, on infrequent occasions, can eliminate tumors altogether. These observations have led to research into various immunologic therapies designed to stimulate a patient's own immune system.

Engineered T-cell–based antitumor immunotherapy uses gene transfer of tumor antigen-specific T-cell receptors (TCR) or synthetic chimeric antigen receptors (CAR-T). CAR-T cells are prepared from the patient's peripheral blood mononuclear cells, which are obtained via a standard leukapheresis procedure. The blood is sent to the manufacturer where the mononuclear cells are enriched for T-cells. The T-cells are expanded in cell culture, washed, and formulated into a suspension, which then is cryopreserved. This process may take several weeks. The product is then infused into the patient. This technique has shown very encouraging results in clinical trials for treatment of types of leukemias and lymphomas. However, CAR-T cells can persist more than six years in patients and can lead to severe adverse events shortly after infusion as well as at later times.

Cytokine-release syndrome (CRS) and other toxicities pose significant risks for patients. Providers should develop toxicity management plans for patients undergoing CAR-T therapy.

In November 2023 the FDA released a statement regarding the possible increased risk of T-cell malignancies following treatment with CAR-T therapy, after receiving reports from clinical trials and/or post marketing adverse event data sources. The release stated that "Although the overall benefits of these products continue to outweigh their potential risks for their approved uses, FDA is investigating the identified risk of T-cell malignancy with serious outcomes, including hospitalization and death, and is evaluating the need for regulatory action." It also advised that "Patients and clinical trial participants receiving treatment with these products should be monitored life-long for new malignancies. In the event that a new malignancy occurs following treatment with these products, contact the manufacturer to report the event and obtain instructions on collection of patient samples for testing for the presence of the Chimeric Antigen Receptor (CAR) transgene."

There are seven FDA-approved CAR-T therapies as of December 2024, some of which were approved under the accelerated approval based on response rate and durability of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). These indications are designated in the chart below with an asterisk.

On June 26, 2025, the FDA removed the REMS program requirements from the CAR-T products.

FDA-approved approved CAR-T therapies indications include:

Trade name	Year Approved	Mechanism	Indication(s)
Abecma® (idecabtagene vicleucel) Q2055	2021	B-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy	Adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.
Aucatzyl® (obecabtagene autoleucel) Q2058	2024	CD19-directed genetically modified autologous T-cell immunotherapy	Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).
Breyanzi® (lisocabtagene maraleucel) Q2054	2021	CD19-directed genetically modified autologous T-cell immunotherapy	Adult patients with large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B, who have:

			• Refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy or • Refractory disease to first-line chemoimmunotherapy or relapse after first line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age or • Relapsed or refractory disease after two or more lines of systemic therapy Adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least 2 prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.* Adult patients with relapsed or refractory follicular lymphoma (FL) who have received 2 or more prior lines of systemic therapy.* Adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least 2 prior lines of systemic therapy, including a Bruton tyrosine kinase (BTK) inhibitor.* Adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least 2 prior lines of systemic therapy.
Carvykti® (ciltacabtagene autoleucel) Q2056	2022	B-cell maturation antigen (BCMA)-directed genetically modified autologous T-cell immunotherapy	Adult patients with relapsed or refractory multiple myeloma who have received at least 1 prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide.
Kymriah® (tisagenlecleucel) Q2042	2017	CD19-directed genetically modified autologous T-cell immunotherapy	Treatment of: • Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse. • Adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma. (Not indicated for treatment of patients with primary central nervous system lymphoma). • Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.*
Tecartus® (brexucabtagene autoleucel) Q2053	2020	CD19-directed genetically modified autologous T-cell immunotherapy	• Adult patients with relapsed or refractory mantle cell lymphoma (MCL).* • Adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).
Yescarta® (axicabtagene ciloleucel) Q2041	2017	CD19-directed genetically modified autologous T-cell immunotherapy	• Adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy. • Adult patients with relapsed or refractory large B-cell

			lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. • Adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.*

Summary	
Effective Date of Policy:	2/23/2026
Applicable Agents	Abecma® (idecabtagene vicleucel), Aucatzyl® (obecabtagene autoleucel), Breyanzi® (lisocabtagene maraleucel), Carvykti® (ciltacabtagene autoleucel), Kymriah® (tisagenlecleucel), Tecartus® (brexucabtagene autoleucel), Yescarta® (axicabtagene ciloleucel)
Approval Timeframe	6 months

This policy applies to all CAR-T therapies for oncologic indications, including new to market agents not listed above.

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy:

Indication	Inclusion Criteria	Recommended Dosing Regimen
Refer to specific product for indication	1. Documented FDA approved indication per prescribing information or supported evidence per NCCN guidelines 2. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 3. Must be prescribed by a Hematologist or Oncologist 4. Must be ≥ 18 years of age	• Refer to FDA prescribing information

Exclusion Criteria

- Therapy will not be covered if any of the below criteria are met:
  - Use as first-line therapy
  - Indication not approved by the FDA and/or supported by NCCN guidelines
  - Any central nervous system (CNS) disease (for example, brain metastases, CNS lymphoma, and a history or presence of CNS disorders such as seizure disorder, cerebrovascular ischemia/hemorrhage, dementia, cerebellar disease, or autoimmune disease with CNS involvement)
  - History of allogeneic stem cell transplant, chimeric antigen receptor therapy, or other genetically modified T-cell therapy

Continuation Criteria

Enrollee will be eligible for one lifetime, single administration of CAR-T therapy. Additional treatment with CAR-T therapy will not be covered. Retreatment is considered Experimental/Investigational when any FDA approved CAR-T therapy, or any other CAR-T therapy still under investigation, has been previously administered.

Considerations

- Please refer to the package insert for detailed dosing information.
- Prior authorization is obtained through the CDPHP pharmacy department.
- Prescription drug benefit is not required for this therapy
- Must be administered at an FDA-certified center
- Some products require failure to systemic therapies. Some of the commonly used agents are listed below for reference in Table 1.

Table 1.

Proteasome inhibitors	Immunomodulatory agents	Anti-CD38 monoclonal antibodies
Kyprolis (carfilzomib)	Thalomide (thalidomide)	Darzalex (daratumumab)
Velcade (bortezomib)	Revlimid (lenalidomide)	Sarclisa (isatuximab)
Ninlaro (ixazomib)	Pomalyst (pomalidomide)	

Administration, Retreatment, and Treatment with Additional or Other Gene/Cellular Therapies

- One-Time Administration
  - Most gene and cellular therapies, whether autologous, allogeneic ("off-the-shelf"), or in vivo gene-transfer therapies, are designed and studied as one-time treatments.
  - Repeat dosing, reinfusion, or sequential therapy with other gene or cellular products has not been established as safe, effective, or clinically appropriate.
- Retreatment/Repeat Administration
  - Retreatment with the same gene or cellular therapy product is considered experimental and investigational because:
    - Clinical trials evaluated these therapies as single-administration interventions
    - Safety, efficacy, and durability of a second administration have not been established
    - Risks of immune activation, insertional mutagenesis, or vector immunity may be increased with repeat dosing
- Treatment with an Additional or Other Gene/Cellular Therapy
  - Treatment with an additional or different gene or cellular therapy after prior exposure to any gene or cellular therapy is also considered experimental and investigational, unless supported by evidence demonstrating:
    - Anticipated clinical benefit beyond available standard therapies
    - Safety of sequential administration
    - Justification for selecting a second gene/cellular intervention after a prior one
    - Meets the criteria established in the Off-Label Use of FDA Approved Drugs 1350/20.000048
  - This includes, but is not limited to:
    - Switching between CAR-T products (e.g., CD19 → CD19 or CD19 → BCMA)
    - Switching between autologous and allogeneic cellular therapies
    - Sequential use of CAR-T, TCR-T, NK-cell therapies, or other genetically engineered cell therapies
    - Receiving a gene therapy after previous gene or cellular therapy exposure
    - Receiving an in vivo gene therapy following any prior vector-based therapy
- Prior Gene/Cell Therapy Exposure
  - An individual is generally not eligible for additional gene or cellular therapy if they have previously received:
    - Any autologous cellular therapy (e.g., CAR-T, TCR-T, TIL),
    - Any allogeneic genetically modified cellular therapy,
    - Any in vivo gene therapy (e.g., AAV, lentiviral vector)
    - Any ex vivo gene-modified cell product
    - Are being considered for any other gene or cellular therapy without documented evidence supporting safety and anticipated benefit.
- Coverage Determination
  - Absent peer-reviewed evidence demonstrating safety and benefit, retreatment or sequential therapy is considered investigational and will not be covered.

References

		Updated	Accessed
1	Acute Lymphoblastic Leukemia. NCCN Clinical Practice Guidelines in Oncology. Version 2.2025	6/2025	8/2025
2	Multiple Myeloma. NCCN Clinical Practice Guidelines in Oncology. Version 2.2026.	7/2025	8/2025
3	B-Cell Lymphomas. NCCN Clinical Practice Guidelines in Oncology. Version 2.2025	2/2025	8/2025
4	Abecma prescribing information, Celgene Corporation, a Bristol-Myers Squibb Company, Summit, NJ. Revised	6/2025	8/2025
5	Breyanzi prescribing information, Juno Therapeutics Inc., a Bristol-Myers Squibb Company, Bothell, WA.	6/2025	8/2025
6	Carvykti prescribing information, Janssen Biotech, Inc., Horsham, PA.	6/2025	8/2025
7	Kymriah prescribing information, Novartis Pharmaceuticals Corporation, East Hanover, NJ.	6/2025	8/2025
8	Tecartus prescribing information, Kite Pharma, Inc, Santa Monica, CA.	6/2025	8/2025

9	Yescarta prescribing information. Kite Pharma Inc, Santa Monica, CA.	6/2025	8/2025
10	FDA Investigating Serious Risk of T-cell Malignancy Following BCMA-Directed or CD19-Directed Autologous Chimeric Antigen Receptor (CAR) T-cell Immunotherapies. U.S. Food & Drugs Administration. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-investigating-serious-risk-t-cell-malignancy-following-bcma-directed-or-cd19-directed-autologous. November 28, 2023.	11/2023	1/2024
11	Aucatzyl prescribing information, Autolus Inc., Gaithersburg, MD.	3/2025	8/2025

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Please follow the national coverage determination guidelines included in the link below: https://www.cms.gov/medicare-coverage-database/details/ncddetails.aspx?ncdid=374&bc=CAAAAAAAAAAA

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 2/23/2026

New: 2/2024

Revised	Reviewed
2/2025, 9/2025, 2/2026	

Revision Date	Changes Made
2/2025	Added Auctazyl (obecabtagene autoleucel) to policy and updated indications for Breyanzi and Yescarta following FDA accelerated pathway approval
9/2025	Requirement for treatment at a "Certified Treatment Center" has been removed from all drug-specific criteria Added J-codes for each agent Updated approval timeframe to 6 months Added provider and age requirement
2/2026	Added in considerations regarding Administration, Retreatment, and Treatment with Additional or Other Gene/Cellular Therapies Added new Breyanzi indication for marginal zone lymphoma
2/2026	Updated indication for Carvykti

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MEDICAL POLICY

Medical Policy Title	**Chimeric Antigen Receptor T-Cell (CAR-T) Therapy for Candidate Selection**
Policy Number	**7.02.11**
Current Effective Date	**7/1/2026**
Next Review Date	**December 2027**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

This policy only applies to an individual if the CAR-T therapy drug has first been approved by the Health Plan Pharmacy.

POLICY STATEMENT(S)

I. Chimeric antigen receptor T-cell (CAR-T) therapy is **medically appropriate** for carefully selected candidates after drug approval by the Health Plam pharmacy and **ALL** of the following criteria are met:

   A. Individual is using as a one-time treatment;

   B. Multidisciplinary team has evaluated the individual and recommends treatment (see policy guidelines for required documentation);

   C. Individual has adequate organ function with no significant deterioration in organ function expected within four (4) weeks after apheresis.

II. CAR-T therapy is **not medically necessary** for individuals that have had a recent allogeneic transplant unless specifically permitted by the product labeling.

RELATED POLICIES

POLICY GUIDELINE(S)

I. Required documentation from the multidisciplinary team that includes the individual's eligibility and risk for CAR-T therapy should include:

   (*Based on FDA approved indications, additional testing and documentation may be necessary to support the use of the medication.)

   A. Place of Service (POS)

      1. Outpatient admission;

      2. If inpatient admission is being requested, include documentation explaining why outpatient services are not appropriate or sufficient for the individual's care;

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B. Clinical Evaluation
    1. Risk benefit analysis completed by treatment center;
    2. Confirmation of diagnosis;
    3. Identification of comorbidities;
    4. Management of co-morbidities;
    5. Current assessment of co-morbidities;
    6. Consult notes (if applicable);

C. Psycho-Social Evaluation
    1. Identification of stressors;

D. Performance Status
    1. Karnofsky performance score;
    2. Palliative Performance Scale (PPS) score); or
    3. Eastern Cooperative Oncology Group (ECOG) performance status;

E. Lab Tests
    1. CBC;
    2. Metabolic profile;
    3. Serologies: CMV, Hepatitis B and C;
    4. HIV testing;

F. Cardiac Assessment
    1. 12 Lead EKG;
    2. Echo or Muga Scan;

G. Pulmonary Assessment
    1. Chest X-ray;
    2. Pulmonary function tests (PFTs) for high-risk for respiratory failure (COPD, emphysema, a-1-antritrypsin deficiency, hepatopulmonary syndrome, or significant smoking history);

H. Age-Appropriate Screening Tests
    1. Please refer to the U.S Preventive Services Task Force (USPSTF) website for list of age-appropriate screening guidelines. https://uspreventiveservicestaskforce.org/uspstf/ [accessed 2025 Sep 17]

DESCRIPTION

CAR T-cell therapy is a form of cancer immunotherapy that involves genetically engineered T-cells. CAR-T therapy is used to treat some types of recurrent blood cancers such as B-cell acute lymphoblastic leukemia (ALL), diffuse large B-Cell lymphoma, follicular lymphoma, high-grade B-cell lymphoma, mantle cell lymphoma, multiple myeloma and primary mediastinal large B-Cell lymphoma.

The process typically begins with the collection of an individual's white blood cells through leukapheresis. These cells are then activated and genetically modified usually via retroviral or lentiviral transduction to express a chimeric antigen receptor that targets cancer cells. Once engineered, the CAR T-cells are expanded to clinically effective quantities, undergo rigorous quality control testing, and are cryopreserved.

Commercial CAR T-cell products are manufactured at centralized facilities, requiring the transport of the individual's apheresis material to the manufacturing site and the final CAR T-cell product back to the treatment center. Before infusion, individuals typically receive lymphodepleting chemotherapy to optimize the immune environment for CAR-T-cell function. The therapy is administered as a single intravenous infusion. Several CAR T-cell products have received FDA approval for the treatment of specific types of hematological malignancies.

SUPPORTIVE LITERATURE

Haslam et al (2023) sought to estimate how many individuals in the U.S. with advanced or metastatic cancer are eligible for and likely to respond to CAR T-cell therapy, based on FDA-approved indications and clinical trial data. In 2017, approximately 2.7% of patients were estimated to be eligible for CAR T-cell therapy, with 2.0% potentially able to respond. By 2023, eligibility increased to 3.9%, with the highest rates seen in large B-cell lymphoma (2.5%) and the lowest in mantle cell lymphoma (0.1%). The estimated response rate also rose to 3.4% in 2023, again with large B-cell lymphoma showing the highest potential response (2.1%). Across pivotal trials, the median response rate was 66.4%, ranging from 25.5% to 98%. However, most approvals were based on single-arm studies using surrogate endpoints, with only two randomized trials demonstrating survival benefits. While CAR T-cell therapies show promising response rates, the overall proportion of eligible and responsive patients among those with advanced cancers remains relatively low.

Pasqui et al (2022) conducted a systematic review to assess the efficacy and safety of CAR T-cell therapy in patients with hematological malignancies. The review included seven parallel randomized controlled trials (RCTs) comparing CAR-T therapy to standard treatments, encompassing a total of 2,464 patients. However, only three trials focused on B-cell lymphomas had available outcome data at the time of analysis. The study found adverse events were frequent but not significantly different from those observed with standard therapies. Survival and progression-related outcomes were supported by low to very low certainty of evidence. Quality of life outcomes were not reported in the available data. The authors concluded that current evidence is insufficient to support the routine use of CAR T-cell therapy outside of clinical trials or compassionate use settings.

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CD19-directed CAR T-cell therapy has shown high initial response rates in children and young adults with relapsed or refractory B-cell acute lymphoblastic leukemia (B-ALL), although relapse remains common.

Shah et al (2021) conducted a phase I trial using autologous CD19.28z CAR T-cells in 50 patients, evaluating both treatment response and long-term outcomes. Overall, 62% achieved complete remission (CR), with 90.3% of those being minimal residual disease (MRD)-negative. Patients who received fludarabine/cyclophosphamide (Flu/Cy) lymphodepletion had significantly better outcomes (69% CR) compared to alternative regimens (25%). Cytokine release syndrome (CRS) occurred in 70% of patients, with 18% experiencing severe cases; neurotoxicity was seen in 20%, but all resolved. The therapy was also effective in patients with central nervous system (CNS) involvement. Median overall survival (OS) for the full cohort was 10.5 months, but among those who underwent allogeneic hematopoietic stem cell transplant (alloHSCT) after achieving MRD-negative CR, median OS extended to 70.2 months, with a 5-year event-free survival (EFS) of 61.9% and a relapse rate of only 9.5%. All MRD-negative CR patients who did not receive alloHSCT relapsed. These findings support the use of sequential CD19.28z CAR T-cell therapy followed by alloHSCT for durable disease control in high-risk pediatric and young adult B-ALL patients, with Flu/Cy lymphodepletion showing superior efficacy and CAR T-cell therapy proving feasible even in cases with active CNS disease.

PROFESSIONAL GUIDELINE(S)

The National Institute for Health and Care Excellence (NICE) provides evidence-based guidance on FDA approved CAR-T treatments for bone marrow and blood cancers, including diffuse large B-cell lymphoma and B-cell acute lymphoblastic leukemia (see reference section for drug specific recommendations from NICE).

National Comprehensive Cancer Network guidelines for B-Cell Lymphomas V3.2025 states that "if patients intend to receive CAR T-cell therapy or CD3 x CD20 bispecific antibody therapy, bendamustine should be used with caution. Delay bendamustine until after CAR-T leukapheresis."

Epperla et al (2023) reported the American Society for Transplantation and Cellular Therapy (ASTCT) Clinical Practice Guidelines for Transplantation and Cellular Therapies in Diffuse Large B Cell Lymphoma. The recommendations state:

- "CAR-T therapy (axi-cel or lisocel) as a standard of care option in DLBCL refractory to first-line chemoimmunotherapy or relapsed within 12 months of first-line chemoimmunotherapy (grade A recommendation)."
- "CAR-T therapy in patients with late relapse who have not achieved remission after second-line therapies (grade A recommendation)."
- "CAR-T therapy in those who are not eligible for autologous-HCT because of comorbidities or age regardless of the timing of relapse (grade B recommendation)."

- "Does not consider secondary CNS involvement a contraindication for administering CAR-T therapy (grade B recommendation)."

Dhakal et al (2022) reported the ASTCT Clinical Practice Recommendations for Transplantation and Cellular Therapies in Multiple Myeloma. The recommendations state:

- "The exact timing and sequencing of therapies like CAR-T in the context of stem cell transplantation and other therapies is not established yet."

Iqbal et al (2024) reported the Clinical Practice Recommendations for Hematopoietic Cell Transplantation and Cellular Therapies in Follicular Lymphoma (FL). This was a collaborative effort on behalf of the ASTCT and the European Society for Blood and Marrow Transplantation. The recommendations state:

- "The panel does not recommend consolidation with CAR T-cell therapy ineligible FL patients incomplete or partial remission after first line therapies, outside the setting of a clinical trial."
- "The panel does not recommend commercially available CAR T-cell therapy ineligible, relapsed (within less than 24 months from receiving chemotherapy and without evidence of histological transformation) FL patients who have achieved complete or partial remission after second line therapies."
- The panel recommends considering CAR T-cell therapy in eligible, relapsed FL patients who have relapsed after an autologous transplant and did not achieve complete or partial remission to most recent anti-lymphoma treatment.
- "The panel recommends CAR T-cell therapy as a treatment option for patients who did not achieve complete or partial remission after second or subsequent line therapies."
- "The panel recommends CAR T-cell therapy ineligible, relapsed FL patients who have relapsed after allogeneic transplant and are untreated or did not achieve complete or partial remission to most recent anti-lymphoma treatment."

Kharfan-Dabaja et al (2025) reported the ASTCT Clinical Practice Recommendations on the Role of Allogeneic Hematopoietic Cell Transplantation and CAR-T Therapy in Patients with Chronic Lymphocytic Leukemia. The recommendations state:

- "The panel recommends CAR T-cell therapy in CLL patients whose disease relapsed and/or was refractory to both a covalent BTK inhibitor and a BCL-2 inhibitor and either responded or did not respond to a noncovalent BTK inhibitor."
- "The panel recommends CAR T-cell therapy for CLL patients whose disease relapsed and/or was refractory to both a covalent BTK inhibitor and a BCL-2 inhibitor."
- "The panel recommends CAR T-cell therapy in CLL patients that relapse after an allo-HCT."

REGULATORY STATUS

For recommendations related to FDA-approved CAR-T therapies, refer to the National Institute for Health and Care Excellence (NICE), which provides evidence-based guidance on CAR-T treatments for bone marrow and blood cancers, including diffuse large B-cell lymphoma and B-cell acute lymphoblastic leukemia (see reference section for drug specific recommendations from NICE).

CAR T-cell therapies that have been approved by the FDA for the treatment of various hematologic malignancies can be found on Pharmacy Policy-103. Available from: https://provider.excellusbcbs.com/documents/d/global/chimeric-antigen-receptor-t-cell-car-t-therapy [accessed 2025 Nov 10]

Drugs

The United States Food and Drug Administration (FDA) is responsible for ensuring the safety, efficacy, and quality of drugs sold in the United States. This includes both prescription and over-the-counter medications. Refer to the FDA Drug website. Available from: https://www.fda.gov/drugs [accessed 2025 Nov 10]

The FDA maintains information for consumers and health professionals on new drug warnings and other safety information, drug label changes, and shortages of medically necessary drug products. Available from: Drug Safety and Availability | FDA [accessed 2025 Nov 10]

Vaccines, Blood, and Biologics

The United States Food and Drug Administration (FDA) regulates vaccines, blood and blood products, and biologics via the Center for Biologics Evaluation and Research (CBER) which ensures the safety, efficacy, and quality of these products. Refer to the FDA vaccines/blood/biologics website. Available from: https://www.fda.gov/vaccines-blood-biologics [accessed 2025 Nov 10]

The FDA maintains information for consumers and health professionals on vaccine, blood and biologics warnings and other safety information. Available from: Recalls (Biologics) | FDA [accessed 2025 Nov 10]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
38225	Harvesting of blood-derived T lymphocytes

Code	Description
38226	Preparation for transport (e.g., cryopreservation)
38227	Receipt and preparation of CAR-T cells
38228	Administration of CAR-T cells

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HCPCS Codes

Code	Description
	See Pharmacy Policy 103 for Applicable Drug Codes

ICD10 Codes

Code	Description
C83.30–C83.39	Diffuse large B-cell lymphoma (DLBCL) (code range)
C91.00–C91.02	Acute lymphoblastic leukemia (ALL) (code range)
C90.00–C90.02	Multiple myeloma (code range)
C86.6	Primary cutaneous CD30-positive T-cell proliferations
C96.0	Multifocal and multisystemic (disseminated) Langerhans-cell histiocytosis
Z80.6	Family history of leukemia
Z80.7	Family history of other malignant neoplasms of lymphoid, hematopoietic and related tissues
Z85.72	Personal history of non-Hodgkin lymphomas
Z92.850	Personal history of Chimeric Antigen Receptor T-cell therapy
Z92.858	Personal history of other cellular therapy
Z92.859	Personal history of cellular therapy, unspecified
Z92.86	Personal history of gene therapy

REFERENCES

Amini L, et al. Preparing for CAR T cell therapy: patient selection, bridging therapies and lymphodepletion. Nat Rev Clin Oncol. 2022 May;19(5):342-355.

Dhakal B, et al. ASTCT Clinical Practice Recommendations for Transplantation and Cellular Therapies in Multiple Myeloma. Transplant Cell Ther. 2022 Jun;28(6):284-293.

Epperla N, et al. ASTCT Clinical Practice Recommendations for Transplantation and Cellular Therapies in Diffuse Large B Cell Lymphoma. Transplant Cell Ther. 2023 Sep;29(9):548-555.

Haslam A, Hoeg TB, Prasad V. Estimation of eligibility for and response to CAR-T therapy in the United States. Blood Adv. 2024 Feb 27;8(4):1032-1036.

Iqbal M, et al. Clinical practice recommendations for hematopoietic cell transplantation and cellular therapies in follicular lymphoma: a collaborative effort on behalf of the American Society for Transplantation and Cellular Therapy and the European Society for Blood and Marrow Transplantation. Transplant Cell Ther. 2024 Sep;30(9):832-843.

Karmali R, et al. Double hit & double expressor lymphomas: a multicenter analysis of survival outcomes with CD19-directed CAR T-cell therapy. Blood Cancer J. 2025 Mar 26;15(1):43.

Kharfan-Dabaja MA, et al. Clinical practice recommendations on the role of allogeneic hematopoietic cell transplantation and chimeric antigen receptor t-cell therapy in patients with chronic lymphocytic leukemia on behalf of the American society for transplantation and cellular therapy. Transplant Cell Ther. 2025 Aug;31(8):494-504.

Lee DW, et al. ASTCT consensus grading for cytokine release syndrome and neurologic toxicity associated with immune effector cells. Biol Blood Marrow Transplant. 2019 Apr;25(4):625-638.

McKenna M, et al. Real-world evidence of the safety and survival with CD19 CAR-T cell therapy for relapsed/refractory solid organ transplant-related PTLD. Br J Haematol. 2023 Jul;202(2):248-255.

National Comprehensive Cancer Network (NCCN). [Internet]. Clinical practice guidelines in oncology. B-Cell Lymphomas. V.3.2025. 2025 Aug 18 [accessed 2025 Nov 10]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf

National Institute for Health and Care Excellence [Internet]. Axicabtagene ciloleucel for treating diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after 2 or more systemic therapies. Technology Appraisal Guidance [TA872]. Published: 28 February 2023. [accessed 2025 Nov 10]. Available from: https://www.nice.org.uk/guidance/ta933

National Institute for Health and Care Excellence [Internet]. Axicabtagene ciloleucel for treating relapsed or refractory diffuse large B-cell lymphoma after first-line chemoimmunotherapy. Technology Appraisal Guidance [TA895]. Published: 7 June 2024. [accessed 2025 Nov 10]. Available at https://www.nice.org.uk/guidance/ta895.

National Institute for Health and Care Excellence [Internet]. Axicabtagene ciloleucel for treating relapsed or refractory follicular lymphoma. Technology Appraisal Guidance [TA894]. Published: 7 June 2024. [accessed 2025 Nov 10]. Available from: https://www.nice.org.uk/guidance/ta894/chapter/1-Recommendations

National Institute for Health and Care Excellence [Internet]. Brexucabtagene autoleucel for treating relapsed or refractory B-cell acute lymphoblastic leukaemia in people 26 years and over. Technology Appraisal Guidance [TA893]. Published: 7 June 2023. [accessed 2025 Nov 10]. Available from: https://www.nice.org.uk/guidance/ta893

National Institute for Health and Care Excellence [Internet]. Brexucabtagene autoleucel for treating relapsed or refractory mantle cell lymphoma. Technology Appraisal Guidance [TA677]: Published: 24 February 2021. [accessed 2025 Nov 10]. Available from: https://www.nice.org.uk/guidance/ta677

National Cancer Institute. [Internet]. CAR T cells: engineering patients' immune cells to treat their cancers. Updated March 2022. [accessed 2025 Nov 10]. Available from: https://www.cancer.gov/about-cancer/treatment/research/car-t-cells

National Institute for Health and Care Excellence Technology [Internet]. Tisagenlecleucel for treating relapsed or refractory B-cell acute lymphoblastic leukemia in people aged 25 years and under. Technology Appraisal Guidance [TA933]. Published 15 May 2024. [accessed 2025 Nov 10]. Available from: https://www.nice.org.uk/guidance/TA975/chapter/1-Recommendations.

National Institute for Health and Care Excellence [Internet]. Tisagenlecleucel for treating relapsed or refractory diffuse large B-cell lymphoma after 2 or more systemic therapies. Technology Appraisal Guidance [TA933]. Published: 29 November 2023. [accessed 2025 Nov 10]. Available from: https://www.nice.org.uk/guidance/ta933

Oluwole OO, et al. Chimeric antigen receptor t-cell therapy in the outpatient setting: an expert panel opinion from the American society for transplantation and cellular therapy. Transplant Cell Ther. 2024 Feb;30(2):131-142.

Pasqui DM, et al. CAR-T cell therapy for patients with hematological malignancies. A systematic review. Eur J Haematol. 2022 Dec;109(6):601-618.

Phina-Ziebin X, et al. Outcome of high-grade B-cell lymphoma compared with other large B-cell lymphoma after CAR-T rescue: a DESCAR-T LYSA study. Blood Adv. 2025 May 27;9(10):2500-2510.

Roddie C, et al. Obecabtagene autoleucel in adults with b-cell acute lymphoblastic leukemia. N Engl J Med. 2024 Dec 12;391(23):2219-2230.

Shah NN, et al. Long-Term Follow-Up of CD19-CAR T-Cell Therapy in Children and Young Adults With B-ALL. J Clin Oncol. 2021 May 20;39(15):1650-1659.

SEARCH TERMS

Adoptive cell therapy and adoptive cell immunotherapy

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Chimeric Antigen Receptor (CAR) T-cell Therapy (110.24) [accessed 2025 Nov 10]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 3/26

Revised:

Reviewed:

Date	Summary of Changes
7/1/2026	New Policy

MEDICAL POLICY

Medical Policy Title	**Chiropractic Care**
Policy Number	**10.01.02**
Current Effective Date	**January 1, 2026**
Next Review Date	**July 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Chiropractic care is considered **medically appropriate** for diagnosis and management of neuromusculoskeletal conditions, within the boundaries set by state licensure, by a licensed Doctor of Chiropractic (DC).

II. Chiropractic care is considered **medically appropriate** when **ALL** of the following criteria are met:

   A. There is documented history, examination, and diagnosis of a neuromusculoskeletal condition;

   B. There is a reasonable expectation of recovery or improvement in function;

   C. Treatment is provided in accordance with standards of generally accepted chiropractic practice;

   D. The diagnostic procedures and therapeutic interventions are clearly related to the patient's symptoms/condition being treated;

   E. Individualized treatment plans incorporate objective measures of patient-based outcomes.

III. Maintenance care begins when the therapeutic goals of a treatment plan have been achieved or when no additional functional progress is apparent or expected to occur. Maintenance care is considered **not medically necessary**.

IV. Chiropractic care is considered **not medically necessary** as a treatment intervention to restore spinal curves or in treatment of idiopathic scoliosis in an asymptomatic patient.

V. Routine or repeat X-ray use to assess the function or structure of the spine is considered **not medically necessary** in the absence of red flags or clinical reasons to suspect serious underlying pathology.

VI. Chiropractic care is considered **investigational** when it is rendered for non-neuromusculoskeletal conditions (e.g., infantile colic, childhood asthma, hypertension, primary dysmenorrhea).

RELATED POLICIES

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Corporate Medical Policy

8.01.24 Therapies (Speech, Physical and Occupational)

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Coverage of chiropractic care is limited to medically necessary services provided by a licensed DC, within the scope of their license, in connection with the detection or correction of spinal misalignment or mechanical/myofascial extremity pain.

II. Contraindications include, but are not limited to, recent compression fracture, severe osteoporosis, inflammatory arthropathy in the active systemic stage, or locally if acute inflammation is present, infections, cauda equina syndrome, progressive or sudden neurological deficit and visceral disease.

III. All chiropractic care is subject to retrospective utilization review for determining medical necessity. Coverage for services determined to be not medically necessary will be denied.

IV. Examples of red flags, which may indicate the possibility of a more serious underlying condition, include back pain and/or back pain with radiculopathy in one or more of the following settings:

   A. History of cancer,
   B. Unexplained weight loss,
   C. Immunosuppression,
   D. Urinary infection,
   E. Intravenous drug use,
   F. Prolonged use of corticosteroids,
   G. Back pain not improved with conservative management,
   H. History of significant trauma,
   I. Minor fall or heavy lift in a potentially osteoporotic or elderly individual,
   J. Prolonged use of steroids,
   K. Acute onset of urinary retention or overflow incontinence,
   L. Loss of anal sphincter tone or fecal incontinence,
   M. Saddle anesthesia, or
   N. Global or progressive motor weakness in the lower limbs.

DESCRIPTION

Chiropractic is a health care profession that focuses on disorders of the musculoskeletal system (primarily the spine) and the nervous system, and their effects on general health. Chiropractic

services are used to treat neuromusculoskeletal complaints, including, but not limited to, back pain, neck pain, pain in the joints of the arms or legs, and headaches. DCs, often referred to as chiropractors, practice a hands-on, drug-free approach to health care that includes patient examination, diagnosis, and treatment. Chiropractors have broad diagnostic skills and are trained to recommend therapeutic and rehabilitative exercises, as well as to provide nutritional, dietary, and lifestyle counseling.

One of the most common and well-known therapeutic procedures performed by DCs is spinal manipulation (sometimes referred to as a "chiropractic adjustment"). The purpose of spinal manipulation is to restore joint mobility by manually applying a controlled force into joints that have become hypomobile – or restricted in their movement – as a result of a tissue injury or restriction. Manipulation, or adjustment, of the affected joint and tissues, restores mobility, potentially alleviating pain, and muscle tightness, and restoring function.

SUPPORTIVE LITERATURE

Chiropractic care has been utilized for the treatment of idiopathic scoliosis' however, scientific evidence is limited, and the efficacy of manual therapy for correcting the scoliotic curve or progression of the curve has not been established in the peer-reviewed published scientific literature. Chiropractic manipulation may be used to improve joint mobility and relieve pain associated with scoliosis.

Plain film radiographs should not be used as a screening procedure without clinical indications. The decision for radiographic re-examination should be based on patient symptoms, physical findings, and the potential impact of the results of the examination on the treatment plan and on the net health outcome for the patient. A literature review performed by Corso et al (2020) did not identify any relevant studies that investigated the diagnostic or therapeutic utility of cervical, thoracic, or lumbar radiographs (in the absence of red flags) for the functional or structural evaluation of the spine. Similarly, Jenkins et al (2018) found limited evidence to support routine spinal X-rays and strong evidence to support potential harms associated with routine spinal X-rays. Without indicators of serious pathology, the increase in information available from X-ray adds little additional benefit to patient health, and may unnecessarily increase patient concern, increase the risk of developing chronic pain, contribute to fear-avoidance behaviors, and contribute to low-value care.

The long-term safety and effectiveness of the use of chiropractic management and manual therapies in the treatment of non-neuromusculoskeletal conditions, including but not limited to hypertension, asthma, colic, and otitis media have not been proven in the medical literature through quality research, such as long-term, randomized, controlled clinical trials. A systematic review was conducted during a Global Summit in September 2019 to evaluate the medical literature on the use of spinal manipulative therapy (SMT) to manage non-musculoskeletal disorders (Cote 2021). Based on six randomized controlled trials, SMT was found to not be superior to sham interventions for the treatment of non-musculoskeletal disorders. The researchers concluded there is no evidence of an effect of SMT for the management of non-musculoskeletal disorders including infantile colic, childhood asthma, hypertension, and primary dysmenorrhea.

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Cabanillas-Barea et al (2023) conducted a systematic review and meta-analysis that evaluated the effectiveness of osteopathy and chiropractic techniques in reducing crying time and increasing sleep time in babies with infantile colic. The outcome measures were hours spent crying and/or sleeping. Five studies with 422 babies total were evaluated. Complementary treatments failed to decrease the crying time (mean difference -1.08, 95% CI: -2.17 to 0.01) and to increase sleeping time (mean difference 1.11, 95% CI: -0.20 to 2.41) compared with no intervention. Authors concluded that osteopathy and chiropractic treatment failed to reduce the crying time and increase sleeping time in babies with infantile colic, compared to no additional intervention.

Trager et al (2026) conducted an evidence-based clinical practice guideline development study for the chiropractic management of adults with cervicogenic headache (CGH) and tension-type headache (TTH). The authors performed an umbrella review of systematic reviews and clinical practice guidelines on nonpharmacological interventions for adults with CGH or TTH published from 2017 to August 2023. Thirty-two relevant articles (31 systematic reviews and 1 clinical practice guideline) were identified and considered "high" or "acceptable" quality. Strong recommendations for CGH chiropractic management include offering spinal manipulation and offering multimodal therapy that includes spinal manipulation and any combination of joint mobilization, soft tissue, and/or modalities. Strong recommendations for TTH management include providing spinal manipulation combined with joint mobilization, soft tissue techniques, and/or modalities, and offering joint mobilization and/or soft tissue techniques. The authors concluded that Chiropractors may appropriately care for individuals with CGH and TTH using a variety of nonpharmacological interventions, including the use of spinal manipulative therapy for patients with CGH, whereas patients with TTH should receive spinal manipulative therapy as a component of multimodal care.

PROFESSIONAL GUIDELINE(S)

American Chiropractic Association. Available from: https://www.acatoday.org/ [accessed 2026 Jun 11]

REGULATORY STATUS

New York State law requires that contracts providing physician services, medical, major medical, or similar comprehensive-type coverage, shall include coverage for chiropractic care. Chiropractic care in New York State is defined as detecting and correcting structural imbalance, distortion, or subluxations in the human body through manual or mechanic means, for the purpose of removing nerve interference effects related to distortion, misalignment, or subluxation of or in the vertebral column.

The United States Food and Drug Administration (FDA) regulates medical devices. All devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Jun 11]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website.

Available from: Medical Device Recalls | FDA [accessed 2026 Jun 11]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

Code Modifier

Code	Description
AT	Acute or active treatment (this modifier should be used when reporting service 98940, 98941, 98942)

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CPT Codes

Code	Description
98940	Chiropractic manipulative treatment (CMT); spinal, 1-2 regions
98941	Chiropractic manipulative treatment (CMT); spinal, 3-4 regions
98942	Chiropractic manipulative treatment (CMT); spinal, 5 regions
98943	Chiropractic manipulative treatment (CMT); extraspinal, 1 or more regions

HCPCS Codes

Code	Description
S8990 (NMN)	Physical or manipulative therapy performed for maintenance rather than restoration

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

Bronfort G, et al. Multidisciplinary integrative care versus chiropractic care for low back pain: a randomized clinical trial. Chiropr Man Therap. 2022 Mar 1;30(1):10.

Bronfort G, et al. Spinal manipulation and clinician-supported biopsychosocial self-management for

acute back pain: the PACBACK randomized clinical trial. JAMA. 2026 Feb 10;335(6):497-510.

Cabanillas-Barea S, et al. Systematic review and meta-analysis showed that complementary and alternative medicines were not effective for infantile colic. Acta Pediatr. 2023 Jul;112(7):1378-1388.

Chaibi A, et al. Spinal manipulative therapy for acute neck pain: a systematic review and meta-analysis of randomized controlled trials. J Clin Med. 2021 Oct 28;10(21):5011.

Corso M, et al. The clinical utility of routine spinal radiographs by chiropractors: a rapid review of the literature. Chiropr Man Therap. 2020 Jul 9;28(1):33.

Cote P, et al. The global summit on the efficacy and effectiveness of spinal manipulative therapy for the prevention and treatment of non-musculoskeletal disorders: a systematic review of the literature. Chiropr Man Therap. 2021 Feb 17;29(1):8.

Gevers-Montoro C, et al. Clinical effectiveness and efficacy of chiropractic spinal manipulation for spine pain. Front Pain Res (Lausanne). 2021 Oct 25;2:765921.

Hawk C, et al. Best Practices for chiropractic management of patients with chronic musculoskeletal pain: a clinical practice guideline. J Altern Complement Med. 2020 Oct;26(10):884-901.

Hays R, et al. Health-related quality of life among united states service members with low back pain receiving usual care plus chiropractic care alone: secondary outcomes of a pragmatic clinical trial. Pain Med. 2022 Aug 31;23(9):1550-1559.

Jenkins H, et al. Current evidence for spinal X-ray use in the chiropractic profession: a narrative review. Chiropr Man Therap. 2018 Nov 21;26:48.

Lynge S, et al. Effectiveness of chiropractic manipulation versus sham manipulation for recurrent headaches in children aged 7-14 years - a randomised clinical trial. Chiropr Man Therap. 2021 Jan 7;29(1):1.

New York State Senate [Internet]. Consolidated Laws of New York. Insurance. Article 32 § 3216. 2026 Jun 5 [accessed 2026 Jun 11] Available from: https://www.nysenate.gov/legislation/laws/ISC/3216

New York State Senate [Internet]. Consolidated Laws of New York. Insurance.Article 32 § 3221. 2026 Jun 5 [accessed 2026 Jun 11]. Available from: https://www.nysenate.gov/legislation/laws/ISC/3221

Thomas JS, et al. Effect of spinal manipulative and mobilization therapies in young adults with mild to moderate chronic low back pain: A randomized clinical trial. JAMA Netw Open. 2020 Aug 3;3(8):e2012589.

Trager RJ, et al. Chiropractic management of adults with cervicogenic or tension-type headaches: development of a clinical practice guideline. J Integr Complement Med. 2026 Apr;32(4):325-344.

Whalen W, et al. Best practices for chiropractic management of adult patients with mechanical low back pain: a clinical practice guideline for chiropractors in the United States. J Manipulative Physiol Ther. 2022 Oct;45(8):551-565.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Article - Chiropractic Services – Medical Policy Article (A57889) [accessed 2026 Jun 11]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
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POLICY HISTORY/REVISION

Committee Approval Dates

New: 12/97

Revised: 04/98, 06/99, 09/99, 11/00, 11/03, 01/05, 10/06, 05/08, 05/09, 05/11, 11/11, 05/12, 05/13, 05/15, 05/17, 3/23, 5/24, 11/25

Reviewed: 03/02, 02/03, 10/05, 09/07, 05/10, 05/14, 05/16, 05/18, 05/19 5/20, 5/21, 5/22, 5/23, 5/25, 9/26

Date	Summary of Changes
1/1/2026	• Transitioned Chiropractic Services policy, 1370/20.000163 to Lifetime Healthcare Companies policy template.
1/1/2023 *No change to effective date of policy	• Removed statement regarding contractual limits.
1/1/2023	• Added section for Medicare Advantage Group in the Product Variations section that coverage will follow policy for Commercial LOB.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: CLINICAL PEER REVIEWERS

POLICY EFFECTIVE DATE:	12/1/2023
Policy Control #:	1370/20.000270
Next Annual Review:	November, 2026

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice,

DESCRIPTIONS

Process used to identify the eligibility and use of licensed physicians to serve as clinical peer reviewers for utilization review decisions, and other health care professionals as clinical peer reviewers. For the purposes of this policy, unless otherwise specified, the term "clinical peer reviewer" will apply to a physician.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

- Review Process for Resource Coordination, 1370/20.000213.

POSITION STATEMENT

CDPHP utilizes clinical peer reviewers when a CDPHP medical director has reviewed a request for service and feels they do not have the clinical expertise to render the determination.

A clinical peer reviewer is:

- A physician who possesses a current and valid non-restricted license to practice medicine **OR**
- A health care professional other than a licensed physician who:
    - Where applicable, possesses a current and valid non-restricted license, certificate, or registration or where no provision for a license, certificate or

registration exists, is credentialed by the national accrediting body appropriate to the profession; **AND**

- Is in the same profession and same or similar specialty as the health care provider who typically manages the medical condition or disease or provides the health care service or treatment under review.

A clinical peer reviewer making a determination on mental health or substance use disorder (SUD) treatment is either:

- A physician who possesses a current and valid non-restricted license to practice medicine and who specializes in behavioral health and has experience in the delivery of mental health or SUD treatment; or

- A health care professional other than a physician who specializes in behavioral health and has experience in the delivery of mental health or SUD treatment and, where applicable, possesses a current and valid non-restricted license, certificate, or registration, or if none exists, is credentialed by the national accrediting body appropriate to the profession.

A clinical peer reviewer making a determination involving treatment of a medically fragile child is:

- A physician who possesses a current and valid non-restricted license to practice medicine and who is board certified or board eligible in pediatric rehabilitation, pediatric critical care, or neonatology
- A physician who possesses a current and valid non-restricted license to practice medicine and is board certified in a pediatric subspecialty directly relevant to the patients medical condition

Only a clinical peer reviewer may determine that the request will be denied.

The clinical peer reviewer must consider all clinical information available to him/her, including the specific needs of the member, available practice guidelines, applicable contract benefits and supporting resource coordination policies and procedures, and assessment of the network delivery system.

POLICY CONSIDERATIONS

If the internal clinical peer reviewer does not feel qualified to review a particular case, an external clinical peer reviewer will be identified from the list of qualified board-certified practitioners.

A health care professional providing health care services to an enrollee will be prohibited from

serving as the clinical peer reviewer for such enrollee in connection with the health care services being requested.

The chosen external clinical peer reviewer will receive a letter outlining the responsibilities of a clinical peer reviewer, an appropriate case summary, and all relevant materials blinded as to the identity of the involved enrollee if no business associate agreement has been signed.

The decision of the clinical peer reviewer will be documented in writing and timely, in accordance with the appropriate applicable regulatory guidelines.

CDPHP renders the final determination based on all information presented including but not limited to the opinion of the clinical peer reviewer.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. The CDPHP Technology Assessment Team
2. National Committee on Quality Assurance (NCQA) 2014 HP Standards and Guidelines: UM 4: Appropriate Professionals.
3. NYS Insurance Law: Article 49, Title I § 4900: Definitions, http://public.leginfo.state.ny.us/LAWSSEAF.cgi?QUERYTYPE=LAWS+&QUERYDATA=$$ISC4900$$@TXISC04900+&LIST=LAW+&BROWSER=EXPLORER+&TOKEN=51554738+&TARGET=VIEW
4. NYS Public Health Law, Article 49, §4903: Utilization Review Determinations, http://public.leginfo.state.ny.us/LAWSSEAF.cgi?QUERYTYPE=LAWS+&QUERYDATA=$$PBH4903$$@TXPBH04903+&LIST=LAW+&BROWSER=EXPLORER+&TOKEN=07247332+&TARGET=VIEW

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: CLINICAL PEER REVIEWERS

POLICY APPROVAL DATES

New: 11/02

Revised: 09/03, 02/05, 12/05, 11/08, 07/11, 11/11, 07/14, 11/14, 01/15, 09/18, 11/21, 11/23

Reviewed: 06/04, 12/06, 12/07, 11/09, 11/10, 11/12, 11/13, 11/15, 11/16, 11/17, 11/19, 11/20, 11/22, 11/24, 11/25

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	
12/1/2023	Policy updated throughout as per changes to law effective 9/1/2023. Policy clean up to remove redundant information throughout this policy and within other policies.
11/1/2021	Under Policy Considerations, to meet DFS regulatory guidelines, added verbiage regarding clinical peer reviewers for behavioral health and substance use disorders treatment.

This Resource Coordination Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI) and Capital District Physicians' Healthcare Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

October 1, 2026

CLINICAL REVIEW PREAUTHORIZATION LIST

The following services may require preauthorization regardless of place of service for the following lines of business:
Commercial products, Essential Plan, Medicare, and Managed Safety Net Products.
Please review the column that applies to the member's specific line of business.

Code Changes Are Highlighted In Grey

IMPORTANT
This list represents those services that require preauthorization with a clinical medical necessity review. Certain services require preauthorization or notification without requiring clinical review.
It is NOT inclusive of all insurance products and procedures requiring preauthorization.
If you have a strategic account, call Customer Care for PA requirements at:
(518) 641-3100 or toll free 1-877-724-2579
Mon. - Fri. 8 a.m. to 5 p.m.

Please verify specific coverage requirements before rendering service.

Please Note: There are some codes that require PA by diagnosis. These additional diagnosis details are included in the last column of this document.

If a code on this list is part of one of the below listed Resource Coordination policies, check the policy for more codes or special prior authorization rules:
• Dental Services Covered Under the Medical Benefit, 1370/20.000417
• Dental Services: Criteria for Use of Hospital Inpatient or Outpatient Ambulatory Facility Services, 1370/20.000181
• Durable Medical Equipment, Prosthetics/Orthotics & Medical Supplies, 1370/20.000509
• Inpatient Rehabilitation: Acute, Subacute, and Skilled: 1370/20.000204
• Second Opinions, 1370/20.000159
• Transitional Care – New Enrollee, 1370/20.000194
• Transitional Care – Provider Leaves the Network, 1370/20.000195

The Category column identifies the medical category associated with a specific procedure code. By using either, the category listed on the PDF or the procedure code itself, users can navigate to the Corporate Medical Policy page: https://provider.cdphp.com/resources/medical-policies **to view all applicable medical policies within that category or related to the selected code.**
Please note that the medical necessity criteria applied during the review process are dependent on the member's plan and may not be outlined in a Corporate Medical Policy.
In some cases, criteria may instead be derived from InterQual®, eMedNY, or CMS guidelines.

To initiate preauthorization requests please follow the below service contact information:

Behavioral Health, Medical & Durable Medical Equipment:

Please go to the Provider Portal by going to this URL,
https://provider.cdphp.com

Health Help:

Phone Requests: Phone: 1-888-673-7038, Monday through Friday from 8:00 a.m. – 6:00 p.m.
Internet Request: https://healthhelp.com/cdphp
Expedited Fax Requests: Fax: 1-844-470-2456

Procedure Code	Category	Commercial Fully Insured (Commercial Products, but not limited to: HMO, PPO, HDPPO, EPO, HDEPO & HNY HMO)	Self-Funded (Self-Funded Products, but not limited to: HMO, PPO, EPO & POS)	Medicare Advantage	Child Health Plus (CHP)	Special Programs (Healthy NY & Essential Plan)	Medicaid Managed Care (Select Plan)	Health and Recovery Plan (HARP)	Diagnosis Requirements (if applicable)
0018M	Transplants	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0071T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0072T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0075T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Not Required	Not Required	
0076T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0102T	Bone and Joint (Orthopedics)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0174T	Miscellaneous & Unlisted Codes	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0175T	Radiology (Imaging) Services	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
0184T	Digestive System (Gastroenterology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0200T	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
0201T	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
0214T	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
0215T	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
0217T	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
0218T	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
0232T	Skin (Dermatology)	Required	Required	Required	Not Required	Required	Not Required	Not Required	
0278T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0331T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0332T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0333T	Nervous System (Neurology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0335T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	

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0339T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Not Required	Not Required	
0342T	Blood Disorder (Hematology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0395T	Radiation Treatment	Required	Required	Required	Required	Required	Not Required	Not Required	
0397T	Miscellaneous & Unlisted Codes	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0408T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Not Required	Not Required	
0409T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Not Required	Not Required	
0441T	Bone and Joint (Orthopedics)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0442T	Miscellaneous & Unlisted Codes	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
0447T	Diabetes (Endocrinology)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0448T	Diabetes (Endocrinology)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0446T	Diabetes (Endocrinology)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0474T	Eyes (Ophthalmology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
0479T	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0480T	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0483T	Heart and Blood Vessel (Cardiovascular)	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
0484T	Heart and Blood Vessel (Cardiovascular)	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
0500T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0515T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Not Required	Not Required	
0516T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Not Required	Not Required	
0517T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Not Required	Not Required	
0519T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Not Required	Not Required	
0520T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Not Required	Not Required	
0525T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0544T	Heart and Blood Vessel (Cardiovascular)	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
0545T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0569T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0570T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0582T	Urinary System(Genitourinary)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0584T	Transplants	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0585T	Transplants	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0586T	Transplants	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0587T	Neuromuscular Stimulation and Electrical Shock Units	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
0594T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0596T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0597T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0600T	Urinary System(Genitourinary)	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
0601T	Urinary System(Genitourinary)	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
0607T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0608T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Not Required	Not Required	
0609T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0610T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0611T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0612T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0615T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0620T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0627T	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
0628T	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	

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0629T	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
0630T	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
0632T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0633T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0634T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0635T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0636T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0637T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0638T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0644T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0645T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0646T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0647T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0648T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0649T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0651T	Digestive System (Gastroenterology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0652T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0653T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0655T	Urinary System(Genitourinary)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0656T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Required	Not Required	Not Required	Not Required	
0657T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0672T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0673T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0686T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0687T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0688T	Eyes (Ophthalmology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0692T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0693T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0696T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0697T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Required	Required	
0698T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0704T	Eyes (Ophthalmology)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0707T	Miscellaneous & Unlisted Codes	Required	Required	Required	Not Required	Required	Not Required	Not Required	
0710T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Required	Required	
0711T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Required	Required	
0712T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Required	Required	
0713T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0714T	Urinary System(Genitourinary)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
0719T	Bone and Joint (Orthopedics)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0720T	Alternative Medicine	Required	Required	Required	Required	Required	Not Required	Not Required	
0738T	Urinary System(Genitourinary)	Required	Required	Required	Required	Required	Not Required	Not Required	
0739T	Urinary System(Genitourinary)	Required	Required	Required	Required	Required	Not Required	Not Required	
0740T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0741T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0742T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Not Required	Not Required	
0743T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0744T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Not Required	Not Required	

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0745T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Not Required	Not Required	
0746T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Not Required	Not Required	
0747T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Not Required	Not Required	
0748T	Digestive System (Gastroenterology)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0749T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0750T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0751T	Laboratory	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0752T	Laboratory	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0753T	Laboratory	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0754T	Laboratory	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0755T	Laboratory	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0756T	Laboratory	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0757T	Laboratory	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0758T	Laboratory	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0759T	Laboratory	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0760T	Laboratory	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0761T	Laboratory	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0762T	Laboratory	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0763T	Laboratory	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0765T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0766T	DME	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0767T	DME	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0770T	Miscellaneous & Unlisted Codes	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0771T	Alternative Medicine	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0772T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0773T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0773T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0774T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0776T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0777T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0778T	Bone and Joint (Orthopedics)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0779T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0780T	Digestive System (Gastroenterology)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0783T	Alternative Medicine	Required	Required	Required	Required	Required	Not Required	Not Required	
0784T	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
0785T	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
0786T	Nervous System (Neurology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
0788T	Nervous System (Neurology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
0789T	Nervous System (Neurology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
0790T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0793T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0794T	Cancer Treatment (Oncology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
0795T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0796T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0797T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0798T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0799T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0800T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	

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0801T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0802T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0803T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0804T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0805T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0806T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0807T	Lungs (Respiratory)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0808T	Lungs (Respiratory)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0810T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0811T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0812T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0813T	Digestive System (Gastroenterology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0815T	Radiology (Imaging) Services	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0816T	Nervous System (Neurology)	Required	Required	Required	Required	Required	Not Required	Not Required	
0817T	Nervous System (Neurology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0820T	Behavioral Health (Psychology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0821T	Behavioral Health (Psychology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0822T	Behavioral Health (Psychology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0823T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0824T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0825T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0827T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0828T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0830T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0831T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0832T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0833T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0834T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0835T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0836T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0837T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0839T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0840T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0841T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0842T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0843T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0844T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0845T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0846T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0847T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0848T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0849T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0850T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0851T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0852T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0853T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0854T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	

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0855T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0856T	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0858T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0860T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0861T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0862T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0863T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0864T	Urinary System(Genitourinary)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0865T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Required	Required	
0866T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Not Required	Not Required	
0867T	Urinary System(Genitourinary)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0868T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0869T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0870T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0871T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0872T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0873T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0874T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0875T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0876T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0881T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0884T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0885T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0886T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0888T	Miscellaneous & Unlisted Codes	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0889T	Behavioral Health (Psychology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0890T	Behavioral Health (Psychology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0891T	Behavioral Health (Psychology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0892T	Behavioral Health (Psychology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0897T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0898T	Cancer Treatment (Oncology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0899T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0900T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0901T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Required	Required	
0902T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0903T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0904T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0905T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0906T	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
0907T	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
0908T	Nervous System (Neurology)	Required	Required	Required	Required	Required	Required	Required	
0909T	Nervous System (Neurology)	Required	Required	Required	Required	Required	Required	Required	
0910T	Nervous System (Neurology)	Required	Required	Required	Required	Required	Required	Required	
0911T	Nervous System (Neurology)	Required	Required	Required	Required	Required	Required	Required	
0912T	Nervous System (Neurology)	Required	Required	Required	Required	Required	Required	Required	
0913T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0914T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	

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0915T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0916T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0917T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0918T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0919T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0920T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0921T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0922T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0923T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0924T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0925T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0932T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0933T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0934T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0935T	Urinary System(Genitourinary)	Required	Required	Required	Required	Required	Required	Required	
0936T	Eyes (Ophthalmology)	Required	Required	Required	Required	Required	Required	Required	
0937T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0938T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0939T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0940T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0941T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0942T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0943T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0944T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Required	Required	
0945T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Required	Required	
0946T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Required	Required	
0947T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Required	Required	
0948T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0949T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0950T	Urinary System(Genitourinary)	Required	Required	Required	Required	Required	Required	Required	
0951T	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Required	Required	Required	Required	Required	
0952T	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Required	Required	Required	Required	Required	
0953T	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Required	Required	Required	Required	Required	
0954T	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Required	Required	Required	Required	Required	
0955T	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Required	Required	Required	Required	Required	
0956T	Nervous System (Neurology)	Required	Required	Required	Required	Required	Required	Required	
0957T	Nervous System (Neurology)	Required	Required	Required	Required	Required	Required	Required	
0958T	Nervous System (Neurology)	Required	Required	Required	Required	Required	Required	Required	
0959T	Nervous System (Neurology)	Required	Required	Required	Required	Required	Required	Required	
0960T	Nervous System (Neurology)	Required	Required	Required	Required	Required	Required	Required	
0961T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Required	Required	
0962T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0963T	Urinary System(Genitourinary)	Required	Required	Required	Required	Required	Required	Required	
0964T	Sleep Medicine	Required	Required	Required	Required	Required	Required	Required	
0965T	Sleep Medicine	Required	Required	Required	Required	Required	Required	Required	
0966T	Sleep Medicine	Required	Required	Required	Required	Required	Required	Required	
0967T	Digestive System (Gastroenterology)	Required	Required	Required	Required	Required	Required	Required	

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0968T	Nervous System (Neurology)	Required	Required	Required	Required	Required	Required	Required	
0969T	Nervous System (Neurology)	Required	Required	Required	Required	Required	Required	Required	
0970T	Cancer Treatment (Oncology)	Required	Required	Required	Required	Required	Required	Required	
0971T	Cancer Treatment (Oncology)	Required	Required	Required	Required	Required	Required	Required	
0972T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Required	Required	
0973T	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
0974T	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
0975T	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
0976T	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
0977T	Digestive System (Gastroenterology)	Required	Required	Required	Required	Required	Required	Required	
0978T	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Required	Required	Required	Required	Required	
0979T	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Required	Required	Required	Required	Required	
0980T	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Required	Required	Required	Required	Required	
0981T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0982T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0983T	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
0986T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Required	Required	
0987T	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Required	Required	
0988T	Nervous System (Neurology)	Required	Required	Required	Required	Required	Required	Required	
0989T	Nervous System (Neurology)	Required	Required	Required	Required	Required	Required	Required	
0990T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0991T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0992T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0993T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0994T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0995T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0996T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0997T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0998T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0999T	Urinary System(Genitourinary)	Required	Required	Required	Required	Required	Required	Required	
1000T	Urinary System(Genitourinary)	Required	Required	Required	Required	Required	Required	Required	
1001T	Urinary System(Genitourinary)	Required	Required	Required	Required	Required	Required	Required	
1002T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1003T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1004T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1005T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1006T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1007T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1008T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1009T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1010T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1011T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1012T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1013T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1014T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1015T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1016T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	

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1017T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1018T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1019T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1020T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1021T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1022T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1023T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1024T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
1025T	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
0035U	Laboratory	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
0080U	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0092U	Laboratory	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
0220U	Genetic Testing	Required	Required	Required	Required	Required	Not Required	Not Required	
0228U	Genetic Testing	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0243U	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0247U	Genetic Testing	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0249U	Genetic Testing	Required	Required	Required	Required	Required	Not Required	Not Required	
0251U	Genetic Testing	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0261U	Laboratory	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0263U	Laboratory	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0295U	Genetic Testing	Required	Required	Required	Not Required	Required	Not Required	Not Required	
0308U	Laboratory	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0309U	Laboratory	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0310U	Genetic Testing	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0312U	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0317U	Laboratory	Required	Required	Required	Required	Required	Not Required	Not Required	
0322U	Genetic Testing	Required	Required	Required	Required	Required	Not Required	Not Required	
0337U	Laboratory	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0338U	Laboratory	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0344U	Laboratory	Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
0358U	Laboratory	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0359U	Laboratory	Required	Required	Required	Required	Required	Not Required	Not Required	
0360U	Laboratory	Required	Required	Required	Required	Required	Not Required	Not Required	
0371U	Genetic Testing	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0372U	Genetic Testing	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0375U	Laboratory	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0376U	Genetic Testing	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0380U	Genetic Testing	Required	Required	Required	Required	Required	Required	Required	
0381U	Laboratory	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0382U	Laboratory	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0383U	Laboratory	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0384U	Laboratory	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0385U	Laboratory	Required	Required	Not Required	Required	Required	Not Required	Not Required	
0387U	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0390U	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0393U	Genetic Testing	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0394U	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	

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0395U	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0399U	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0404U	Genetic Testing	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
0406U	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0407U	Laboratory	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
0412U	Genetic Testing	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
0414U	Genetic Testing	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
0418U	Genetic Testing	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
0456U	Genetic Testing	Required	Required	Required	Required	Required	Required	Required	
0462U	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0463U	Genetic Testing	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
0480U	Laboratory	Required	Required	Required	Required	Required	Not Required	Not Required	
0502U	Laboratory	Required	Required	Required	Required	Required	Not Required	Not Required	
0558U	Digestive System (Gastroenterology)	Required	Required	Required	Required	Required	Required	Required	
0559U	Laboratory	Required	Required	Required	Required	Required	Required	Required	
0568U	Genetic Testing	Required	Required	Required	Required	Required	Required	Required	
0570U	Laboratory	Required	Required	Required	Required	Required	Required	Required	
0573U	Laboratory	Required	Required	Required	Required	Required	Required	Required	
0574U	Laboratory	Required	Required	Required	Required	Required	Required	Required	
0591U	Genetic Testing	Required	Required	Required	Required	Required	Required	Required	
0596U	Genetic Testing	Required	Required	Required	Required	Required	Required	Required	
0599U	Laboratory	Required	Required	Required	Required	Required	Required	Required	
0609U	Genetic Testing	Required	Required	Required	Required	Required	Required	Required	
10040	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Required	Required	Required	
11920	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
11950	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Required	Required	Required	
11951	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Required	Required	Required	
11952	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Required	Required	Required	
11954	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
15771	Reconstructive Surgery and/or Cosmetic Services	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
15772	Reconstructive Surgery and/or Cosmetic Services	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
15775	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Required	Required	Required	
15776	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Required	Required	Required	
15780	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Required	Not Required	Not Required	
15781	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Required	Not Required	Not Required	
15782	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Required	Required	Required	
15783	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
15786	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
15788	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Not Required	Required	Required	
15789	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Not Required	Required	Required	
15792	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Not Required	Required	Required	
15793	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Not Required	Required	Required	
15820	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Required	Required	Required	Required	
15821	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Not Required	Required	Required	
15822	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Not Required	Required	Required	
15823	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Required	Required	Required	Required	
15824	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Not Required	Required	Required	

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15825	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Not Required	Required	Required	
15826	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Required	Required	Required	
15828	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Required	Required	Required	
15829	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Not Required	Required	Required	
15830	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Required	Required	Required	
15832	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Required	Required	Required	
15833	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Required	Required	Required	Required	
15834	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Not Required	Required	Required	
15835	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Not Required	Required	Required	
15836	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Required	Required	Required	
15837	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Not Required	Required	Required	
15838	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Required	Required	Required	Required	
15839	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Required	Required	Required	
15847	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Required	Required	Required	
15876	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Required	Required	Required	
15877	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Required	Required	Required	
15878	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Required	Required	Required	
15879	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Required	Required	Required	
17106	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Not Required	Required	Required	
17107	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Required	Required	Required	
17108	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Required	Required	Required	
17360	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Not Required	Required	Required	
17380	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Required	Required	Required	Required	
19300	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Required	Required	Required	
19316	Reconstructive Surgery and/or Cosmetic Services	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
19318	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Required	Required	Required	Required	
19325	Reconstructive Surgery and/or Cosmetic Services	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
19328	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
19330	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
19340	Reconstructive Surgery and/or Cosmetic Services	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
19342	Reconstructive Surgery and/or Cosmetic Services	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
19350	Reconstructive Surgery and/or Cosmetic Services	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
19355	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
19357	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
19370	Reconstructive Surgery and/or Cosmetic Services	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
19371	Reconstructive Surgery and/or Cosmetic Services	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
19380	Reconstructive Surgery and/or Cosmetic Services	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
20983	Cancer Treatment (Oncology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
21120	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
21121	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
21122	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
21123	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
21125	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
21127	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
21137	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
21138	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
21139	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Required	Required	Required	Required	Required	

Procedure Code	Category	Commercial Fully Insured (Commercial Products, but not limited to: HMO, PPO, HDPPO, EPO, HDEPO & HNY HMO)	Self-Funded (Self-Funded Products, but not limited to: HMO, PPO, EPO & POS)	Medicare Advantage	Child Health Plus (CHP)	Special Programs (Healthy NY & Essential Plan)	Medicaid Managed Care (Select Plan)	Health and Recovery Plan (HARP)	Diagnosis Requirements (if applicable)
21142	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
21143	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
21172	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
21175	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
21179	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
21180	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
21181	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
21182	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
21183	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
21184	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
21193	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Required	Required	Required	
21194	Sleep Medicine	Not Required	Not Required	Required	Required	Required	Required	Required	
21195	Sleep Medicine	Required	Required	Required	Required	Required	Required	Required	
21198	Sleep Medicine	Not Required	Not Required	Required	Required	Required	Required	Required	
21240	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
21242	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
21243	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
21245	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
21246	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
21270	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
21280	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
21282	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
21740	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
21742	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
21743	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Not Required	Required	Not Required	
22836	Bone and Joint (Orthopedics)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
22837	Bone and Joint (Orthopedics)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
22838	Bone and Joint (Orthopedics)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
22860	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Required	Required	
27278	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Required	Required	
29800	Bone and Joint (Orthopedics)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
29804	Bone and Joint (Orthopedics)	Required	Required	Not Required	Required	Required	Required	Required	
30117	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Required	Required	Required	Required	Required	
30400	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Not Required	Required	Required	
30410	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Required	Required	Required	
30420	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Required	Required	Required	
30430	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Required	Required	Required	
30435	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Required	Required	Required	
30450	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Not Required	Required	Required	
30468	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Required	Not Required	Required	Required	Required	
30469	ENT	Required	Required	Required	Required	Required	Required	Required	
31242	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Required	Not Required	Required	Required	Required	
31243	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Required	Not Required	Required	Required	Required	
31571	Miscellaneous & Unlisted Codes	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
31627	Lungs (Respiratory)	Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
32851	Transplants	Required	Required	Not Required	Not Required	Not Required	Required	Required	
32852	Transplants	Required	Required	Not Required	Not Required	Not Required	Required	Required	

Procedure Code	Category	Commercial Fully Insured (Commercial Products, but not limited to: HMO, PPO, HDPPO, EPO, HDEPO & HNY HMO)	Self-Funded (Self-Funded Products, but not limited to: HMO, PPO, EPO & POS)	Medicare Advantage	Child Health Plus (CHP)	Special Programs (Healthy NY & Essential Plan)	Medicaid Managed Care (Select Plan)	Health and Recovery Plan (HARP)	Diagnosis Requirements (if applicable)
32853	Transplants	Required	Required	Not Required	Not Required	Required	Required	Required	
32854	Transplants	Required	Required	Not Required	Not Required	Not Required	Required	Required	
33269	Heart and Blood Vessel (Cardiovascular)	Not Required	Not Required	Required	Required	Required	Required	Required	
33367	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
33368	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
33369	Heart and Blood Vessel (Cardiovascular)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
33419	Heart and Blood Vessel (Cardiovascular)	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
33933	Transplants	Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
33935	Transplants	Required	Required	Not Required	Required	Required	Not Required	Not Required	
33944	Transplants	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
33945	Transplants	Required	Required	Not Required	Not Required	Required	Required	Required	
34841	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
34842	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
34843	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
34844	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
34846	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
34847	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
34848	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
36465	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Required	Required	Required	
36466	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Required	Required	Required	
36470	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
36471	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
36482	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Required	Not Required	Not Required	
36483	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
36522	Skin (Dermatology)	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
37241	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Required	Required	Required	
37242	Urinary System(Genitourinary)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Not Required	Not Required	Not Required	Not Required	PA is **Required** for the following diagnosis codes: N40.1
37243	Radiation Therapy	Required	Required	Not Required	Required	Required	Required	Required	
37788	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
37790	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
38205	Transplants	Required	Required	Not Required	Required	Required	Not Required	Not Required	
38206	Transplants	Required	Required	Not Required	Not Required	Required	Not Required	Not Required	
38211	Transplants	Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
38230	Transplants	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
38232	Transplants	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
38240	Transplants	Required	Required	Not Required	Required	Required	Required	Required	
38241	Transplants	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
41512	Sleep Medicine	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
43192	Digestive System (Gastroenterology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
43201	Digestive System (Gastroenterology)	Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
43210	Digestive System (Gastroenterology)	Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
43236	Digestive System (Gastroenterology)	Required	Required	Not Required	Not Required	Not Required	Required	Not Required	
43284	Digestive System (Gastroenterology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
43285	Digestive System (Gastroenterology)	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
43290	Digestive System (Gastroenterology)	Required	Required	Required	Required	Required	Required	Required	
43291	Digestive System (Gastroenterology)	Required	Required	Required	Required	Required	Required	Required	
43497	Experimental and Investigational Procedures/ Services	Required	Required	Not Required	Not Required	Not Required	Required	Required	

Procedure Code	Category	Commercial Fully Insured (Commercial Products, but not limited to: HMO, PPO, HDPPO, EPO, HDEPO & HNY HMO)	Self-Funded (Self-Funded Products, but not limited to: HMO, PPO, EPO & POS)	Medicare Advantage	Child Health Plus (CHP)	Special Programs (Healthy NY & Essential Plan)	Medicaid Managed Care (Select Plan)	Health and Recovery Plan (HARP)	Diagnosis Requirements (if applicable)
43647	Digestive System (Gastroenterology)	Required	Required	Not Required	Not Required	Not Required	Required	Required	
43648	Digestive System (Gastroenterology)	Required	Required	Not Required	Required	Required	Required	Required	
43770	Digestive System (Gastroenterology)	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
43774	Digestive System (Gastroenterology)	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
43842	Digestive System (Gastroenterology)	Not Required	Not Required	Not Required	Required	Required	Required	Required	
43845	Digestive System (Gastroenterology)	Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
43846	Digestive System (Gastroenterology)	Not Required	Not Required	Not Required	Not Required	Required	Not Required	Required	
43847	Digestive System (Gastroenterology)	Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
43848	Digestive System (Gastroenterology)	Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
43881	Digestive System (Gastroenterology)	Required	Required	Not Required	Required	Required	Required	Required	
43882	Digestive System (Gastroenterology)	Required	Required	Not Required	Required	Required	Required	Required	
43889	Digestive System (Gastroenterology)	Required	Required	Required	Required	Required	Required	Required	
44135	Transplants	Required	Required	Not Required	Required	Required	Required	Required	
44136	Transplants	Required	Required	Not Required	Required	Required	Required	Required	
47135	Transplants	Required	Required	Not Required	Required	Required	Required	Required	
47370	Cancer Treatment (Oncology)	Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
47371	Cancer Treatment (Oncology)	Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
47379	Digestive System (Gastroenterology)	Required (by diagnosis)	Required (by diagnosis)	Not Required	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for the following diagnosis codes: E66.01, E66.2, Z68.35, Z68.36, Z68.37, Z68.38, Z68.39, Z68.40, Z68.41,
47381	Cancer Treatment (Oncology)	Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
47382	Cancer Treatment (Oncology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
48160	Transplants	Required	Required	Not Required	Required	Not Required	Required	Required	
48554	Transplants	Required	Required	Not Required	Not Required	Not Required	Required	Required	
50320	Transplants	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
50360	Transplants	Required	Required	Not Required	Required	Required	Required	Required	
50365	Transplants	Required	Required	Not Required	Not Required	Required	Required	Required	
50370	Transplants	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
50380	Transplants	Required	Required	Not Required	Required	Required	Required	Required	
50592	Cancer Treatment (Oncology)	Required	Required	Required	Not Required	Not Required	Required	Required	
50593	Cancer Treatment (Oncology)	Required	Required	Required	Not Required	Not Required	Required	Not Required	
51715	Urinary System(Genitourinary)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
52284	Urinary System(Genitourinary)	Required	Required	Required	Not Required	Required	Required	Required	
52441	Urinary System(Genitourinary)	Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
52443	Urinary System(Genitourinary)	Required	Required	Required	Required	Required	Required	Required	
52597	Urinary System(Genitourinary)	Required	Required	Required	Required	Required	Required	Required	
53854	Urinary System(Genitourinary)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
54220	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
54230	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
54240	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
54250	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
54400	Erectile Dysfunction	Required	Required	Not Required	Not Required	Not Required	Required	Required	
54401	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
54405	Erectile Dysfunction	Required	Required	Not Required	Not Required	Not Required	Required	Required	
54406	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
54408	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
54410	Erectile Dysfunction	Required	Required	Not Required	Not Required	Not Required	Required	Required	
54411	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
54415	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	

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54416	Erectile Dysfunction	Required	Required	Not Required	Not Required	Not Required	Required	Required	
54417	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
55873	Cancer Treatment (Oncology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
55877	Urinary System(Genitourinary)	Required	Required	Required	Required	Required	Required	Required	
55880	Urinary System(Genitourinary)	Required	Required	Required	Not Required	Required	Not Required	Not Required	
55970	Gender Affirmation	Required	Required	Required	Not Required	Required	Not Required	Not Required	
55980	Gender Affirmation	Required	Required	Required	Not Required	Required	Not Required	Not Required	
56620	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Required	Required	Required	Required	
58580	Cancer Treatment (Oncology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
58674	Cancer Treatment (Oncology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
61715	Nervous System (Neurology)	Required	Required	Required	Required	Required	Not Required	Not Required	
61736	Miscellaneous & Unlisted Codes	Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
61863	Nervous System (Neurology)	Not Required	Required	Not Required	Not Required	Not Required	Required	Not Required	
61867	Nervous System (Neurology)	Not Required	Required	Not Required	Required	Not Required	Not Required	Not Required	
61868	Nervous System (Neurology)	Not Required	Not Required	Not Required	Required	Not Required	Required	Not Required	
61885	Nervous System (Neurology)	Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
61886	Nervous System (Neurology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
62263	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Required	Required	
62264	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Required	Required	
62287	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Required	Required	
62331	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Required	Required	
63032	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Required	Required	
63650	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Required	Required	
63655	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Required	Required	
63663	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Required	Required	
63664	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Required	Required	
63685	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Required	Required	
64454	Bone and Joint (Orthopedics)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
64555	Nervous System (Neurology)	Required	Required	Required	Not Required	Required	Required	Required	
64561	Nervous System (Neurology)	Required	Required	Not Required	Not Required	Not Required	Required	Not Required	
64567	Durable Medical Equipment	Required	Required	Required	Required	Required	Required	Required	
64568	Nervous System (Neurology)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Not Required	Not Required	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** G47.33
64581	Nervous System (Neurology)	Required	Required	Required	Not Required	Not Required	Not Required	Required	
64585	Nervous System (Neurology)	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
64590	Nervous System (Neurology)	Required	Required	Required	Not Required	Required	Required	Required	
64595	Nervous System (Neurology)	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
64624	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
64625	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
64628	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
64629	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
64999	Nervous System (Neurology)	Required	Required	Required	Not Required	Required	Required	Required	
66179	Eyes (Ophthalmology)	Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
66180	Eyes (Ophthalmology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
66183	Eyes (Ophthalmology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
67900	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Required	Required	Required	Required	
67901	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Not Required	Required	Required	
67902	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Required	Required	Required	Required	

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67903	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Required	Required	Required	Required	
67904	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Required	Required	Required	Required	
67906	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
67908	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Required	Required	Required	
67909	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Not Required	Not Required	Required	Required	Required	
67911	Reconstructive Surgery and/or Cosmetic Services	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
69300	Reconstructive Surgery and/or Cosmetic Services	Required	Required	Required	Not Required	Not Required	Required	Required	
69705	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Required	Not Required	Required	Not Required	Not Required	
69706	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Not Required	Required	Required	Required	Required	
69714	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
69717	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
69719	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
69730	Ears and Nose and Throat (Otorhinolaryngology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
69799	Ears and Nose and Throat (Otorhinolaryngology)	Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
75577	Radiology (Imaging) Services	Required	Required	Required	Required	Required	Required	Required	
77436	Radiation Therapy	Required	Required	Required	Required	Required	Required	Required	
77437	Radiation Therapy	Required	Required	Required	Required	Required	Required	Required	
77438	Radiation Therapy	Required	Required	Required	Required	Required	Required	Required	
77439	Radiation Therapy	Required	Required	Required	Required	Required	Required	Required	
81490	Laboratory	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
81599	Genetic Testing	Required	Required	Required	Not Required	Required	Required	Required	
86152	Laboratory	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
86153	Laboratory	Required	Required	Required	Required	Required	Not Required	Not Required	
89251	Womens Health (Obstetrics and Gynecology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
89253	Womens Health (Obstetrics and Gynecology)	Required	Required	Not Required	Not Required	Required	Not Required	Not Required	
90867	Behavioral Health (Psychology)	Required	Required	Required	Required	Required	Required	Required	
90868	Behavioral Health (Psychology)	Required	Required	Not Required	Required	Required	Required	Required	
90869	Behavioral Health (Psychology)	Required	Required	Required	Required	Required	Required	Required	
92145	Eyes (Ophthalmology)	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
92507	Therapy and Rehabilitation	Required for Ages 19 and Under	Required for Ages 19 and Under	Required for Ages 19 and Under	Not Required	Required for Ages 19 and Under	Required for Ages 19 and Under	Required for Ages 19 and Under	
92508	Therapy and Rehabilitation	Required for Ages 19 and Under	Required for Ages 19 and Under	Not Required	Not Required	Required for Ages 19 and Under	Not Required	Not Required	
92519	Nervous System (Neurology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
92526	Therapy and Rehabilitation	Required for Ages 19 and Under	Required for Ages 19 and Under	Required for Ages 19 and Under	Not Required	Required for Ages 19 and Under	Not Required	Not Required	
92972	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Not Required	Not Required	
93980	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
93981	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
95782	Sleep Medicine	Required	Required	Not Required	Not Required	Not Required	Required	Required	
95783	Sleep Medicine	Required	Required	Not Required	Not Required	Not Required	Required	Required	
95803	Sleep Medicine	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
95805	Sleep Medicine	Required	Required	Required	Not Required	Required	Required	Required	
95807	Sleep Medicine	Required	Required	Not Required	Not Required	Not Required	Required	Required	
95808	Sleep Medicine	Required	Required	Not Required	Not Required	Not Required	Required	Required	
95810	Sleep Medicine	Required	Required	Not Required	Required	Required	Required	Required	
95811	Sleep Medicine	Required	Required	Not Required	Required	Required	Required	Required	
97607	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
97608	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
97610	Skin (Dermatology)	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	

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98979	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
98984	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
98985	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
98986	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
99445	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
99470	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
A0140	Transportation	Not Required	Not Required	Required	Required	Required	Required	Required	
A0426	Transportation	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
A2001	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
A2002	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A2004	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A2005	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
A2008	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A2009	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A2010	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A2011	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A2012	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
A2013	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A2014	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A2015	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A2016	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A2017	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A2018	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A2019	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
A2020	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
A2021	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
A2026	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A2027	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
A2028	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
A2029	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
A2036	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
A2037	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
A2038	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
A2039	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
A4468	Durable Medical Equipment	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A4540	Durable Medical Equipment	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A4575	Durable Medical Equipment	Required	Required	Required	Required	Required	Required	Required	
A9272	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
A9282	Miscellaneous & Unlisted Codes	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
C1605	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
C1761	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
C1767	Nervous System (Neurology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
C1783	Eyes (Ophthalmology)	Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
C1813	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
C1821	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
C2614	Bone and Joint (Orthopedics)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
C2622	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	

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C7567	Lungs (Respiratory)	Required	Required	Required	Required	Required	Required	Required	
C9354	Skin (Dermatology)	Required	Required	Not Required	Required	Not Required	Required	Required	
C9356	Skin (Dermatology)	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
C9727	Sleep Medicine	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
C9734	Miscellaneous & Unlisted Codes	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
C9764	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
C9765	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
C9766	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
C9767	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
C9772	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
C9773	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
C9774	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
C9775	Heart and Blood Vessel (Cardiovascular)	Required	Required	Required	Required	Required	Required	Required	
C9785	Digestive System (Gastroenterology)	Required	Required	Not Required	Not Required	Required	Required	Required	
C9808	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
C9809	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Required	Required	
C9817	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Required	Required	
E0193	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Required	Required	
E0194	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0215	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E0217	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E0240	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0245	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0255	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0256	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E0260	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0261	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E0266	Durable Medical Equipment	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E0274	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	
E0277	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0290	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0291	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E0292	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0294	Durable Medical Equipment	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	
E0295	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0296	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0297	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0301	Durable Medical Equipment	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E0302	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0303	Durable Medical Equipment	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	
E0304	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	
E0316	Durable Medical Equipment	Y if rental or over 1K	Y if rental or if purchase over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0328	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E0371	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E0372	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E0445	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
E0446	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	

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E0466	Sleep Medicine	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0467	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
E0468	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0469	Lungs (Respiratory)	Required	Required	Required	Required	Required	Not Required	Not Required	
E0470	Durable Medical Equipment	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	
E0471	Durable Medical Equipment	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	
E0472	Durable Medical Equipment	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	
E0481	Lungs (Respiratory)	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0482	Lungs (Respiratory)	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E0483	Lungs (Respiratory)	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0485	Sleep Medicine	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
E0486	Lungs (Respiratory)	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	
E0490	Sleep Medicine	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
E0491	Sleep Medicine	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
E0492	Sleep Medicine	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
E0493	Sleep Medicine	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
E0500	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Required	Required	
E0561	Durable Medical Equipment	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	
E0562	Durable Medical Equipment	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	
E0601	Durable Medical Equipment	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	Required beyond Initial 3 month rental	
E0619	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E0625	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Not Required	Y if rental or over 1K	Required	Not Required	Not Required	
E0627	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Required	Required	
E0630	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Required	Required	
E0637	Home Care & Home Infusion Nursing Visits	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E0638	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0641	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0642	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0650	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0651	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	
E0652	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	
E0655	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Required	Required	Required	
E0656	Durable Medical Equipment	Not Required	Not Required	Required	Required	Not Required	Not Required	Not Required	
E0658	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0659	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0660	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0666	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Required	Required	
E0667	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0669	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E0670	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E0671	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0673	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0675	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E0676	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	
E0677	Durable Medical Equipment	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
E0678	Durable Medical Equipment	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
E0679	Durable Medical Equipment	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	

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E0680	Durable Medical Equipment	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
E0681	Durable Medical Equipment	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
E0682	Durable Medical Equipment	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
E0683	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E0691	Durable Medical Equipment	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	
E0692	Durable Medical Equipment	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	
E0693	Durable Medical Equipment	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	
E0694	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E0715	Urinary System(Genitourinary)	Required	Required	Required	Required	Required	Required	Required	
E0716	Durable Medical Equipment	Y if rental or over 1K	Y if rental or if purchase over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0721	Durable Medical Equipment	Required	Required	Required	Required	Required	Required	Required	
E0732	Durable Medical Equipment	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
E0733	Durable Medical Equipment	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
E0734	Durable Medical Equipment	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
E0735	Nervous System (Neurology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
E0736	Durable Medical Equipment	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
E0737	Durable Medical Equipment	Required	Required	Required	Required	Required	Required	Required	
E0738	Bone and Joint (Orthopedics)	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0739	Bone and Joint (Orthopedics)	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0743	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E0747	Bone and Joint (Orthopedics)	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	
E0748	Bone and Joint (Orthopedics)	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E0749	Bone and Joint (Orthopedics)	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	
E0760	Bone and Joint (Orthopedics)	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0764	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E0765	Digestive System (Gastroenterology)	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E0766	Cancer Treatment (Oncology)	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0767	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E0769	Durable Medical Equipment	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	
E0781	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E0782	Durable Medical Equipment	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
E0783	Durable Medical Equipment	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
E0791	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
E0856	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E0912	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E0935	Durable Medical Equipment	Not Required	Not Required	Y for purchases over 1K	Not Required	Not Required	Not Required	Not Required	
E0936	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Not Required	Not Required	
E0941	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E0945	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1002	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E1003	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E1004	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E1005	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E1006	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E1007	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E1008	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E1009	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	

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E1010	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E1011	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E1016	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1031	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1036	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1038	Durable Medical Equipment	Not Required	Not Required	Not Required	Y for purchases over 1K	Not Required	Not Required	Not Required	
E1039	Durable Medical Equipment	Not Required	Not Required	Not Required	Y for purchases over 1K	Not Required	Not Required	Not Required	
E1050	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1060	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1070	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1086	Durable Medical Equipment	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	
E1087	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1088	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1089	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1090	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1092	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1100	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1110	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1130	Durable Medical Equipment	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
E1140	Durable Medical Equipment	Not Required	Not Required	Required	Required	Not Required	Not Required	Not Required	
E1150	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1160	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1161	Durable Medical Equipment	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E1170	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1171	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1172	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1180	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1190	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1195	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1220	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1221	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E1222	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E1223	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E1224	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E1228	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E1229	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E1230	Durable Medical Equipment	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1231	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E1232	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E1233	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E1234	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E1235	Durable Medical Equipment	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1236	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E1237	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E1238	Durable Medical Equipment	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1239	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E1240	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	

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E1250	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1260	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1270	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1280	Durable Medical Equipment	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1285	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1290	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1295	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1298	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E1301	Durable Medical Equipment	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
E1800	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1801	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
E1802	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1803	Durable Medical Equipment	Required	Required	Required	Required	Required	Not Required	Not Required	
E1804	Durable Medical Equipment	Required	Required	Required	Required	Required	Not Required	Not Required	
E1807	Durable Medical Equipment	Required	Required	Required	Required	Required	Not Required	Not Required	
E1808	Durable Medical Equipment	Required	Required	Required	Required	Required	Not Required	Not Required	
E1810	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1811	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
E1813	Durable Medical Equipment	Required	Required	Required	Required	Required	Not Required	Not Required	
E1814	Durable Medical Equipment	Required	Required	Required	Required	Required	Not Required	Not Required	
E1815	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1818	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
E1822	Durable Medical Equipment	Required	Required	Required	Required	Required	Not Required	Not Required	
E1823	Durable Medical Equipment	Required	Required	Required	Required	Required	Not Required	Not Required	
E1826	Durable Medical Equipment	Required	Required	Required	Required	Required	Not Required	Not Required	
E1827	Durable Medical Equipment	Required	Required	Required	Required	Required	Not Required	Not Required	
E1828	Durable Medical Equipment	Required	Required	Required	Required	Required	Not Required	Not Required	
E1829	Durable Medical Equipment	Required	Required	Required	Required	Required	Not Required	Not Required	
E1830	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1840	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E1902	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E1905	Durable Medical Equipment	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
E2000	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E2204	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2228	Durable Medical Equipment	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E2230	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	
E2293	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E2294	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E2295	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E2298	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	Not Required	
E2301	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	
E2310	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2311	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2312	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2321	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E2322	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E2325	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	

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E2327	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2328	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2329	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2330	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2331	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2341	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E2343	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E2351	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E2358	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2359	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2366	Durable Medical Equipment	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
E2368	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2369	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2370	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2371	Durable Medical Equipment	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
E2373	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2374	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2375	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2376	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2377	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2378	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2397	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	
E2402	Skin (Dermatology)	Y for purchases over 1K	Y for purchases over 1K	Y for purchases over 1K	Not Required	Y for purchases over 1K	Y for purchases over 1K	Y for purchases over 1K	
E2500	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E2502	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E2504	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E2506	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E2508	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2510	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E2511	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E2512	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Required	Required	Required	
E2513	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Not Required	
E2599	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E2609	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2616	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2617	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2621	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2626	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E2627	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Y if rental or over 1K	Y if rental or over 1K	
E2628	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E2629	Durable Medical Equipment	Not Required	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	
E3000	Durable Medical Equipment	Not Required	Not Required	Y if rental or over 1K	Not Required	Not Required	Not Required	Not Required	
E3200	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
E8000	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Not Required	Not Required	
E8001	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Not Required	Not Required	
E8002	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Not Required	Y if rental or over 1K	Not Required	Not Required	
G0276	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	

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G0277	Miscellaneous & Unlisted Codes	Required	Required	Required	Required	Required	Not Required	Not Required	
G0341	Transplants	Required	Required	Not Required	Required	Required	Not Required	Not Required	
G0342	Transplants	Required	Required	Not Required	Required	Required	Not Required	Not Required	
G0343	Transplants	Required	Required	Not Required	Required	Required	Not Required	Not Required	
G0428	Bone and Joint (Orthopedics)	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
G0429	Sleep Medicine	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
G0555	Durable Medical Equipment	Required	Required	Required	Required	Required	Required	Required	
J0270	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
J2440	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
J2760	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
K0800	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
K0801	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
K0806	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
K0808	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
K0826	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
K0831	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
K0835	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
K0836	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
K0850	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
K0858	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
K0860	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
K0861	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
K0862	Durable Medical Equipment	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
L1007	Bone and Joint (Orthopedics)	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
L3999	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
L5657	Miscellaneous & Unlisted Codes	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
L5856	Durable Medical Equipment	Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
L5857	Durable Medical Equipment	Required	Required	Not Required	Not Required	Required	Required	Required	
L5858	Durable Medical Equipment	Required	Required	Not Required	Not Required	Required	Not Required	Not Required	
L5973	Durable Medical Equipment	Not Required	Not Required	Not Required	Required	Required	Not Required	Required	
L5990	Durable Medical Equipment	Not Required	Not Required	Not Required	Required	Not Required	Required	Not Required	
L6034	Miscellaneous & Unlisted Codes	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
L6035	Miscellaneous & Unlisted Codes	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
L6036	Miscellaneous & Unlisted Codes	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
L6038	Miscellaneous & Unlisted Codes	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
L6039	Miscellaneous & Unlisted Codes	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	Y if rental or over 1K	
L7900	Urinary System(Genitourinary)	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
L7902	Erectile Dysfunction	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
L8600	Reconstructive Surgery and/or Cosmetic Services	Not Required	Required	Not Required	Required	Not Required	Not Required	Not Required	
L8604	Urinary System(Genitourinary)	Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
L8605	Urinary System(Genitourinary)	Required	Required	Not Required	Not Required	Required	Not Required	Not Required	
L8612	Eyes (Ophthalmology)	Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
L8701	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
L8702	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Not Required	Not Required	
M0075	Miscellaneous & Unlisted Codes	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
M0076	Bone and Joint (Orthopedics)	Required	Required	Required	Required	Required	Required	Required	
Q2026	Skin (Dermatology)	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	

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Q4101	Skin (Dermatology)	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Not Required	
Q4108	Skin (Dermatology)	Required	Required	Required	Required	Not Required	Required	Required	
Q4111	Skin (Dermatology)	Required	Required	Not Required	Not Required	Required	Not Required	Not Required	
Q4112	Skin (Dermatology)	Required	Required	Required	Required	Not Required	Required	Required	
Q4113	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4114	Skin (Dermatology)	Required	Required	Required	Required	Not Required	Not Required	Not Required	
Q4115	Skin (Dermatology)	Required	Required	Required	Required	Not Required	Required	Required	
Q4116	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4118	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4122	Skin (Dermatology)	Required	Required	Required	Required	Not Required	Required	Required	
Q4123	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4125	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Required	Required	
Q4126	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4127	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4128	Skin (Dermatology)	Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4130	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4133	Skin (Dermatology)	Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4134	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4135	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Required	Required	
Q4136	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4137	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4140	Skin (Dermatology)	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Q4141	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4142	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Required	Required	
Q4143	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Required	Required	
Q4145	Skin (Dermatology)	Required	Required	Not Required	Required	Required	Required	Required	
Q4146	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4147	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4148	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4149	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Required	Required	
Q4150	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Required	Required	
Q4152	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4153	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4154	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4155	Skin (Dermatology)	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Q4156	Skin (Dermatology)	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Q4157	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4158	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Required	Required	
Q4159	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4160	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4161	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4162	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4163	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4164	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4165	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4166	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4167	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Required	Required	

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Q4169	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4171	Skin (Dermatology)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
Q4173	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4175	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4176	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4177	Skin (Dermatology)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
Q4178	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4179	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4180	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4181	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4183	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4184	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4185	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4186	Skin (Dermatology)	Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4188	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4189	Skin (Dermatology)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
Q4190	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4191	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4192	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4193	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4194	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4195	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4196	Skin (Dermatology)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
Q4197	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4198	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4199	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4200	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4201	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4212	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4217	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4224	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Required	Required	
Q4225	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4229	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4230	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4232	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4233	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4234	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4235	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4236	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4237	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4238	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4239	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4240	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4241	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4242	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4245	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4246	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	

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Q4247	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4248	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4249	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4250	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4251	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4252	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4253	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4254	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4255	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4256	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4257	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4258	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4259	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4260	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4261	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4262	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4263	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4264	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4265	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4266	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4267	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4268	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4269	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4270	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4271	Skin (Dermatology)	Required	Required	Required	Required	Required	Not Required	Not Required	
Q4272	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4273	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4274	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4275	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4276	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4278	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4279	Skin (Dermatology)	Required	Required	Required	Not Required	Required	Not Required	Not Required	
Q4280	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4281	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4282	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4283	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4284	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4285	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4286	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4287	Skin (Dermatology)	Required	Required	Required	Not Required	Required	Not Required	Not Required	
Q4288	Skin (Dermatology)	Required	Required	Required	Not Required	Required	Not Required	Not Required	
Q4289	Skin (Dermatology)	Required	Required	Required	Not Required	Required	Not Required	Not Required	
Q4290	Skin (Dermatology)	Required	Required	Required	Not Required	Required	Not Required	Not Required	
Q4291	Skin (Dermatology)	Required	Required	Required	Not Required	Required	Not Required	Not Required	
Q4292	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4293	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4294	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	

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Q4295	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4296	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4297	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4298	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4299	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4300	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4301	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4302	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4303	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4304	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4305	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4306	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4307	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4308	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4309	Skin (Dermatology)	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Q4310	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4311	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4312	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4313	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4314	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4315	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4316	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4317	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4318	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4319	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4320	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4321	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4322	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4323	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4324	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4325	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4326	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4327	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4328	Skin (Dermatology)	Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
Q4329	Skin (Dermatology)	Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
Q4330	Skin (Dermatology)	Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
Q4331	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4332	Skin (Dermatology)	Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Q4333	Skin (Dermatology)	Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
Q4334	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4335	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4336	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4337	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4338	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4339	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4340	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4341	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	

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Q4342	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4343	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4344	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4345	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4346	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4347	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4348	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4349	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4350	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4351	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4352	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4353	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4368	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4369	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4370	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4371	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4372	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4373	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4375	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4376	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4377	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4378	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4379	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4380	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4382	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4383	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4384	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4385	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4386	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4387	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4388	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4389	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4390	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4391	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4392	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4393	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4394	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4395	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4396	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4397	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4398	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4399	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4400	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4401	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4402	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4403	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4404	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	

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Q4405	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4406	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4407	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4408	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4409	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4410	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4411	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4412	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4413	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4414	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4415	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4416	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4417	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q4420	Skin (Dermatology)	Required	Required	Required	Required	Required	Required	Required	
Q5160	Medical Specialty Drug	Required	Not Required	Required	Required	Required	Required	Required	
S1030	Diabetes (Endocrinology)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
S1031	Diabetes (Endocrinology)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
S2053	Transplants	Not Required	Not Required	Not Required	Required	Required	Required	Required	
S2054	Transplants	Not Required	Not Required	Not Required	Required	Required	Required	Required	
S2065	Transplants	Not Required	Required	Not Required	Required	Required	Required	Required	
S2066	Reconstructive Surgery and/or Cosmetic Services	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	Required (by diagnosis)	PA is **Required** for All diagnosis codes **EXCEPT:** Z42.1, Z90.1, Z90.10, Z90.11, Z90.12, Z90.13
S2102	Transplants	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
S2120	Blood Disorder (Hematology)	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
S2150	Transplants	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
S5102	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
S5125	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
S5160	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
S5161	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
S8080	Radiology (Imaging) Services	Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
S9055	Skin (Dermatology)	Required	Required	Not Required	Required	Required	Not Required	Not Required	
S9123	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
S9124	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
S9960	Transportation	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
S9961	Transportation	Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
T1000	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
T1001	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
T1002	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
T1003	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
T1019	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
T1020	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
T2024	Home Care & Home Infusion Nursing Visits	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
T2034HE	Miscellaneous & Unlisted Codes	Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required	Notification Required	
T2034ET	Miscellaneous & Unlisted Codes	Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required	Notification Required	
T5001	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
V5014	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
V5140	Durable Medical Equipment	Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Inpatient Mental Health Admissions		Notification Required	Notification Required	Notification Required	Notification Required	Notification Required	Notification Required	Notification Required	

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Inpatient Substance Use Rehabilitation Admissions		Required	Required	Not Required	Not Required	Required	Not Required	Not Required	
Inpatient Substance Use Detoxification Admissions		Notification Required within 2 Business Days	Required	Not Required	Not Required	Notification Required within 2 Business Days	Notification Required within 2 Business Days	Notification Required within 2 Business Days	
Inpatient Residential Mental Health Admissions		Notification Required	Notification Required	Notification Required	Notification Required	Notification Required	Notification Required	Notification Required	
Inpatient Residential Substance Use Admissions		Notification Required	Required	Required	Notification Required	Notification Required	Notification Required	Notification Required	
0004M	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0006M	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0007M	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0011M	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0012M	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0013M	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0016M	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0017M	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0020M	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0202T	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
0213T	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
0216T	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
0219T	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
0220T	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
0221T	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
0274T	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
0345T	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
0571T	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
0572T	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
0573T	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
0574T	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
0580T	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
0614T	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
0695T	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
0001U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0005U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0016U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0017U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0018U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0019U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0022U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0023U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0026U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0027U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0030U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0032U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0034U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0036U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0037U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0040U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0045U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0046U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0047U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	

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0048U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0049U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0050U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0055U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0060U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0069U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0070U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0071U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0072U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0073U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0074U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0075U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0076U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0078U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0084U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0087U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0088U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0089U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0090U	Cancer Treatment (Oncology)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0091U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0094U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0101U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0102U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0103U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0111U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0113U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0114U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0118U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0120U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0129U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0130U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0133U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0134U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0136U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0137U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0138U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0153U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0154U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0155U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0156U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0157U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0158U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0159U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0160U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0161U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0162U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0169U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	

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0170U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0171U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0172U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0173U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0175U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0177U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0179U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0180U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0181U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0182U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0183U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0184U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0185U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0186U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0187U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0188U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0189U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0190U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0191U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0192U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0193U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0194U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0195U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0196U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0197U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0198U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0199U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0200U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0201U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0203U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0205U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0209U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0211U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0212U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0213U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0214U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0215U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0216U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0217U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0218U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0221U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0222U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0229U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0230U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0231U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0232U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0233U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	

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0234U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0235U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0236U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0237U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0238U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0239U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0242U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0244U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0245U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0246U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0250U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0252U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0253U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0254U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0258U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0260U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0262U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0264U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0265U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0266U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0267U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0268U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0269U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0270U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0271U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0272U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0273U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0274U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0276U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0277U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0278U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0282U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0285U	Miscellaneous & Unlisted Codes	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0286U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0287U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0288U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0289U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0290U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0291U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0292U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0293U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0294U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0296U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0297U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0298U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0299U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0300U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	

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0306U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0307U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0313U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0314U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0315U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0318U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0319U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0320U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0326U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0327U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0329U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0331U	Miscellaneous & Unlisted Codes	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0332U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0333U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0334U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0335U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0336U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0339U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0340U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0341U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0343U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0345U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0347U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0348U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0349U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0350U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0355U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0356U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0362U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0363U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0364U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0368U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0378U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0379U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0388U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0389U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0391U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0392U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0396U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0398U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0400U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0401U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0403U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0405U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0409U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0410U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0411U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	

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0413U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0417U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0419U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0420U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0421U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0422U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0424U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0425U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0426U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0433U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0434U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0437U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0438U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0439U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0440U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0444U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0449U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0452U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0453U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0454U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0460U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0461U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0465U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0466U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0467U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0469U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0471U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0473U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0474U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0475U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0476U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0477U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0478U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0481U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0485U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0486U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0487U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0488U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0489U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0493U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0494U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0495U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0496U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0497U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0498U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0499U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0500U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	

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0501U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0506U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0507U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0510U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0512U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0513U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0516U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
0523U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0529U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0530U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0532U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0533U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0534U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0536U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0537U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0538U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0539U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0540U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0543U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0549U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0552U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0553U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0554U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0555U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0560U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0561U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0562U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0565U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0566U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0567U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0569U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0571U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0575U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0576U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0578U	Cancer Treatment (Oncology)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0582U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0583U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0586U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0592U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0597U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0602U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0605U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
0611U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0612U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0613U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0616U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0617U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

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0618U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0619U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0620U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0621U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0622U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0623U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0624U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0625U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0626U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0627U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0628U	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0630U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0631U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0632U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0633U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0634U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0635U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0641U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0642U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0643U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0644U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0645U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0646U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0647U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0648U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0649U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0650U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0651U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0652U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0653U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0657U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0658U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0659U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0662U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0663U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0664U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0665U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0668U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0670U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0671U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0672U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0673U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0674U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0675U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0676U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0677U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0678U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0679U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0680U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0681U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0682U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0683U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0684U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0685U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0686U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0687U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0688U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0689U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0690U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0691U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0693U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

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0695U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0696U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
0697U	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
22206	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22207	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22210	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22212	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22214	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22220	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22222	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22224	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22510	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22511	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22513	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22514	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22526	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22532	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22533	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22548	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22551	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22554	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22556	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22558	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22586	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22590	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22595	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22600	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22610	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22612	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22630	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22633	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22800	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22802	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22804	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22808	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22810	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22812	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22818	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22819	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22849	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22850	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22852	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22855	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22856	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22857	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22861	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22862	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22864	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22865	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
22867	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
22869	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
23031	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23035	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23040	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23044	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23100	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23101	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23107	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23120	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23125	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23130	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23140	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23145	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23146	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23150	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23155	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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23170	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23172	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23174	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23180	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23182	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23184	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23190	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23195	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23200	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23210	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23220	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23334	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23335	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23400	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23405	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23406	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23410	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23412	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23415	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23420	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23430	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23440	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23450	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23455	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23460	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	

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23462	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23465	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23466	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23470	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
23472	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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23700	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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27005	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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27025	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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27050	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27052	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27054	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27057	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27060	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27062	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27065	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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27071	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27075	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27076	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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27078	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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27125	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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27137	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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27140	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27146	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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27176	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27177	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27178	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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27284	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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27301	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27303	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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27331	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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27334	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27335	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27340	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27347	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27355	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27356	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27357	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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27365	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27372	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27403	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27405	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	

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27407	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27409	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27412	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
27415	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27416	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27418	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27420	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27422	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27424	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27425	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27427	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27428	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
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27466	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27470	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27472	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27486	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27487	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27488	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27495	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27516	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27517	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27519	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27570	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
27580	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29805	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29806	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29807	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29819	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29820	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29821	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29822	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29823	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29824	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29825	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29827	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29828	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29850	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29851	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29855	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29856	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29860	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29861	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29862	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29863	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29866	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29867	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29868	Miscellaneous & Unlisted Codes	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29870	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29871	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29873	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29874	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29875	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29876	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29877	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29879	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29880	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29881	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29882	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29883	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29884	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29885	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29886	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29887	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29888	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29889	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29914	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29915	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
29916	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33202	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33203	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33206	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33207	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33208	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	

Procedure Code	Category	Commercial Fully Insured (Commercial Products, but not limited to: HMO, PPO, HDPPO, EPO, HDEPO & HNY HMO)	Self-Funded (Self-Funded Products, but not limited to: HMO, PPO, EPO & POS)	Medicare Advantage	Child Health Plus (CHP)	Special Programs (Healthy NY & Essential Plan)	Medicaid Managed Care (Select Plan)	Health and Recovery Plan (HARP)	Diagnosis Requirements (if applicable)
33210	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33211	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33212	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33213	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33214	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33215	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33216	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33217	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33218	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33220	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33221	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33222	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33223	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33224	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33226	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33227	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33228	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33229	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33230	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33231	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33233	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33234	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33235	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33236	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33237	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33238	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33240	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33241	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33243	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33244	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33249	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33262	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
33263	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
33264	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33270	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33271	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33272	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33273	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33274	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
33275	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
33285	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33286	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33289	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
33340	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
33361	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33362	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33363	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	

Procedure Code	Category	Commercial Fully Insured (Commercial Products, but not limited to: HMO, PPO, HDPPO, EPO, HDEPO & HNY HMO)	Self-Funded (Self-Funded Products, but not limited to: HMO, PPO, EPO & POS)	Medicare Advantage	Child Health Plus (CHP)	Special Programs (Healthy NY & Essential Plan)	Medicaid Managed Care (Select Plan)	Health and Recovery Plan (HARP)	Diagnosis Requirements (if applicable)
33364	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33365	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33366	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33418	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33975	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33976	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33977	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33978	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33979	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33980	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33981	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33982	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33983	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33990	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33991	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33992	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33993	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
33995	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
62320	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
62321	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
62322	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
62323	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
62330	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
62380	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
63001	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63003	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63005	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63011	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63012	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63015	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63016	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63017	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63020	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63030	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63040	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63042	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63045	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63046	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63047	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63050	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63051	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63055	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63056	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63064	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63075	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63077	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63081	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63085	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63087	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63090	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63101	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63102	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63185	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63190	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63191	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63197	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63200	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63250	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63251	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63252	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63300	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63301	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63302	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63303	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63304	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63305	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63306	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
63307	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
64451	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
64479	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
64483	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
64490	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
64493	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
64633	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
64635	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	

Procedure Code	Category	Commercial Fully Insured (Commercial Products, but not limited to: HMO, PPO, HDPPO, EPO, HDEPO & HNY HMO)	Self-Funded (Self-Funded Products, but not limited to: HMO, PPO, EPO & POS)	Medicare Advantage	Child Health Plus (CHP)	Special Programs (Healthy NY & Essential Plan)	Medicaid Managed Care (Select Plan)	Health and Recovery Plan (HARP)	Diagnosis Requirements (if applicable)
70336	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70450	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70460	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70470	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70471	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70480	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70481	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70482	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70486	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70487	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70488	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70490	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70491	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70492	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70496	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70498	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70540	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70542	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70543	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70544	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70545	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70546	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70547	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70548	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70549	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70551	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70552	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70553	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
70554	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
70555	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
71250	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
71260	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
71270	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
71271	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
71275	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
71550	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
71551	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
71552	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
71555	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72125	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72126	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72127	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72128	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72129	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72130	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72131	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72132	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72133	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72141	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72142	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72146	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72147	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72148	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72149	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72156	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72157	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72158	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72159	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72191	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72192	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72193	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72194	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72195	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72196	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72197	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
72198	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73200	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73201	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73202	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73206	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73218	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73219	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73220	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73221	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73222	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73223	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73225	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73700	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73701	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73702	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73706	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73718	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73719	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73720	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73721	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73722	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73723	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
73725	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
74150	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
74160	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
74170	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
74174	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

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74175	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
74176	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
74177	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
74178	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
74181	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
74182	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
74183	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
74185	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
74261	Digestive System (Gastroenterology)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
74262	Digestive System (Gastroenterology)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
74263	Digestive System (Gastroenterology)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
74712	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
75557	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
75559	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
75561	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
75563	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
75572	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
75573	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
75635	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
76380	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
76390	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
76391	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
77046	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
77047	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
77048	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
77049	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
77084	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78429	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78430	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78431	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78432	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78433	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78451	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78452	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78453	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78454	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78459	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78466	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78468	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78469	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78472	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78473	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78481	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78483	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78491	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78492	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78494	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78608	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78609	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78811	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78812	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78813	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78814	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78815	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
78816	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81105	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81106	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81107	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81108	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81109	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81110	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81111	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81112	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81120	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81121	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81161	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81162	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81163	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81164	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81165	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81166	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81167	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81168	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81170	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81171	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81172	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81173	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81174	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81175	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81176	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81177	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81178	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81179	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81180	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81181	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81182	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81183	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81184	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81185	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81186	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81187	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81188	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Procedure Code	Category	Commercial Fully Insured (Commercial Products, but not limited to: HMO, PPO, HDPPO, EPO, HDEPO & HNY HMO)	Self-Funded (Self-Funded Products, but not limited to: HMO, PPO, EPO & POS)	Medicare Advantage	Child Health Plus (CHP)	Special Programs (Healthy NY & Essential Plan)	Medicaid Managed Care (Select Plan)	Health and Recovery Plan (HARP)	Diagnosis Requirements (if applicable)
81189	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81190	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81191	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81192	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81193	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81194	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81195	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81200	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81201	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81202	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81203	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81204	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81205	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81206	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81207	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81208	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81209	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81210	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81212	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81215	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81216	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81217	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81218	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81219	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81221	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81222	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81223	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81224	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81225	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81226	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81227	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81228	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81229	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81230	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81231	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81232	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81233	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81234	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81235	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81236	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81237	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81238	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81239	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81240	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81241	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81242	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81243	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81244	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81245	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81246	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81247	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81248	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81249	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81250	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81251	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81252	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81253	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81254	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81255	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81256	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81257	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81258	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81259	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81260	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81261	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81262	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81263	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81264	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81265	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81266	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81267	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81268	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81269	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81270	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81271	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81272	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81273	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81274	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81275	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81276	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81277	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81278	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81279	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81283	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81284	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81285	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81286	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81287	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81288	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81289	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81290	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81291	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	

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81292	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81293	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81294	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81295	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81296	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81297	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81298	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81299	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81300	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81301	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81302	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81303	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81304	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81305	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81306	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81307	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81308	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81309	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81310	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81311	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81312	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81313	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81314	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81315	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81316	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81317	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81318	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81319	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81320	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81321	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81322	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81323	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81324	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81325	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81326	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81327	Digestive System (Gastroenterology)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81328	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81330	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81331	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81332	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81333	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81334	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81335	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81336	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81337	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81338	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81339	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81340	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81341	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81342	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81343	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81344	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81345	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81346	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81347	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81348	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81349	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81350	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81351	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81352	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81353	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81354	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81355	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81357	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81360	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81361	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81362	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81363	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81364	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81370	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81371	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81372	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81373	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81374	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81375	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81376	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81377	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81378	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81379	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81380	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81381	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81382	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81383	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81400	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81401	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81402	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81403	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81404	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81405	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81406	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81407	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81408	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Procedure Code	Category	Commercial Fully Insured (Commercial Products, but not limited to: HMO, PPO, HDPPO, EPO, HDEPO & HNY HMO)	Self-Funded (Self-Funded Products, but not limited to: HMO, PPO, EPO & POS)	Medicare Advantage	Child Health Plus (CHP)	Special Programs (Healthy NY & Essential Plan)	Medicaid Managed Care (Select Plan)	Health and Recovery Plan (HARP)	Diagnosis Requirements (if applicable)
81410	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81411	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81412	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81413	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81414	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81415	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81416	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81417	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81418	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81419	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81422	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81425	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81426	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81427	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81430	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81431	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81432	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81434	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81435	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81437	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81439	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81440	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81441	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81442	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81443	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81445	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81448	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81449	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81450	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81451	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81455	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81456	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81457	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81458	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81459	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81460	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81462	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81463	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81464	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81465	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81470	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81471	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81479	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81493	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81504	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81507	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81518	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81519	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81520	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81521	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81522	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81523	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81524	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
81525	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81529	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81540	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81541	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81542	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81546	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81551	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81552	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81554	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81558	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
81595	Laboratory	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93228	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
93229	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
93264	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
93451	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93452	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93453	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93454	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93455	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93456	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93457	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93458	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93459	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93460	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93461	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Procedure Code	Category	Commercial Fully Insured (Commercial Products, but not limited to: HMO, PPO, HDPPO, EPO, HDEPO & HNY HMO)	Self-Funded (Self-Funded Products, but not limited to: HMO, PPO, EPO & POS)	Medicare Advantage	Child Health Plus (CHP)	Special Programs (Healthy NY & Essential Plan)	Medicaid Managed Care (Select Plan)	Health and Recovery Plan (HARP)	Diagnosis Requirements (if applicable)
93593	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93594	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93595	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93596	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93597	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
93642	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
93745	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
A9587	Radiology (Imaging) Services	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Not Required	Not Required	PA is **Required** for the following diagnosis codes: C61, Z8546, R9721, C7982, D075, D291, D400 & D4959
A9593	Radiology (Imaging) Services	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	PA is **Required** for the following diagnosis codes: C61, Z8546, R9721, C7982, D075, D291, D400 & D4959
A9594	Radiology (Imaging) Services	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	PA is **Required** for the following diagnosis codes: C61, Z8546, R9721, C7982, D075, D291, D400 & D4959
A9595	Radiology (Imaging) Services	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	PA is **Required** for the following diagnosis codes: C61, Z8546, R9721, C7982, D075, D291, D400 & D4959
A9596	Radiology (Imaging) Services	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	PA is **Required** for the following diagnosis codes: C61, Z8546, R9721, C7982, D075, D291, D400 & D4959
A9597	Radiology (Imaging) Services	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	PA is **Required** for the following diagnosis codes: C61, Z8546, R9721, C7982, D075, D291, D400 & D4959
A9608	Radiology (Imaging) Services	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	PA is **Required** for the following diagnosis codes: C61, Z8546, R9721, C7982, D075, D291, D400 & D4959
A9613	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
A9616	Radiology (Imaging) Services	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Required through Health Help (by diagnosis)	Not Required	Not Required	PA is **Required** for the following diagnosis codes: C61, Z8546, R9721, C7982, D075, D291, D400 & D4959
A9800	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C1721	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C1722	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C1764	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C1777	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C1779	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C1785	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C1786	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C1882	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C1895	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C1896	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C1898	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C1899	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C1900	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C2619	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C2620	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C2621	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C2624	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C8900	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8901	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8902	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8903	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8905	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8906	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8908	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8909	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8910	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8911	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8912	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8913	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8914	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8918	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8919	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8920	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8931	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8932	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8933	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8934	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8935	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C8936	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C9757	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
C9762	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
C9763	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
E0610	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
E0615	Durable Medical Equipment	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	

Procedure Code	Category	Commercial Fully Insured (Commercial Products, but not limited to: HMO, PPO, HDPPO, EPO, HDEPO & HNY HMO)	Self-Funded (Self-Funded Products, but not limited to: HMO, PPO, EPO & POS)	Medicare Advantage	Child Health Plus (CHP)	Special Programs (Healthy NY & Essential Plan)	Medicaid Managed Care (Select Plan)	Health and Recovery Plan (HARP)	Diagnosis Requirements (if applicable)
E0616	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
G0219	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
G0235	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
G0252	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
G0260	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
G0327	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
G0448	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
G9143	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	
K0606	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
K0607	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
K0608	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
K0609	Heart and Blood Vessel (Cardiovascular)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Not Required	Not Required	
S2118	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
S2350	Bone and Joint (Orthopedics)	Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required through Health Help	Required through Health Help	Required through Health Help	
S3800	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S3840	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S3841	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S3842	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S3844	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S3845	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S3846	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S3849	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S3850	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S3852	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S3853	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S3854	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S3861	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S3865	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S3866	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S3870	Genetic Testing	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S8037	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
S8042	Radiology (Imaging) Services	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

January 1, 2027

UTILIZATION MANAGEMENT STANDARD
CLINICAL REVIEW PREAUTHORIZATION LIST

The following services may require preauthorization regardless of place of service for the following lines of business:
Commercial products, Essential Plan, Medicare, and Managed Safety Net Products.
Please review the column that applies to the member's specific line of business.

Code Changes Are Highlighted In Grey

IMPORTANT

This list represents those services that require preauthorization with a clinical medical necessity review. Certain services require preauthorization or notification without requiring clinical review.
It is NOT inclusive of all insurance products and procedures requiring preauthorization.
If you have a strategic account, call Customer Care for PA requirements at:
(518) 641-3100 or toll free 1-877-724-2579
Mon. - Fri. 8 a.m. to 5 p.m.

Please verify specific coverage requirements before rendering service.

Please Note: There are some codes that require PA by diagnosis. These additional diagnosis details are included in the last column of this document.

The Category column identifies the medical category associated with a specific procedure code. By using either, the category listed on the PDF or the procedure code itself, users can navigate to the Corporate Medical Policy page: https://provider.cdphp.com/resources/medical-policies **to view all applicable medical policies within that category or related to the selected code.**
Please note that the medical necessity criteria applied during the review process are dependent on the member's plan and may not be outlined in a Corporate Medical Policy.
In some cases, criteria may instead be derived from InterQual®, eMedNY, or CMS guidelines.

To initiate preauthorization requests please follow the below service contact information:

Behavioral Health, Medical & Durable Medical Equipment:
Please go to the Provider Portal by going to this URL,
https://provider.cdphp.com

Health Help:
Phone Requests: Phone: 1-888-673-7038, Monday through Friday from 8:00 a.m. – 6:00 p.m.
Internet Request: https://www.healthhelp.com/guidelines/
Fax Requests:
STAT Case Request: PROD -866-872-1616
Standard Case Request: PROD -866-872-1611
Clinicals: PROD -866-872-1571

Is the code BH, DME, Health Help, or Medical?	Category	Procedure Code	Revenue Code	Rate Code	Commercial Fully Insured (Commercial Products, but not limited to: HMO, PPO, HDPPO, EPO, HDEPO & HNY HMO)	Self-Funded (Self-Funded Products, but not limited to: HMO, PPO, EPO & POS)	Medicare Advantage	Child Health Plus (CHP)	Special Programs (Healthy NY & Essential Plan)	Medicaid Managed Care (Select Plan)	Health and Recovery Plan (HARP)	Diagnosis Requirements (if applicable)
BH/Medical	Behavioral Health (Psychology)	90867			Required	Required	Not Required	Required	Required	Required	Required	
BH/Medical	Behavioral Health (Psychology)	90868			Required	Required	Not Required	Required	Required	Required	Required	
BH/Medical	Behavioral Health (Psychology)	90869			Required	Required	Not Required	Required	Required	Required	Required	
BH	Behavioral Health (Psychology)	0820T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	0821T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	0822T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	0889T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	0890T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	0891T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	0892T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	90899	None		Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	96130	None		Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	96130	0780		Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	96130	0789		Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	96130	0918		Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	96131	None		Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	96131	0780		Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	96131	0789		Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	96131	0918		Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	H0004	0911		Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required	Not Required	
BH	Behavioral Health (Psychology)	H0035	None		PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	Not Required	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	
BH	Behavioral Health (Psychology)	H0035	0900		PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	Not Required	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	
BH	Behavioral Health (Psychology)	H0035	0912		PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	Not Required	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	
BH	Behavioral Health (Psychology)	H0035	0913		PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	Not Required	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	
BH	Behavioral Health (Psychology)	H0036	None		Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required only for CORE (Community Oriented Recovery Empowerment)	
BH	Behavioral Health (Psychology)	H0036	0900		Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required only for CORE (Community Oriented Recovery Empowerment)	
BH	Behavioral Health (Psychology)	H0036	0911		Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required only for CORE (Community Oriented Recovery Empowerment)	

BH	Behavioral Health (Psychology)	H0038	None		Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required only for Children and Family Treatment and Support Services (CFTSS)	Notification Required only for CORE (Community Oriented Recovery Empowerment)	
BH	Behavioral Health (Psychology)	H0038	0900		Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required only for Children and Family Treatment and Support Services (CFTSS)	Notification Required only for CORE (Community Oriented Recovery Empowerment)	
BH	Behavioral Health (Psychology)	H0038	0911		Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required only for CORE (Community Oriented Recovery Empowerment)	
BH	Behavioral Health (Psychology)	H2012	None		Required	Required	Not Required	Not Required	Required	Not Required	Not Required	
BH Continuing Day Treatment	Behavioral Health (Psychology)	H2012	0907		Required	Required	Not Required	Not Required	Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	H2012	0919		Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Behavioral Health (Psychology)	H2014	None		Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required only for CORE (Community Oriented Recovery Empowerment)	
BH	Behavioral Health (Psychology)	H2014	0900		Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required only for CORE (Community Oriented Recovery Empowerment)	
BH	Behavioral Health (Psychology)	H2014	0911		Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required only for CORE (Community Oriented Recovery Empowerment)	
BH	Behavioral Health (Psychology)	H2014HA	0240	8012	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2014HAUK	0900	8003	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2014HAUK	0911	8003	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2014HAUN	0240	8013	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2014HAUP	0240	8014	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2014HAUKUN	0900	8004	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2014HAUKUN	0911	8004	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2014HAUKUP	0900	8005	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2014HAUKUP	0911	8005	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2015HA	0900	8009	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2015HA	0911	8009	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2015HAUN	0900	8010	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2015HAUN	0911	8010	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2015HAUP	0900	8011	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2015HAUP	0911	8011	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	

BH	Behavioral Health (Psychology)	H2017	None		Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required only for Children and Family Treatment and Support Services (CFTSS)	Notification Required only for CORE (Community Oriented Recovery Empowerment)	
BH	Behavioral Health (Psychology)	H2017	0900		Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required only for Children and Family Treatment and Support Services (CFTSS)	Notification Required only for CORE (Community Oriented Recovery Empowerment)	
BH	Behavioral Health (Psychology)	H2017	0911		Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required only for Children and Family Treatment and Support Services (CFTSS)	Notification Required only for CORE (Community Oriented Recovery Empowerment)	
BH	Behavioral Health (Psychology)	H2023	None		Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
BH	Behavioral Health (Psychology)	H2023	0900		Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
BH	Behavioral Health (Psychology)	H2023	0911		Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
BH	Behavioral Health (Psychology)	H2023HA	0900	8015	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2023HA	0911	8015	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	H2034	None		Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required	Notification Required	
BH	Behavioral Health (Psychology)	H2036	None		Notification Required	Notification Required	Not Required	Notification Required	Notification Required	Notification Required	Notification Required	
BH	Behavioral Health (Psychology)	H2036	0902		Notification Required	Notification Required	Not Required	Notification Required	Notification Required	Notification Required	Notification Required	
BH	Behavioral Health (Psychology)	H2036	1002		Notification Required	Notification Required	Not Required	Notification Required	Notification Required	Notification Required	Notification Required	
BH	Behavioral Health (Psychology)	S0201	None		PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	Required	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	
BH	Behavioral Health (Psychology)	S5150			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
BH	Behavioral Health (Psychology)	S5150HA	0900	8023	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5150HA	0911	8023	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5150HAHKHQ	0900	8026	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5150HAHKHQ	0911	8026	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5150HAHQ	0900	8027	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5150HAHQ	0911	8027	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5150HAET	0900	8028	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5150HAET	0911	8028	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5150HAUN		8065	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5150HAUN	0900	8065	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5150HAUN	0911	8065	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5150HB			Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required	Notification Required	
BH	Behavioral Health (Psychology)	S5150HR			Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required	Notification Required	
BH	Behavioral Health (Psychology)	S5151			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	

BH	Behavioral Health (Psychology)	S5151HA	0900	8024	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5151HA	0911	8024	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5151HAHK	0900	8025	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5151HAHK	0911	8025	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5151HAET	0900	8029	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5151HAET	0911	8029	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5151HAETHK	0900	8030	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5151HAETHK	0911	8030	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5151HAUN		8066	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5151HAUN	0900	8065	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5151HAUN	0911	8065	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	S5151HB			Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required	Notification Required	
BH (Excludes Chemical Dependency Diagnosis)	Behavioral Health (Psychology)	S9480	None		PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	Not Required	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	
BH (Excludes Chemical Dependency Diagnosis)	Behavioral Health (Psychology)	S9480	0905		PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	Not Required	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	
BH	Behavioral Health (Psychology)	T2013			Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
BH	Behavioral Health (Psychology)	T2015	None		Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
BH	Behavioral Health (Psychology)	T2015	0900		Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
BH	Behavioral Health (Psychology)	T2015	0911		Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
BH	Behavioral Health (Psychology)	T2015HA	0900	8006	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	T2015HA	0911	8006	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	T2015HAUN	0900	8007	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	T2015HAUN	0911	8007	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	T2015HAUP	0900	8008	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Behavioral Health (Psychology)	T2015HAUP	0911	8008	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	

BH	Therapy and Rehabilitation	T2017			Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
BH	Therapy and Rehabilitation	T2019	None		Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
BH	Therapy and Rehabilitation	T2020HA	0240	7933	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Therapy and Rehabilitation	T2020HAUN	0240	7934	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Therapy and Rehabilitation	T2020HAUP	0240	7935	Not Required	Not Required	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	Notification Required only for the initial service period of 60 days/96 units/24 hours; Prior Authorization Required for Concurrent Review beyond the intial service period.	Not Required	
BH	Miscellaneous & Unlisted Codes	T2034HE		4625	Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required	Notification Required	
BH	Miscellaneous & Unlisted Codes	T2034ET		4626	Not Required	Not Required	Not Required	Not Required	Not Required	Notification Required	Notification Required	
BH	Behavioral Health (Psychology)		0124		PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	Not Required	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	
BH	Behavioral Health (Psychology)		0126		PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	Not Required	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	
BH	Behavioral Health (Psychology)		0128		PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	Not Required	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	
BH	Behavioral Health (Psychology)		1002		PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	Not Required	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	
BH	Behavioral Health (Psychology)		1001		PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	Not Required	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	PLEASE READ IN FULL (If a service is Rendered in NYS, Notification is Required. If out of NYS, Authorization is Required)	
Inpatient Admissions (except routine Maternity) to any facility including hospital, elective and direct admit, behavioral health, substance abuse, and hospital to hospital transfers.	N/A	Inpatient Admissions (except routine Maternity) to any facility including hospital, elective and direct admit, behavioral health, substance abuse, and hospital to hospital transfers.			Required	Required	Required	Required	Required	Required	Required	
DME	Diabetes (Endocrinology)	A4238			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Diabetes (Endocrinology)	A4239			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	A4468			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	A4520			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	A4540			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	A4554			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	A4560			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	A4575			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	A4593			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	A6503			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Skin (Dermatology)	A9272			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	A9280			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	A9281			Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	A9282			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0193			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0194			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0215			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0217			Required	Required	Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0240			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0245			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0255			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0256			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0260			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0261			Required	Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0266			Not Required	Not Required	Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0274			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0277			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E0290			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0291			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0292			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0294			Not Required	Not Required	Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0295			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	

DME	Durable Medical Equipment	E0296			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0297			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0301			Not Required	Not Required	Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0302			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E0303			Not Required	Not Required	Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0304			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0316			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E0328			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0371			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0372			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0445			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0446			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Sleep Medicine	E0466			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E0467			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0468			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Sleep Medicine	E0472			Not Required	Not Required	Not Required	Required	Required	Required	Required	
DME	Lungs (Respiratory)	E0481			Required	Required	Not Required	Required	Required	Required	Required	
DME	Lungs (Respiratory)	E0482			Required	Required	Not Required	Not Required	Not Required	Required	Required	
DME	Lungs (Respiratory)	E0483			Required	Required	Required	Required	Required	Required	Required	
DME	Sleep Medicine	E0485			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Lungs (Respiratory)	E0486			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Sleep Medicine	E0490			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Sleep Medicine	E0491			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Sleep Medicine	E0492			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Sleep Medicine	E0493			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0500			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0619			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Home Care & Home Infusion Nursing Visits	E0625			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
DME	Home Care & Home Infusion Nursing Visits	E0627			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Home Care & Home Infusion Nursing Visits	E0630			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0637			Required	Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0638			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E0641			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E0642			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E0650			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E0651			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0652			Required	Required	Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0655			Not Required	Not Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E0656			Not Required	Not Required	Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0658			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0659			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0660			Not Required	Not Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E0666			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0667			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0669			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0670			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0671			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0673			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0675			Required	Required	Not Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0676			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0677			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0678			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0679			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0680			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0681			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0682			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0691			Not Required	Not Required	Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0692			Not Required	Not Required	Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0693			Not Required	Not Required	Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0694			Required	Required	Required	Required	Required	Not Required	Not Required	
DME	Urinary System(Genitourinary)	E0715			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0721			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0732			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0733			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0734			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	

DME	Nervous System (Neurology)	E0735			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0736			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	E0738			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	E0739			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	E0747			Required	Required	Required	Not Required	Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	E0748			Required	Required	Required	Required	Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	E0749			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	E0760			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E0764			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Digestive System (Gastroenterology)	E0765			Required	Required	Required	Required	Required	Not Required	Not Required	
DME	Cancer Treatment (Oncology)	E0766			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E0781			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0782			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0783			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0791			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E0856			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0912			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0935			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0936			Required	Required	Required	Not Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0941			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E0945			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1002			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E1003			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E1004			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E1005			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E1006			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E1007			Required	Required	Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E1008			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E1009			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E1010			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E1011			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E1016			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1022			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1023			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1031			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1036			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1038			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1039			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1050			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1060			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1070			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1086			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1087			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1088			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1089			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1090			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1092			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1100			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1110			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1130			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1140			Not Required	Not Required	Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1150			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1160			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1161			Not Required	Not Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E1170			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1171			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1172			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1180			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1190			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1195			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	

DME	Durable Medical Equipment	E1220			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1221			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1222			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1223			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1224			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1228			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E1229			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E1230			Not Required	Not Required	Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1231			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1232			Required	Required	Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1233			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E1234			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E1235			Not Required	Not Required	Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1236			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E1237			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1238			Not Required	Not Required	Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1239			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1240			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1250			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1260			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1270			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1280			Not Required	Not Required	Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1285			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1290			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1295			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1298			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E1301			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	E1800			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	E1801			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	E1802			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	E1810			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	E1811			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	E1815			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	E1818			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	E1830			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	E1840			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1902			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E1905			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2000			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Diabetes (Endocrinology)	E2102			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Diabetes (Endocrinology)	E2103			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2204			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2228			Required	Not Required	Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2230			Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2293			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2294			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2295			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2298			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2301			Required	Required	Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2310			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2311			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2312			Required	Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2321			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2322			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2325			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2327			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2328			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2329			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2330			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2331			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	

DME	Durable Medical Equipment	E2341			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2343			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2351			Required	Required	Not Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2358			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2359			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2366			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2368			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2369			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2370			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2371			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2373			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2374			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2375			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2376			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2377			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2378			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2397			Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
DME	Skin (Dermatology)	E2402			Required	Required	Required	Not Required	Required	Required	Required	
DME	Durable Medical Equipment	E2500			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E2502			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E2504			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E2506			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E2508			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2510			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E2511			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E2512			Not Required	Not Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E2599			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	E2609			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2616			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2617			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2621			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2626			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2627			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	E2628			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E2629			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	E8000			Required	Required	Required	Not Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E8001			Required	Required	Required	Not Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	E8002			Required	Required	Required	Not Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	K0002			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	K0005			Not Required	Not Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0006			Not Required	Not Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0007			Not Required	Not Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0008			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	K0009			Not Required	Not Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0010			Required	Required	Not Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	K0011			Not Required	Not Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0012			Required	Required	Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	K0013			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	K0014			Required	Required	Not Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	K0108			Not Required	Not Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0739			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	K0800			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0801			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0802			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0806			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0807			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0808			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0812			Required	Required	Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	K0813			Required	Required	Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	K0814			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0815			Required	Required	Not Required	Required	Required	Required	Required	

DME	Durable Medical Equipment	K0816			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0820			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0821			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0822			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0823			Not Required	Not Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0824			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0825			Not Required	Not Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0826			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0827			Required	Required	Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	K0828			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0829			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0830			Required	Required	Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	K0831			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0835			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0836			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0837			Required	Required	Required	Not Required	Required	Required	Required	
DME	Durable Medical Equipment	K0838			Required	Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	K0839			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0840			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0841			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0842			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0843			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0848			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0849			Required	Required	Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	K0850			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0851			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0852			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0853			Required	Required	Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	K0854			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0855			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0856			Required	Required	Required	Not Required	Required	Required	Required	
DME	Durable Medical Equipment	K0857			Required	Required	Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	K0858			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0859			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0860			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0861			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0862			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0863			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0864			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0868			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0869			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0870			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0871			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0877			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0878			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0879			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0880			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0884			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	K0885			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0886			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0890			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K0891			Required	Required	Not Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	K1037			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	L0720			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	L0999			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Bone and Joint (Orthopedics)	L1007			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	L1200			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Bone and Joint (Orthopedics)	L1300			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Bone and Joint (Orthopedics)	L1499			Required	Not Required	Not Required	Not Required	Required	Required	Required	
DME	Durable Medical Equipment	L1844			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	

DME	Durable Medical Equipment	L1846			Required	Required	Required	Required	Required	Required	Required	
DME	Bone and Joint (Orthopedics)	L1933			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	L1950			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Bone and Joint (Orthopedics)	L1952			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	L2006			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	L2034			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	L5020			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	L5050			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Miscellaneous & Unlisted Codes	L5657			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Miscellaneous & Unlisted Codes	L5827			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	L5828			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	L5856			Not Required	Not Required	Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	L5857			Required	Required	Required	Not Required	Required	Required	Required	
DME	Durable Medical Equipment	L5858			Required	Required	Required	Not Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	L5859			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	L5969			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	L5973			Required	Not Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	L5976			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	L5990			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
DME	Durable Medical Equipment	L5999			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	L6026			Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
DME	Miscellaneous & Unlisted Codes	L6034			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Miscellaneous & Unlisted Codes	L6035			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Miscellaneous & Unlisted Codes	L6036			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Miscellaneous & Unlisted Codes	L6038			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Miscellaneous & Unlisted Codes	L6039			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	L6621			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Miscellaneous & Unlisted Codes	L6700			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	L6880			Required	Required	Required	Required	Required	Required	Required	
DME	Durable Medical Equipment	L6882			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	L6925			Required	Not Required	Required	Required	Required	Not Required	Not Required	
DME	Durable Medical Equipment	L6930			Required	Required	Not Required	Not Required	Required	Not Required	Not Required	
DME	Miscellaneous & Unlisted Codes	L7406			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	L7499			Not Required	Not Required	Not Required	Required	Required	Required	Required	
DME	Urinary System(Genitourinary)	L7900			Not Required	Not Required	Required	Not Required	Not Required	Required	Required	
DME	Erectile Dysfunction	L7902			Not Required	Not Required	Required	Not Required	Not Required	Required	Required	
DME	Bone and Joint (Orthopedics)	L8692			Required	Required	Required	Required	Not Required	Required	Required	
DME	Bone and Joint (Orthopedics)	L8701			Required	Required	Required	Required	Required	Not Required	Not Required	
DME	Bone and Joint (Orthopedics)	L8702			Required	Required	Required	Required	Required	Not Required	Not Required	
DME	Diabetes (Endocrinology)	S1030			Required	Required	Not Required	Required	Required	Not Required	Not Required	
DME	Diabetes (Endocrinology)	S1031			Required	Required	Not Required	Required	Required	Not Required	Not Required	
DME	Childrens Health (Pediatric)	S1040			Required	Required	Not Required	Required	Not Required	Required	Not Required	
DME	Durable Medical Equipment	S5160			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	S5161			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	T4521			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	T4522			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	T4523			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	T4524			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	T4525			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	T4526			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	T4527			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	T4528			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	T4530			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	T4533			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	T4534			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	T4535			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	T4537			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	T4541			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
DME	Durable Medical Equipment	T5001			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	V5014			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
DME	Durable Medical Equipment	V5140			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	

Medical	Miscellaneous & Unlisted Codes	0071T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0072T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0075T			Required	Required	Required	Required	Required	Required	Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0076T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0174T			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Miscellaneous & Unlisted Codes	0184T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	0232T			Required	Required	Required	Not Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0278T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Nervous System (Neurology)	0333T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0335T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0339T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Blood Disorder (Hematology)	0342T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0345T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0358T			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Miscellaneous & Unlisted Codes	0379T			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Miscellaneous & Unlisted Codes	0397T			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0442T			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Diabetes (Endocrinology)	0446T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Diabetes (Endocrinology)	0447T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Diabetes (Endocrinology)	0448T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Eyes (Ophthalmology)	0474T			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	0479T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	0480T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0483T			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0484T			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0544T			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0545T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0569T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0570T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Transplants	0584T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Transplants	0585T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Transplants	0586T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Neuromuscular Stimulation and Electrical Shock Units	0587T			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0596T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0597T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0615T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0620T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0632T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0644T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0645T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0646T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0647T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Digestive System (Gastroenterology)	0651T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0652T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0653T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0672T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0673T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0686T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0687T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Eyes (Ophthalmology)	0688T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0692T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0693T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Eyes (Ophthalmology)	0704T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0707T			Required	Required	Not Required	Not Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0740T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0741T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Radiology (Imaging) Services	0743T			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0744T			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0745T			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0746T			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Digestive System (Gastroenterology)	0748T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0749T			Required	Required	Not Required	Required	Required	Not Required	Not Required	

Medical	Miscellaneous & Unlisted Codes	0750T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0751T			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0752T			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0753T			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0754T			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0755T			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0756T			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0757T			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0758T			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0759T			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0760T			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0761T			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0762T			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0763T			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0765T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0770T			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Alternative Medicine	0771T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0772T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0773T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0774T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0776T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0777T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Bone and Joint (Orthopedics)	0778T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0779T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Digestive System (Gastroenterology)	0780T			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0793T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Cancer Treatment (Oncology)	0794T			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0804T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0805T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0806T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Lungs (Respiratory)	0807T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Lungs (Respiratory)	0808T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0810T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0811T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0812T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Digestive System (Gastroenterology)	0813T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Radiology (Imaging) Services	0815T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Nervous System (Neurology)	0816T			Required	Required	Required	Required	Required	Required	Required	
Medical	Nervous System (Neurology)	0817T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0827T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0828T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0830T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0831T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0832T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0833T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0834T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0835T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0836T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0837T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0839T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0840T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0841T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0842T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0843T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0844T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0845T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0846T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0847T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0848T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0849T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0850T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0851T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0852T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0853T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0854T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0855T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0856T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0858T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0860T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Urinary System(Genitourinary)	0864T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0868T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0869T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0870T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0871T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0872T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0873T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0874T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0875T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0876T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0881T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	

Medical	Miscellaneous & Unlisted Codes	0884T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0885T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0886T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	0888T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0897T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Cancer Treatment (Oncology)	0898T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Nervous System (Neurology)	0908T			Required	Required	Required	Required	Required	Required	Required	
Medical	Nervous System (Neurology)	0911T			Required	Required	Required	Required	Required	Required	Required	
Medical	Nervous System (Neurology)	0912T			Required	Required	Required	Required	Required	Required	Required	
Medical	Miscellaneous & Unlisted Codes	0913T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0914T			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	0932T			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Urinary System(Genitourinary)	0941T			Required	Required	Required	Required	Required	Required	Required	
Medical	Urinary System(Genitourinary)	0942T			Required	Required	Required	Required	Required	Required	Required	
Medical	Urinary System(Genitourinary)	0943T			Required	Required	Required	Required	Required	Required	Required	
Medical	Urinary System(Genitourinary)	0963T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Digestive System (Gastroenterology)	0977T			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Nervous System (Neurology)	0988T			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Urinary System(Genitourinary)	0999T			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Urinary System(Genitourinary)	1000T			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Urinary System(Genitourinary)	1001T			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0035U			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0080U			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0092U			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0243U			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0261U			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0263U			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0308U			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0309U			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0312U			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0317U			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0344U			Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
Medical	Laboratory	0360U			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0375U			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0381U			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0382U			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0383U			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0384U			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0385U			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Laboratory	0387U			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0390U			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0394U			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0395U			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0399U			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0406U			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0407U			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0462U			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0468U			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	0514U			Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
Medical	Laboratory	0515U			Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	11920			Not Required	Not Required	Not Required	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for all diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	11950			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	11951			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	11952			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	11954			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Bone and Joint (Orthopedics)	13100			Not Required	Not Required	Not Required	Required (By Diagnosis - see last column)	Not Required	Not Required	Not Required	PA is **Required** for all diagnosis codes **EXCEPT**: C56.1, C56.2, C79.61, C79.62, C48.1.,C50.011, C50.012, C50.019, C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419, C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919, C56.3, C79.63, C79.81, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.10, Z90.11, Z90.12, Z90.14, C50A0, C50A1, C50A2, Z1505
Medical	Reconstructive Surgery and/or Cosmetic Services	13102			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	14000			Not Required	Not Required	Not Required	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Not Required	Not Required	PA is **Required** for all diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13

Medical	Reconstructive Surgery and/or Cosmetic Services	14301			Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	PA is **Required** for all diagnosis codes **EXCEPT:** C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Skin (Dermatology)	15011			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	15013			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	15015			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	15017			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15650			Not Required	Not Required	Not Required	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for all diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	15770			Not Required	Not Required	Not Required	Required (By Diagnosis - see last column)	Not Required	Not Required	Not Required	PA is **Required** for all diagnosis codes **EXCEPT**: C56.1, C56.2, C79.61, C79.62, C48.1,C50.011, C50.012, C50.019, C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419, C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919, C56.3, C79.63, C79.81, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.10, Z90.11, Z90.12, Z90.14, C50A0, C50A1, C50A2, Z1505
Medical	Reconstructive Surgery and/or Cosmetic Services	15771			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for all diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	15772			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for all diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	15773			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Not Required	Not Required	PA is **Required** for All Diagnosis Codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	15774			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Not Required	Not Required	PA is **Required** for All Diagnosis Codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	15775			Required	Required	Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15776			Required	Required	Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15780			Required	Required	Required	Not Required	Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15781			Required	Required	Not Required	Not Required	Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15782			Required	Required	Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15783			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15786			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15788			Required	Required	Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15789			Required	Required	Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15792			Required	Required	Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15793			Required	Required	Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15820			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15821			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15822			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15823			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15824			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15825			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15826			Required	Required	Required	Required	Required	Required	Required	

Medical	Reconstructive Surgery and/or Cosmetic Services	15828			Required	Required	Not Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15829			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15830			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15832			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15833			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15834			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15835			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15836			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15837			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15838			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15839			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15840			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15845			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15847			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15876			Required	Required	Not Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15877			Required	Required	Not Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15878			Required	Required	Not Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	15879			Required	Required	Not Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	17106			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	17107			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	17108			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	17360			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	17380			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	17999			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	19300			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	19316			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Not Required	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	19318			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Not Required	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	19325			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	19328			Not Required	Not Required	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z80.3, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	19330			Not Required	Not Required	Not Required	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13

Medical	Reconstructive Surgery and/or Cosmetic Services	19340			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	19342			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	19350			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	19355			Not Required	Not Required	Not Required	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	19357			Not Required	Not Required	Not Required	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	19370			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	19371			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	19380			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Reconstructive Surgery and/or Cosmetic Services	19499			Not Required	Not Required	Not Required	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for all diagnosis codes **EXCEPT**: C48.1, C50.011, C50.012, C50.019, C50.111, C50.112, C50.119, C50.211, C50.212, C50.219, C50.311, C50.312, C50.319, C50.411, C50.412, C50.419, C50.511, C50.512, C50.519, C50.611, C50.612, C50.619, C50.811, C50.812, C50.819, C50.911, C50.912, C50.919, C56.1, C56.2, C56.3, C79.61, C79.62, C79.63, C79.81, C84.7A, D05.00,D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z40.01, Z40.02, Z40.03, Z42.1, Z853, Z90.10, Z90.11, Z90.12, Z90.13, C50A0, C50A1, C50A2 & Z1505
Medical	Cancer Treatment (Oncology)	20982			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Cancer Treatment (Oncology)	20983			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21120			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21121			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21122			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21123			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21125			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21127			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21137			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21139			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Sleep Medicine	21141			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21142			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21143			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21145			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21146			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	

Medical	Reconstructive Surgery and/or Cosmetic Services	21147			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Sleep Medicine	21150			Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
Medical	Sleep Medicine	21151			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	
Medical	Sleep Medicine	21154			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Sleep Medicine	21155			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21159			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21172			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21175			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21179			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21180			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21181			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21182			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21183			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21184			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21188			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21193			Required	Required	Required	Required	Required	Required	Required	
Medical	Sleep Medicine	21194			Not Required	Not Required	Required	Required	Required	Required	Required	
Medical	Sleep Medicine	21195			Required	Required	Required	Required	Required	Required	Required	
Medical	Sleep Medicine	21196			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Sleep Medicine	21198			Not Required	Not Required	Required	Required	Required	Required	Required	
Medical	Sleep Medicine	21199			Not Required	Not Required	Required	Required	Required	Required	Required	
Medical	Sleep Medicine	21206			Not Required	Not Required	Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21208			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Bone and Joint (Orthopedics)	21240			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Bone and Joint (Orthopedics)	21242			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Bone and Joint (Orthopedics)	21243			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Sleep Medicine	21244			Not Required	Not Required	Required	Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21245			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21246			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21247			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21256			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21270			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21280			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21282			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21296			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21299			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21740			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21742			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	21743			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Bone and Joint (Orthopedics)	22836			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required
Medical	Bone and Joint (Orthopedics)	22837			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required
Medical	Bone and Joint (Orthopedics)	22838			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required
Medical	Bone and Joint (Orthopedics)	29800			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Bone and Joint (Orthopedics)	29804			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	30117			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	30120			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	30400			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	30410			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	30420			Required	Required	Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	30430			Required	Required	Not Required	Not Required	Not Required	Required	Required	

Medical	Reconstructive Surgery and/or Cosmetic Services	30435			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	30450			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	30462			Required	Required	Not Required	Required	Not Required	Required	Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	30468			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	30469			Required	Required	Required	Required	Required	Required	Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	30802			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	30999			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	31242			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	31243			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	31295			Required	Required	Required	Required	Required	Required	Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	31296			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	31297			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	31298			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	32664			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Transplants	32851			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Transplants	32852			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Transplants	32853			Required	Required	Not Required	Not Required	Required	Required	Required	
Medical	Transplants	32854			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Heart and Blood Vessel (Cardiovascular)	33258			Not Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	33265			Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	33340			Required	Required	Required	Not Required	Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	33361			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	33362			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	33363			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	33364			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	33365			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	33366			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	33418			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Transplants	33933			Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
Medical	Transplants	33935			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Transplants	33944			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Transplants	33945			Required	Required	Not Required	Not Required	Required	Required	Required	
Medical	Heart and Blood Vessel (Cardiovascular)	33999			Required	Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	34703			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Not Required	
Medical	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	34705			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	34841			Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
Medical	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	34842			Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
Medical	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	34843			Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
Medical	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	34844			Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
Medical	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	34846			Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
Medical	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	34847			Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
Medical	Endovascular Grafts for Abdominal Aortic & Thoracic Aneurysms	34848			Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	36465			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	36466			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	36470			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	36471			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	36475			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	36476			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	36478			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	

Medical	Reconstructive Surgery and/or Cosmetic Services	36479			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	36482			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	36483			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	36522			Not Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	37241			Required	Required	Not Required	Not Required	Required	Required	Required	
Medical	Urinary System(Genitourinary)	37242			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Not Required	Not Required	Not Required	Not Required	PA is **Required** for the following diagnosis codes: N40.1
Medical	Miscellaneous & Unlisted Codes	37262			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	37279			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	37700			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	37718			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	37722			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	37761			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	37765			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	37766			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	37780			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	37788			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	37790			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Transplants	38205			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Transplants	38206			Required	Required	Required	Not Required	Required	Not Required	Not Required	
Medical	Transplants	38210			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Transplants	38211			Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
Medical	Transplants	38230			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Transplants	38232			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Transplants	38240			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Transplants	38241			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Transplants	38242			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Sleep Medicine	41512			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Sleep Medicine	42145			Required	Required	Required	Required	Required	Required	Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	42835			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Digestive System (Gastroenterology)	43192			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Digestive System (Gastroenterology)	43201			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Digestive System (Gastroenterology)	43210			Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
Medical	Digestive System (Gastroenterology)	43236			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43284			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Digestive System (Gastroenterology)	43290			Required	Required	Required	Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43291			Required	Required	Required	Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43497			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43647			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43648			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43659			Required	Required	Not Required	Not Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43770			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43772			Required	Required	Required	Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43774			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43775			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43842			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43845			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43846			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43847			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43848			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43881			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43882			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43886			Required	Required	Required	Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43887			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43889			Required	Required	Required	Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	43999			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Transplants	44135			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Transplants	44136			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Digestive System (Gastroenterology)	47000			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Not Required	Not Required	Not Required	Not Required	Not Required	PA is **Required** for the following diagnosis codes: E66.01, E66.2, Z68.35, Z68.36, Z68.37, Z68.38, Z68.39, Z68.40, Z68.41, Z68.42, Z68.43, Z68.44, Z68.45, E66.0, E66.09, E66.3, E66.811, E66.812, E66.813, E66.89,E66.9
Medical	Digestive System (Gastroenterology)	47001			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Not Required	Not Required	Not Required	Not Required	Not Required	PA is **Required** for the following diagnosis codes: E66.01, E66.2, Z68.35, Z68.36, Z68.37, Z68.38, Z68.39, Z68.40, Z68.41, Z68.42, Z68.43, Z68.44, Z68.45, E66.0, E66.09, E66.3, E66.811, E66.812, E66.813, E66.89,E66.9
Medical	Digestive System (Gastroenterology)	47100			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Not Required	Not Required	Not Required	Not Required	Not Required	PA is **Required** for the following diagnosis codes: E66.01, E66.2, Z68.35, Z68.36, Z68.37, Z68.38, Z68.39, Z68.40, Z68.41, Z68.42, Z68.43, Z68.44, Z68.45, E66.0, E66.09, E66.3, E66.811, E66.812, E66.813, E66.89,E66.9

Medical	Transplants	47135			Required	Required	Required	Required	Required	Required	Required	
Medical	Cancer Treatment (Oncology)	47370			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Cancer Treatment (Oncology)	47371			Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Digestive System (Gastroenterology)	47379			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Not Required	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for the following diagnosis codes: E66.01, E66.2, Z68.35, Z68.36, Z68.37, Z68.38, Z68.39, Z68.40, Z68.41, Z68.42, Z68.43, Z68.44, Z68.45, E66.0, E66.09, E66.3, E66.811, E66.812, E66.813, E66.89,E66.9
Medical	Cancer Treatment (Oncology)	47381			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Cancer Treatment (Oncology)	47382			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Transplants	48160			Required	Required	Not Required	Required	Not Required	Required	Required	
Medical	Transplants	48554			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Transplants	50320			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Transplants	50360			Required	Required	Required	Required	Required	Required	Required	
Medical	Transplants	50365			Required	Required	Not Required	Not Required	Required	Required	Required	
Medical	Transplants	50370			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Transplants	50380			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Cancer Treatment (Oncology)	50592			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Cancer Treatment (Oncology)	50593			Required	Required	Required	Not Required	Not Required	Required	Not Required	
Medical	Urinary System(Genitourinary)	51715			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Urinary System(Genitourinary)	52284			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Urinary System(Genitourinary)	52441			Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Urinary System(Genitourinary)	52443			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Urinary System(Genitourinary)	52597			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Urinary System(Genitourinary)	53854			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Urinary System(Genitourinary)	53865			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Urinary System(Genitourinary)	53866			Not Required	Not Required	Not Required	Not Required	Required	Not Required	Required	
Medical	Erectile Dysfunction	54220			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	54230			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	54231			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	54235			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	54240			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	54250			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	54400			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	54401			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	54405			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	54406			Not Required	Not Required	Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	54408			Not Required	Not Required	Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	54410			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	54411			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	54415			Not Required	Not Required	Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	54416			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	54417			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Urinary System(Genitourinary)	54440			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Transplants	54680			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Erectile Dysfunction	55870			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Cancer Treatment (Oncology)	55873			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Urinary System(Genitourinary)	55877			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Urinary System(Genitourinary)	55880			Required	Required	Required	Not Required	Required	Not Required	Not Required	
Medical	Gender Affirmation	55970			Required	Required	Required	Not Required	Required	Not Required	Not Required	
Medical	Gender Affirmation	55980			Required	Required	Required	Not Required	Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	56620			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	56625			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Gender Affirmation	56805			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Womens Health (Obstetrics and Gynecology)	58150			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58152			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58180			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58260			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58262			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58263			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58270			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58280			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A

Medical	Womens Health (Obstetrics and Gynecology)	58285			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58290			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58291			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58292			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58294			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58541			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58542			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58543			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C56.3, C79.63, C51.8, C51.9, C52.0, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.9, C57.00, C57.01, C57.02, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.62, C79.61, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z1505, Z8044, Z854A, Z8600A
Medical	Womens Health (Obstetrics and Gynecology)	58544			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Not Required	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58550			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Not Required	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58552			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58553			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Not Required	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58554			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58570			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58571			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58572			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Womens Health (Obstetrics and Gynecology)	58573			Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	Required (By Diagnosis - see last column)	PA is **Required** for All diagnosis codes **EXCEPT**: C45.9, C51.0, C51.1, C51.2, C51.8, C51.9, C52, C53.0, C53.1, C53.8, C53.9, C54.0, C54.1, C54.2, C54.3, C54.8, C54.9, C55, C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.10, C57.11, C57.12, C57.20, C57.21, C57.22, C57.3, C57.4, C57.7, C57.8, C57.9, C58, C76.2, C76.3, C77.2, C77.5, C79.60, C79.61, C79.62, C79.63, C79.82, C79.89, C79.9, C80.0, C80.1, D06.0, D06.1, D06.7, D06.9, D07.0, D07.1, D07.2, D07.30, D07.39, Z15.04, Z15.05, Z80.44, Z85.4A, Z86.00A
Medical	Cancer Treatment (Oncology)	58580			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Cancer Treatment (Oncology)	58674			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Cancer Treatment (Oncology)	60660			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Cancer Treatment (Oncology)	60661			Required	Required	Required	Not Required	Required	Not Required	Required	
Medical	Nervous System (Neurology)	61715			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Miscellaneous & Unlisted Codes	61736			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Nervous System (Neurology)	61863			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Nervous System (Neurology)	61867			Not Required	Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Nervous System (Neurology)	61868			Not Required	Not Required	Not Required	Required	Not Required	Required	Not Required	
Medical	Nervous System (Neurology)	61885			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Nervous System (Neurology)	61886			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Nervous System (Neurology)	64553			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	
Medical	Nervous System (Neurology)	64555			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Nervous System (Neurology)	64561			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Durable Medical Equipment	64567			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Nervous System (Neurology)	64568			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Nervous System (Neurology)	64581			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Sleep Medicine	64582			Required	Required	Not Required	Required	Required	Required	Required	

Medical	Nervous System (Neurology)	64590			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	64822			Not Required	Not Required	Not Required	Not Required	Required	Not Required	Not Required	
Medical	Eyes (Ophthalmology)	66179			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Eyes (Ophthalmology)	66180			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Eyes (Ophthalmology)	66183			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	67900			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	67901			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	67902			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	67903			Required	Required	Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	67904			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	67906			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	67908			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	67909			Required	Required	Not Required	Not Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	67911			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	67999			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	69300			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	69705			Required	Required	Required	Not Required	Required	Not Required	Not Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	69706			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	69714			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	69717			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	69719			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	69730			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	69799			Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Laboratory	81490			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Womens Health (Obstetrics and Gynecology)	89251			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Womens Health (Obstetrics and Gynecology)	89253			Required	Required	Not Required	Not Required	Required	Not Required	Not Required	
Medical	Digestive System (Gastroenterology)	91111			Required	Not Required	Required	Not Required	Not Required	Required	Required	
Medical	Digestive System (Gastroenterology)	91112			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Digestive System (Gastroenterology)	91113			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Eyes (Ophthalmology)	92145			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Therapy and Rehabilitation	92507			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Therapy and Rehabilitation	92508			Required	Required	Not Required	Not Required	Required	Required	Required	
Medical	Nervous System (Neurology)	92519			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Therapy and Rehabilitation	92526			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Miscellaneous & Unlisted Codes	92972			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	93452			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Required	
Medical	Heart and Blood Vessel (Cardiovascular)	93454			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Heart and Blood Vessel (Cardiovascular)	93458			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Heart and Blood Vessel (Cardiovascular)	93459			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Miscellaneous & Unlisted Codes	93702			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	93980			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	93981			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Sleep Medicine	95782			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Sleep Medicine	95783			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Sleep Medicine	95803			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Sleep Medicine	95805			Required	Required	Required	Not Required	Required	Required	Required	
Medical	Sleep Medicine	95807			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Sleep Medicine	95808			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Sleep Medicine	95810			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Sleep Medicine	95811			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Nervous System (Neurology)	96132			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Nervous System (Neurology)	96133			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Behavioral Health (Psychology)	96136			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Behavioral Health (Psychology)	96137			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Behavioral Health (Psychology)	96138			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Nervous System (Neurology)	96139			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	97607			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	

Medical	Skin (Dermatology)	97608			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Transportation	A0140			Not Required	Not Required	Required	Required	Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	A0426			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2001			Required	Required	Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	A2002			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2004			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2005			Required	Required	Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	A2007			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	A2008			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2009			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2010			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2011			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2012			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2013			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2014			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2015			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2016			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2017			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2018			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2019			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2020			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2021			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2026			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2027			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	A2028			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	A2029			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	A2030			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2031			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2032			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2033			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2034			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2035			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2036			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2037			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2038			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	A2039			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Durable Medical Equipment	A6512			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Durable Medical Equipment	A9999			Not Required	Not Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Heart and Blood Vessel (Cardiovascular)	C1761			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Nervous System (Neurology)	C1767			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Eyes (Ophthalmology)	C1783			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Erectile Dysfunction	C1813			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	C2622			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	C9354			Required	Required	Not Required	Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	C9356			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Sleep Medicine	C9727			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	C9734			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Miscellaneous & Unlisted Codes	C9764			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	C9765			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	C9766			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	C9767			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	C9772			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	C9773			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	C9774			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	C9775			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Digestive System (Gastroenterology)	C9785			Required	Required	Not Required	Not Required	Required	Required	Required	
Medical	Urinary System (Genitourinary)	E0201			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Sleep Medicine	E0470			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Sleep Medicine	E0471			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Sleep Medicine	E0601			Not Required	Not Required	Not Required	Not Required	Required	Required	Required	
Medical	Durable Medical Equipment	E0769			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Durable Medical Equipment	E1399			Required	Required	Required	Required	Required	Required	Required	
Medical	Durable Medical Equipment	E3000			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Miscellaneous & Unlisted Codes	G0277			Required	Required	Required	Required	Required	Required	Required	
Medical	Transplants	G0341			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Transplants	G0342			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Transplants	G0343			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Sleep Medicine	G0429			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Erectile Dysfunction	J0270			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	J2440			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Erectile Dysfunction	J2760			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Durable Medical Equipment	K0898			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Durable Medical Equipment	K0899			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Durable Medical Equipment	L2999			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Durable Medical Equipment	L3999			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Durable Medical Equipment	L8499			Required	Required	Required	Required	Required	Required	Required	
Medical	Reconstructive Surgery and/or Cosmetic Services	L8600			Not Required	Required (By Diagnosis - see last column)	Not Required	Required (By Diagnosis - see last column)	Not Required	Not Required	Not Required	PA is **Required** for All diagnosis codes **EXCEPT**: C48.1, C50.019, C50.011, C50.012, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, C50.A0, C50.A1, C50.A2, C50.521, C56.1, C56.2, C56.3, C79.60, C79.61, C79.81, C79.62, C79.63, C84.7A, D05.00, D05.01, D05.02, D05.10, D05.11, D05.12, D05.80, D05.81, D05.82, D05.90, D05.91, D05.92, D24.1, D24.2, D24.9, D49.3, Z15.01, Z15.02, Z15.05, Z40.01, Z40.02, Z40.03, Z42.1, Z85.3, Z90.11, Z90.12, Z90.13
Medical	Urinary System(Genitourinary)	L8604			Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Urinary System(Genitourinary)	L8605			Required	Required	Not Required	Not Required	Required	Required	Required	
Medical	Eyes (Ophthalmology)	L8612			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	

Medical	Miscellaneous & Unlisted Codes	M0075			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q2026			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4101			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4108			Required	Required	Required	Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4111			Required	Required	Not Required	Not Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4112			Required	Required	Required	Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4113			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4114			Required	Required	Required	Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4115			Required	Required	Required	Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4116			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4118			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4122			Required	Required	Required	Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4123			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4125			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4126			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4127			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4128			Not Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4130			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4133			Not Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4134			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4135			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4136			Required	Required	Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4137			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4140			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4141			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4142			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4143			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4145			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4146			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4147			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4148			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4149			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4150			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4152			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4153			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4154			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4155			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4156			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4157			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4158			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4159			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4160			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4161			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4162			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4163			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4164			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4165			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4166			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4167			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4169			Required	Required	Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4170			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4171			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4173			Required	Required	Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4174			Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4175			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4176			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4177			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4178			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4179			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4180			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4181			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4183			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4184			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4185			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4186			Required	Not Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4188			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4189			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4190			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4191			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4192			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4193			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4194			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4195			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4196			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4197			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4198			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4199			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4200			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4201			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4212			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4217			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4224			Required	Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	Q4225			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4229			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4230			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4232			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4233			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4234			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4235			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4236			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4237			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4238			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4239			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4240			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4241			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4242			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4245			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4246			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4247			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4248			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4249			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4250			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4251			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4252			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4253			Required	Required	Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4254			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4255			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4256			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4257			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	

Medical	Skin (Dermatology)	Q4258			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4259			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4260			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4261			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4262			Required	Required	Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4263			Required	Required	Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4264			Required	Required	Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4265			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4266			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4267			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4268			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4269			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4270			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4271			Required	Required	Required	Required	Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4272			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4273			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4274			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4275			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4276			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4278			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4279			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4280			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4281			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4282			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4283			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4284			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4285			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4286			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4287			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4288			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4289			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4290			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4291			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4292			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4293			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4294			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4295			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4296			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4297			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4298			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4299			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4300			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4301			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4302			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4303			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4304			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4305			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4306			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4307			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4308			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4309			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4310			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4311			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4312			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4313			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4314			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4315			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4316			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4317			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4318			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4319			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4320			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4321			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4322			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4323			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4324			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4325			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4326			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4327			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4331			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4332			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4334			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4335			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4336			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4337			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4338			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4339			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4340			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4341			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4342			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4343			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4344			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4345			Required	Required	Not Required	Required	Required	Required	Required	
Medical	Skin (Dermatology)	Q4346			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4347			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4348			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4349			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4350			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4351			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4352			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4353			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4354			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4355			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4356			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4357			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4358			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4359			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4360			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4361			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4362			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4363			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4364			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4365			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4366			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4367			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4368			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4369			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4370			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4371			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4372			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	

Medical	Skin (Dermatology)	Q4373			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4375			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4376			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4377			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4378			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4379			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4380			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4382			Required	Required	Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4383			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4384			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4385			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4386			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4387			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4388			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4389			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4390			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4391			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4392			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4393			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4394			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4395			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4396			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Skin (Dermatology)	Q4397			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Ears and Nose and Throat (Otorhinolaryngology)	S1091			Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Transplants	S2053			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Transplants	S2054			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Transplants	S2065			Not Required	Required	Not Required	Required	Required	Required	Required	
Medical	Transplants	S2102			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Blood Disorder (Hematology)	S2120			Not Required	Not Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Transplants	S2150			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Home Care & Home Infusion Nursing Visits	S5102			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Home Care & Home Infusion Nursing Visits	S5130			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Home Care & Home Infusion Nursing Visits	S5199			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Skin (Dermatology)	S9055			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Home Care & Home Infusion Nursing Visits	S9123			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Home Care & Home Infusion Nursing Visits	S9124			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Transportation	S9960			Required	Required	Not Required	Required	Not Required	Not Required	Not Required	
Medical	Transportation	S9961			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Home Care & Home Infusion Nursing Visits	T1000			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Home Care & Home Infusion Nursing Visits	T1001	None		Not Required	Not Required	Not Required	Not Required	Not Required	Required (for LTSS ONLY)	Required (for LTSS ONLY)	
Medical	Home Care & Home Infusion Nursing Visits	T1001	780		Not Required	Not Required	Not Required	Not Required	Not Required	Required (for LTSS ONLY)	Required (for LTSS ONLY)	
Medical	Home Care & Home Infusion Nursing Visits	T1001	789		Not Required	Not Required	Not Required	Not Required	Not Required	Required (for LTSS ONLY)	Required (for LTSS ONLY)	
Medical	Home Care & Home Infusion Nursing Visits	T1002			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Home Care & Home Infusion Nursing Visits	T1003			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Home Care & Home Infusion Nursing Visits	T1019			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Home Care & Home Infusion Nursing Visits	T1020			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Durable Medical Equipment	T1999			Not Required	Not Required	Not Required	Required	Required	Required	Required	
Medical	Home Care & Home Infusion Nursing Visits	T2024			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Home Care & Home Infusion Nursing Visits	T2028			Not Required	Not Required	Not Required	Required	Not Required	Required (Ages 22 & older)	Not Required	
Medical	Durable Medical Equipment	T2029			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Home Care & Home Infusion Nursing Visits	T2038			Not Required	Not Required	Not Required	Not Required	Not Required	Required (Only for Moving Assistance/Community transition, for HCBS or CFCO program)	Required (Only required for Moving Assistance/Community transition, for CFCO program)	
Medical	Home Care & Home Infusion Nursing Visits	T2039			Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Durable Medical Equipment	T5999			Required	Required	Not Required	Required	Required	Not Required	Not Required	
Medical	Eyes (Ophthalmology)	V2199			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Eyes (Ophthalmology)	V2499			Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Eyes (Ophthalmology)	V2787			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Eyes (Ophthalmology)	V2788			Required	Required	Not Required	Not Required	Not Required	Not Required	Not Required	
Medical	Eyes (Ophthalmology)	V2799			Not Required	Not Required	Not Required	Not Required	Not Required	Required	Required	
Medical	Hospice Services	NONE	0650		Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Hospice Services	NONE	0651		Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Hospice Services	NONE	0652		Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Hospice Services	NONE	0655		Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Hospice Services	NONE	0656		Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Hospice Services	NONE	0657		Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Hospice Services	NONE	0659		Not Required	Not Required	Not Required	Required	Not Required	Required	Required	
Medical	Neonatal Intensive Care	NONE	0172		Notification Required	Notification Required	Not Required	Notification Required	Notification Required	Notification Required	Notification Required	
Medical	Neonatal Intensive Care	NONE	0173		Notification Required	Notification Required	Not Required	Notification Required	Notification Required	Notification Required	Notification Required	
Medical	Neonatal Intensive Care	NONE	0174		Notification Required	Notification Required	Not Required	Notification Required	Notification Required	Notification Required	Notification Required	
Medical	Neonatal Intensive Care	NONE	0179		Notification Required	Notification Required	Not Required	Notification Required	Notification Required	Notification Required	Notification Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	0213T			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	0216T			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22207			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22214			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22224			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22526			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22533			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22548			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22551			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	

Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22554			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22558			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22590			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22595			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22600			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22612			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22630			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22633			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22800			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22802			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22804			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22808			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22810			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22812			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22856			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22857			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22861			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	22862			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23120			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23125			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23130			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23410			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23412			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23415			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23420			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23430			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23440			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23450			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23455			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23460			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23462			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23465			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23466			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23470			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23472			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23473			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23474			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	23700			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27096			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27125			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27130			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27132			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27134			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27137			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27138			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27332			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27333			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27403			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27405			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27412			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27415			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27416			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27418			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27420			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27422			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27424			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27425			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27427			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27428			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Not Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27429			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	

Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27438			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27446			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27447			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27486			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27487			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27488			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	27570			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29805			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29806			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29807			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29819			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29820			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29821			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29822			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29823			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29824			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29825			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29827			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29828			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29860			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29861			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29862			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29863			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29866			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29867			Required through Health Help	Required through Health Help	Required through Health Help	Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Miscellaneous & Unlisted Codes	29868			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29870			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29873			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29874			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29875			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29876			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29877			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29879			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29880			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29881			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29882			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29883			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29884			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29888			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29889			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29914			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29915			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	29916			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	62320			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	62321			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	62322			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	62323			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	62330			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	62380			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63001			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63005			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63012			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63015			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63017			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63020			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63030			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63040			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63042			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63045			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63047			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	

Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63050			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63051			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63056			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63075			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63101			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	63102			Required through Health Help	Required through Health Help	Required through Health Help	Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	64451			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Required	Required	Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	64479			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	64483			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	64490			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	64493			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	64633			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	64635			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	G0260			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help/Medical (MSK and Pain)	Bone and Joint (Orthopedics)	S2118			Required through Health Help	Required through Health Help	Required through Health Help	Not Required	Not Required	Not Required	Not Required	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	0571T			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	0572T			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	0574T			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	0614T			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	0695T			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33202			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33203			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33206			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33207			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33208			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33210			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33211			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33212			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33213			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33214			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33215			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33216			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33217			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33218			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33220			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33221			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33222			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33223			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33224			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33226			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33227			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33228			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33229			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33230			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33231			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33240			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33249			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33262			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33263			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33264			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33270			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33271			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33273			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33274			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33285			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33289			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33975			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33976			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33979			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33981			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33982			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33983			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33990			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33991			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33993			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	33995			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	93228			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	93229			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	93264			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	93745			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	C1764			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	C2624			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	G0448			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	K0606			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	K0607			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	K0608			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Cardiac Impl. Devices)	Heart and Blood Vessel (Cardiovascular)	K0609			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0004M			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0006M			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0007M			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0011M			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0012M			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0013M			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0016M			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0017M			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0020M			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0001U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0005U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0016U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Health Help (Genetics)	Genetic Testing	0017U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0018U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0019U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0022U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0023U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0026U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0027U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0030U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0032U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0034U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0036U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0037U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0040U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0045U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0046U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0047U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0048U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0049U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0050U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0055U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0060U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0069U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0070U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0071U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0072U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0073U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0074U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0075U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0076U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0084U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0087U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0088U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0089U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0090U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0091U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0094U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0101U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0102U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0103U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0111U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0113U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0114U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0118U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0120U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0129U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0130U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0133U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0134U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0136U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0137U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0138U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0153U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0154U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0155U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0156U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0157U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0158U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0159U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0160U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0161U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Health Help (Genetics)	Genetic Testing	0162U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0169U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0170U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0171U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0172U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0173U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0175U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0177U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0179U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0180U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0181U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0182U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0183U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0184U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0185U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0186U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0187U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0188U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0189U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0190U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0191U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0192U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0193U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0194U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0195U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0196U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0197U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0198U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0199U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0200U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0201U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0203U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0205U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0209U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0211U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0212U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0213U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0214U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0215U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0216U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0217U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0218U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0221U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0222U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0229U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0230U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0231U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0232U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0233U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0234U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0235U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0236U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0237U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0238U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0239U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0242U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0244U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0245U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0246U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0250U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Health Help (Genetics)	Genetic Testing	0252U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0253U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0254U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0258U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0260U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0262U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0264U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0265U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0266U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0267U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0268U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0269U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0270U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0271U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0272U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0273U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0274U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0276U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0277U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0278U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0282U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0285U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0286U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0287U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0288U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0289U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0290U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
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Health Help (Genetics)	Genetic Testing	0294U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0296U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0297U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
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Health Help (Genetics)	Genetic Testing	0299U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0300U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0306U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0307U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0313U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0314U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0315U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0318U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0319U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0320U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0326U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0327U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0329U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0331U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0332U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0333U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0334U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0335U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0336U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0339U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0340U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0341U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0343U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0345U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0347U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0348U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Health Help (Genetics)	Genetic Testing	0349U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0350U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0355U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0356U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0362U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0363U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0364U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0368U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0378U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0379U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0388U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0389U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0391U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0392U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0398U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0400U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0401U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0403U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0405U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0409U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0410U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0411U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0413U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0417U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0419U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0420U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0422U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0424U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0425U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0426U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0433U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0434U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0437U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0438U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0439U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0440U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0444U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0449U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0452U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0453U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0454U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0460U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0461U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0465U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0466U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0467U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0469U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0471U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0473U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0474U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0475U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0476U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0477U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0478U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0481U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0485U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0486U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0487U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0488U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0489U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Health Help (Genetics)	Genetic Testing	0493U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0494U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0495U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0496U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0497U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0498U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0499U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0500U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0501U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0506U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0507U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0510U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0512U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0513U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0516U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0523U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0529U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0530U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0532U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0533U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0534U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0536U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0537U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0538U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0539U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0540U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0543U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0549U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0552U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0553U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0554U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0555U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0560U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0561U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0562U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0565U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0566U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0567U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0569U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0571U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0575U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0576U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0578U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0582U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0583U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0586U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0592U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0597U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0602U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0605U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0611U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0612U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0613U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0616U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0617U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0618U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0619U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0620U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0621U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0622U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Health Help (Genetics)	Genetic Testing	0623U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0624U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0625U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0626U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0627U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0628U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0630U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0631U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0632U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0633U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0634U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0635U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0641U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0642U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0643U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0644U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0645U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0646U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0647U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0648U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0649U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0650U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0651U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0652U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0653U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0657U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0658U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0659U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0662U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0663U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0664U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0665U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0668U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0670U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0671U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0672U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0673U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0674U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0675U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0676U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0677U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0678U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0679U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0680U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0681U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0682U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0683U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0684U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0685U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0686U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0687U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0688U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0689U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0690U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0691U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0693U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0695U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0696U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	0697U			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81105			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Health Help (Genetics)	Genetic Testing	81106			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81107			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81108			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81109			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81110			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81111			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81112			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
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Health Help (Genetics)	Genetic Testing	81121			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81161			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81162			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81163			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81164			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81165			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81166			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81167			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81168			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81170			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81171			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81172			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81173			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81174			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81175			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81176			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81177			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81178			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81179			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81180			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81181			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81182			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81183			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81184			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81185			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81186			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81187			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81188			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81189			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81190			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81191			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81192			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81193			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81194			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81195			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81200			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81201			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81202			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81203			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81204			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81205			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81206			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81207			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81208			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81209			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81210			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81212			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81215			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81216			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81217			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81218			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81219			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Health Help (Genetics)	Genetic Testing	81220			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81221			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81222			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81223			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81224			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81225			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81226			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81227			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81228			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81229			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81230			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81231			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81232			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81233			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81234			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81235			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81236			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81237			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
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Health Help (Genetics)	Genetic Testing	81253			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
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Health Help (Genetics)	Genetic Testing	81337			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
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Health Help (Genetics)	Genetic Testing	81344			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81345			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
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Health Help (Genetics)	Genetic Testing	81347			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
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Health Help (Genetics)	Genetic Testing	81362			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81363			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
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Health Help (Genetics)	Genetic Testing	81373			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
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Health Help (Genetics)	Genetic Testing	81375			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
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Health Help (Genetics)	Genetic Testing	81377			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
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Health Help (Genetics)	Genetic Testing	81383			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81400			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
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Health Help (Genetics)	Genetic Testing	81402			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81403			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
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Health Help (Genetics)	Genetic Testing	81406			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81407			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
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Health Help (Genetics)	Genetic Testing	81411			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81412			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81413			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81414			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81415			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81416			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81417			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81418			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81419			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81420			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81422			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81425			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81426			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81427			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81430			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81431			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81432			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Health Help (Genetics)	Genetic Testing	81434			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81435			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81437			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81439			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81440			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81441			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81442			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81443			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81445			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81448			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81449			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81450			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81451			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81455			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81456			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81457			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81458			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81459			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81460			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81462			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81463			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81464			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81465			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81470			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81471			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81479			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81493			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81504			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81507			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81518			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81519			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81520			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81521			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81522			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81523			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81524			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81525			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81529			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81540			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81541			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81542			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81546			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81551			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81552			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81554			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81558			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	81595			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	G0327			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	G9143			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	S3800			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	S3840			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	S3841			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	S3842			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	S3844			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	S3845			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	S3846			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	S3849			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	S3850			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	S3852			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	S3853			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Health Help (Genetics)	Genetic Testing	S3854			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	S3861			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	S3865			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	S3866			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Genetics)	Genetic Testing	S3870			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	0395T			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77371			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77372			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77373			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77402			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77407			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77412			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77423			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77424			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77425			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77437			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77438			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77520			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77522			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77523			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77525			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77761			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77762			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77763			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77767			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77768			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77770			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77771			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77772			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77778			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	77789			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	G0339			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	G0340			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	G0458			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiation Therapy)	Radiation Therapy	G0563			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70336			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70450			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70460			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70470			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70471			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70480			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70481			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70482			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70486			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70487			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70488			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70490			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70491			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70492			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70496			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70498			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70540			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70542			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70543			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70544			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70545			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70546			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70547			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70548			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70549			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70551			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70552			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70553			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70554			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	70555			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	71250			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	71260			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	71270			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	71271			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	71275			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	71550			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	71551			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	71552			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	71555			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72125			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72126			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72127			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72128			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72129			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72130			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72131			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72132			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72133			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72141			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72142			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72146			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72147			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72148			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72149			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72156			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72157			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72158			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72159			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72191			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72192			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72193			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72194			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72195			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72196			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72197			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	72198			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73200			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73201			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73202			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73206			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73218			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73219			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73220			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73221			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73222			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73223			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73225			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73700			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73701			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73702			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73706			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73718			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73719			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73720			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73721			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73722			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73723			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	73725			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	74150			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	74160			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	74170			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	74174			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	74175			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	74176			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	74177			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	74178			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	74181			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	74182			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	74183			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	74185			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Digestive System (Gastroenterology)	74261			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Digestive System (Gastroenterology)	74262			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Digestive System (Gastroenterology)	74263			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	75557			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	75559			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	75561			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	75563			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	75571			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	75572			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	75573			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	75574			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	75577			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	75635			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	76380			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	76390			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	76391			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	77084			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78429			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78430			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78431			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78432			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78433			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78451			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78452			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78453			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78454			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78459			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78466			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78468			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78469			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78481			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78491			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78492			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78608			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78609			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78811			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78812			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78813			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78814			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78815			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	78816			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	A9587			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	A9593			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	A9594			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	A9595			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Health Help (Radiology/Imaging)	Radiology (Imaging) Services	A9596			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	A9597			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	A9608			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	A9613			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	A9616			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	A9800			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8900			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8901			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8902			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8909			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8910			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8911			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8912			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8913			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8914			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8918			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8919			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8920			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8931			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8932			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8933			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8934			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8935			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C8936			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C9762			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C9763			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	C9791			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	G0219			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	G0235			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	G0252			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	S8037			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	
Health Help (Radiology/Imaging)	Radiology (Imaging) Services	S8042			Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	Required through Health Help	

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

The drug Clinical Review Prior-Authorization (CRPA) process is designed to ensure that newly approved (FDA) drugs are used appropriately in cases where a drug poses potential efficacy, quality, toxicity, or utilization concerns for the members and the Health Plan. In addition, this policy may be used for medications that have significant concerns about safety or inappropriate use, but do not warrant a stand-alone policy. The Pharmacy Management clinical team reviews the drugs found in this policy. A Letter of Medical Necessity (LOMN), Exception Form, or Prior Authorization Form completion is required for consideration of drug coverage under this policy.

Summary

Effective Date of Policy:	8/13/26
HCPCS	J0491, J1306, J1440, J2724
Duration	Per product

Required Criteria for Approval

Ceprotin (Protein C Concentrate, Human) - Medical

1. Must be followed by a hematologist
2. Have a diagnosis of severe congenital protein C deficiency confirmed by antigenic and functional plasma coagulation assays
3. Approval is for 2 years

HCPCS: J2724

Leqvio (inclisiran) - Medical

1. The medication must be prescribed by or in consultation with a cardiologist, endocrinologist, lipidologist, nephrologist AND
2. The patient must have one of the following diagnoses (a, b, c OR d):
    a. Clinical atherosclerotic cardiovascular disease (ASCVD)
        i. Patient must be 18 years of age or older AND
        ii. Must have a history of acute coronary syndrome, myocardial infarction (MI), stable or unstable angina, coronary/other arterial revascularization, stroke, TIA, peripheral arterial disease, or other documented atherosclerotic disease (such as coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, or Carotid plaque with ≥ 50% stenosis)
    b. Heterozygous Familial Hypercholesterolemia (HeFH)
        i. Patient must be 12 years of age or older AND
        ii. Molecular genetic testing must demonstrate evidence of an LDL-R mutation, LDLRAP1 mutation, familial defective apo B100, or a PCSK9 mutation OR
        iii. Diagnosis must be confirmed as "definite" according to the World Health Organization Criteria (Dutch Lipid Network) OR Simon-Broome Register Diagnostic Criteria [Refer to table 1 and table 2 in the appendix]. Documentation of the following must be provided to calculate an accurate score:
            A. Patient's first-degree relatives with ANY of the following:
                a. Tendon xanthoma
                b. Corneal arcus c
                c. Known LDL-C >95th percentile by age and gender for country
                d. Known premature (< 55 years, men < 60 years, women) coronary heart disease (CHD)
            B. Patient's child(ren) < 18 years with LDL-C / 95th percentile by age and gender for country
            C. Patient's baseline LDL-C level prior to use of ALL-cholesterol lowering medications
            D. Patient's history of CHD

E. Patient's history of cerebral or peripheral vascular disease
F. Physical exam finding of tendon xanthoma
G. Physical exam finding of corneal arcus

c. Primary hypercholesterolemia without ASCVD or HeFH
   i. Patient must be 18 years of age or older AND
   ii. Patient is at high risk for ASCVD as evidenced by one of the following (documentation must be submitted):
      A. Severe hypercholesterolemia with an untreated LDL-C ≥ 190 mg/dL and poorly controlled risk factors (i.e., age > 35, male sex, obesity, smoking, hypertension, low HDL-C < 35 mg/DL) OR
      B. American Heart Association Predicting Risk of cardiovascular Disease EVENTs (PREVENT-ASCVD) 10-year risk equation ≥ 5% OR
      C. American College of Cardiology/American Heart Association (ACC/AHA) pooled cohort risk assessment score ≥ 7.5% OR
      D. Framingham Risk Score ≥ 20% OR
      E. Coronary artery calcium (CAC) score ≥ 300 OR
      F. Lp(a) ≥ 125 nmol/L (≥ 50 mg/dL)

d. Homozygous familial hypercholesterolemia (HoFH)
   i. Patient is 12 to < 18 years of age AND
   ii. Patient must meet one of the following (A or B):
      A. Molecular genetic testing must demonstrate two mutant allelles on different chromosomes at the LDLR, LDLRAP1, APOB, or PSCK9 genes or show at least 2 such pathogenic variants at different loci
         a. Coverage will not be provided for patients with evidence of two LDLR negative alleles (null homozygous) as these genotypes have little to no response to medications that inhibit proprotein convertase subtilisin kexin type 9 (PCSK9)
      B. Patient has a history of untreated LDL-C > 400 mg/dL with either (a or b)
         a. Xanthoma before the age of 10 years OR
         b. Evidence of heterozygous familial hypercholesterolemia in at least one parent

3. The provider must attest that a discussion with the patient has taken place regarding lifestyle modifications (i.e., a heart healthy diet, the importance of exercise, and smoking cessation [if applicable])
4. Documentation of baseline LDL-C level must be provided- measurement must occur within 60 days prior to treatment
5. The patient must have failed to reach target LDL-C while receiving treatment with high-intensity statin therapy (i.e., atorvastatin 80 mg/day or rosuvastatin 40 mg/day), or maximally tolerated statin therapy, for at least 8 weeks
   a. Target LDL-C for:
      i. ASCVD: < 55 mg/dL
      ii. HeFH for adults 18 and older: < 70 mg/dL
      iii. HeFH or HoFH for adolescents 12 to < 18: < 100 mg/dL
      iv. Primary Hyperlipidemia:
         A. Severe hypercholesterolemia: < 100 mg/dL
         B. PREVENT-ASCVD 10-year risk equation 5% to < 100 mg/dL
         C. PREVENT-ASCVD 10-year risk equation ≥ 10%: < 70 mg/dL
         D. ACC/AHA pooled cohort risk assessment score ≥ 7.5% to < 20%: < 100 mg/dL
         E. ACC/AHA pooled cohort risk assessment score ≥ 20%: < 70 mg/dL
         F. Framingham Risk Score ≥ 20% : < 70 mg/dL
         G. CAC ≥ 300: < 70 mg/dL
         H. Lp(a) ≥ 125 nmol/L (≥ 50 mg/dL): < 70 mg/dL
   b. If patient is unable to tolerate statin therapy, documentation in progress notes must include:
      i. A contraindication to statin therapy according to FDA labeling OR
      ii. History of statin-related rhabdomyolysis:
         A. Must have symptoms consistent with rhabdomyolysis (i.e., muscle pain, swelling, and weakness, dark urine) AND
         B. Must have creatine kinase (CK) level > 10 times upper limit of normal, myoglobinuria, or acute renal failure (increase in serum creatinine > 0.5 mg/dL) AND

C. Patient was receiving a statin at the time of the event and symptoms resolved upon discontinuation of the statin OR

iii. History of statin intolerance. Documentation must include the following:

A. Inability to tolerate at least 2 different statins

a. At least 1 statin must be hydrophilic (such as pravastatin, fluvastatin, or rosuvastatin) starting at the lowest starting average daily dose AND

b. Intolerance associated with confirmed, intolerable statin-related adverse effects (i.e., muscle related symptoms) or significant biomarker abnormalities (i.e., ALT/AST > 3 times the upper limit of normal accompanied by increase in total bilirubin > 2 times the upper limit of normal) AND

c. Non-statin causes of muscle symptoms or biomarker abnormalities have been ruled out (for example, hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders such as polymyalgia rheumatic, steroid myopathy, vitamin D deficiency, or primary muscle disease)

6. The patient must have serious side effects or drug failure to Repatha
7. If patient can tolerate statins, Leqvio must be prescribed in combination with the maximum tolerated dose of a statin
8. Leqvio will not be approved in combination with Praluent, Repatha, Lerochol, Nexletol, or Nexlizet as current medical literature does not support this
9. Approval timeframes: 6 months for initial, 12 months for all recertifications
   a. Initial recertification requires:
      i. Documentation of adequate reduction in LDL cholesterol defined as:
         A. ≥ 40% reduction in LDL as compared to baseline LDL level or reduction to LDL goal for patients with a diagnosis of ASCVD OR
         B. Reduction in LDL level as compared to baseline LDL level for patients with a diagnosis of HeFH, HoFH, or primary hypercholesterolemia without ASCVD or HeFH AND
      ii. Continued adherence to a high intensity statin at maximum tolerated dose (if patient is able to tolerate) AND
      iii. Continued adherence to lifestyle modifications (non-smoker, diet, and exercise)
   b. Subsequent recertification requires:
      i. Documentation that confirms the patient has maintained an adequate reduction in LDL cholesterol compared to baseline
      ii. Continued adherence to a high intensity statin at maximum tolerated dose (if patient is able to tolerate) AND
      iii. Continued adherence to lifestyle modifications (non-smoker, diet, and exercise)
10. Approved dosing: 284 mg administered as a single subcutaneous injection initially, again at 3 months, and then every 6 months thereafter

HCPCS: J1306

Rebyota (fecal microbiota,live-jslm) - Medical

1. The patient must be at least 18 years of age AND
2. Must be prescribed by, or in consultation with, an Infectious Disease or GI specialist AND
3. Rebyota must be used to prevent the recurrence of Clostridioides difficile infection (CDI) AND
4. The patient must have a recurrent episode of Clostridioides difficile infection (CDI) AND
5. The patient must have had a positive stool test for the presence of Clostridioides difficile toxin within the past 30 days AND
6. Current CDI must be controlled following completion of at least 10 days of standard of care antibiotic therapy (e.g., vancomycin, fidaxomicin) AND
7. Administration must take place within 24-72 hours following the completion of an antibiotic course used for CDI treatment AND
8. Patient must not be immune compromised
9. Retreatment with Rebyota for the same CDI will not be covered
10. Rebyota will not be covered for the treatment of Clostridioides difficile infection (CDI) or any other non-FDA approved indications
11. Approval will be granted for 1 month to allow for administration of a single dose a. All approvals are valid only when it is confirmed that Rebyota will be administered within the required timeframe relative to the CDI antibiotic course (i.e., therapeutic window of administration). As such, providers must confirm, prior to approval (on initial or appeal), that the member will receive the therapy within the therapeutic window of administration. If the therapeutic window of administration has expired, the request will not be approved.

12. Approved dosing: 150 mL single dose

HCPCS: J1440

Saphnelo (anifrolumab-fnia) - Medical

1. Must be 18 years of age or older
2. Must be prescribed by or in consultation with a rheumatologist
3. Must have a confirmed diagnosis of active Systemic Lupus Erythematosus (SLE)
    a. A diagnosis of SLE is confirmed by the presence of autoantibodies (such as antinuclear antibodies [ANA], anti-double-stranded DNA [anti-dsDNA] antibodies, anti-Smith [anti-Sm] antibodies)
        i. Due to lab variability in standards for positive values, values reported as "positive" from that lab are acceptable
4. Must be used in combination with standard-of-care therapy (i.e., prednisone, hydroxychloroquine, azathioprine, mycophenolate mofetil, methotrexate)
5. Must not have severe active lupus nephritis or severe active central nervous system (CNS) lupus
6. For new starts only: All requests for Saphnelo will require clinical justification why Benlysta SQ cannot be used (i.e., inability to self-inject)
    a. The use of Saphnelo in combination with Benlysta will not be approved as these medications have not been studied for use together
7. Initial approval will be for 6 months. Continuations for 1 year will require documentation of a decrease in disease signs and symptoms (including reduction in disease flares) from baseline
8. Subsequent reauthorizations for 1 year at a time require documentation of maintenance of improvement in disease signs and symptoms (including reduction in disease flares) from baseline.
9. The approved dose is 300 mg IV (intravenous) once every 4 weeks

HCPCS: J0491

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.
- Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
    - Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition.
- Supportive documentation of previous drug use must be submitted for any criteria that require a trial of a preferred agent if the preferred drug is not found in claims history.

Appendix

Table 1: Diagnostic Criteria for the Clinical Diagnosis of HeFH (WHO)

	Criteria	Score
Family history	First-degree relative known with premature CAD[a] and/or first-degree relative with LDL-C >95th percentile	1
	First-degree relative with tendon xanthomata and/or children <18 y with LDL-C >95th percentile	2
Clinical history	Patient has premature CAD[a]	2
	Patient has premature cerebral/peripheral vascular disease	1
Physical examination	Tendon xanthomata	6
	Arcus cornealis age <45 y	4
LDL-C	>8.5 mmol/L (> ≈330 mg/dL)	8
	6.5-8.4 mmol/L (≈250-329 mg/dL)	5
	5.0-6.4 mmol/L (≈190-249 mg/dL)	3
	4.0-4.9 mmol/L (≈155-189 mg/dL)	1
Definite FH		Score >8
Probable FH		Score 6-8
Possible FH		Score 3-5
No diagnosis		Score <3

CAD: coronary artery disease; FH: familial hypercholesterolemia; HeFH: heterozygous familial hypercholesterolemia; LDL-C: low-density lipoprotein cholesterol; WHO: World Health Organization.
[a] Premature CAD: male before age 55, women before age 60.

Table 2: Simone-Broome Criteria for Diagnosis of FH

FH	Criteria
Definite	• TC >6.7 mmol/L or LDL-C >4.0 mmol/L in a child aged <16 y OR • TC >7.5 mmol/L or LDL-C >4.9 mmol/L in an adult (levels either pretreatment or highest on-treatment) PLUS Tendon xanthomas in patient, or in first-degree relative (parent, sibling or child), or in second-degree relative (grandparent, uncle, or aunt) OR • DNA-based evidence of an LDL-R mutation, familial defective apo B_{100}, or a PCSK9 mutation.
Possible	• TC >6.7 mmol/L or LDL-C >4.0 mmol/L in a child aged <16 y OR • TC >7.5 mmol/L or LDL-C >4.9 mmol/L in an adult (levels either pretreatment or highest on-treatment) AND AT LEAST ONE OF THE FOLLOWING • Family history of myocardial infarction: <50 y of age in second-degree relative or <60 y of age in first-degree relative • Family history of raised TC: >7.5 mmol/L in adult first- or second-degree relative or >6.7 mmol/L in child or sibling aged <16 y.

apo: apolipoprotein; FH: familial hypercholesterolemia; LDL-C: low-density lipoprotein cholesterol; LDL-R: low-density lipoprotein receptor; PCSK9: proprotein convertase subtilisin/kexin type 9; TC: total cholesterol.

References

		Updated	Accessed
	Ceprotin [prescribing information]. Baxalta US Inc. Lexington, MA	8/2021	5/2026
	Rebyota [prescribing information]. Ferring Pharmaceuticals by Rebiotix, Inc. Roseville, MN	11/2022	1/2026
	Infectious Diseases: Clostridioides Difficile. IPD Analytics.		1/2026
	Stuart Johnson, Valéry Lavergne, Andrew M Skinner, Anne J Gonzales-Luna, Kevin W Garey, Ciaran P Kelly, Mark H Wilcox, Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides difficile Infection in Adults, Clinical Infectious Diseases, Volume 73, Issue 5, 1 September 2021, Pages e1029–e1044, https://doi.org/10.1093/cid/ciab549	6/2021	1/2026
	Kelly, Colleen R. MD, AGAF, FACG[1]; Fischer, Monika MD, MSc, AGAF, FACG[2]; Allegretti, Jessica R. MD, MPH, FACG[3]; LaPlante, Kerry PharmD, FCCP, FIDSA[4]; Stewart, David B. MD, FACS, FASCRS[5]; Limketkai, Berkeley N. MD, PhD, FACG (GRADE Methodologist)[6]; Stollman, Neil H. MD, FACG[7]. ACG Clinical Guidelines: Prevention, Diagnosis, and Treatment of Clostridioides difficile Infections. The American Journal of Gastroenterology 116(6):p 1124-1147, June 2021. | DOI: 10.14309/ajg.0000000000001278	6/2021	1/2026
	Izmirly PM, Parton H, Wang L, McCune WJ, Lim SS, Drenkard C, Ferucci ED, Dall'Era M, Gordon C, Helmick CG, Somers EC. Prevalence of Systemic Lupus Erythematosus in the United States: Estimates From a Meta-Analysis of the Centers for Disease Control and Prevention National Lupus Registries. Arthritis Rheumatol.	6/2021	5/2026

	2021 Jun;73(6):991-996. doi: 10.1002/art.41632. Epub 2021 Apr 23. PMID: 33474834; PMCID: PMC8169527.		
	Fanouriakis A, Kostopoulou M, Andersen J, et al. EULAR recommendations for the management of systemic lupus erythematosus: 2023 Update. Ann Rheum Dis 2023; 17 October 2023 doi:10.1136/ard-2023-224762.	1/2024	5/2026
	Morand EF, et al. Trial of Anifrolumab in Active Systemic Lupus Erythematosus. N Engl J Med 2020; 382:211-221.	12/2019	5/2026
	Saphnelo [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP	4/2026	5/2026
	Fanouriakis A, Tziolos N, Bertsias G, *et al.* Update on the diagnosis and management of systemic lupus erythematosus. *Annals of the Rheumatic Diseases* 2021;**80:**14-25.	10/2020	5/2026

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 8/13/2026

New: 5/2026

Revised	Reviewed
8/2026	

Revision Date	Changes Made
8/2026	Added Leqvio and revised criteria Updated Rebyota positive stool test

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MEDICAL POLICY

Medical Policy Title	**Cochlear Implants and Auditory Brainstem Implants**
Policy Number	**7.01.26**
Current Effective Date	**June 1, 2026**
Next Review Date	**March 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

This policy addresses cochlear implants and auditory brainstem implants only. Therefore, bone conduction, semi-implantable and fully implantable hearing aids (e.g., Branemark bone-anchored hearing aid or BAHA System, Esteem Implanted Hearing System, Vibrant Soundbridge System, and RetroX Hearing System) are not addressed in this policy.

POLICY STATEMENT(S)

Cochlear Implants (Unilateral and Bilateral) for Bilateral Sensorineural Hearing Loss (SNHL)

I. Unilateral and bilateral* cochlear implants are considered **medically appropriate** as a prosthetic for hearing loss when **ALL** of the following criteria are met:

   A. The prosthetic is approved by the U.S. Food and Drug Administration (FDA) (Refer to Regulatory section) for the individual's age;

   B. Individual has bilateral severe-to-profound SNHL defined as a pure-tone average (PTA) of >70 decibels (dB HL) at 500 hertz (Hz), 1000 Hz, and 2000 Hz;

   C. There has been limited or no benefit from appropriately fit hearing aids;

   D. Physician attestation of the willingness of the individual or family to undergo an extended program of auditory rehabilitation;

   E. None of the following contraindications for cochlear implants are present:

      1. Cochlear aplasia (absence of cochlear development);

      2. Deafness due to lesions of the eighth cranial (acoustic) nerve or central auditory pathway;

      3. Infection of the external or middle ear (e.g., otitis media) or other active aural disease processes.

*Bilateral cochlear implantation should be considered only when it has been determined that the alternative of unilateral cochlear implant plus hearing aid in the contralateral ear will not result in a binaural benefit (e.g., in those individuals with hearing loss of a magnitude where a hearing aid will not produce the required amplification).

Unilateral Cochlear Implants for Single-Sided Deafness (SSD) or Asymmetric Hearing Loss (AHL)

II. Unilateralc ochlear implants are considered **medically appropriate** as a prosthetic for SSD or AHL when **ALL** of the following criteria are met:

A. Individual is five (5) years of age or older (Refer to Regulatory section);

B. There has been limited or no benefit from appropriately fit hearing aids;

C. Individual has **EITHER** of the following:

1. Profound SNHL (defined as a PTA of >90 dB HL at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz) in one ear and normal hearing or mild SNHL in the other ear (defined as a PTA up to 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz, 4000 Hz); **or**

2. Profound SNHL (defined as a PTA of >90 dB HL at 500 Hz, 1000 Hz, 2000 Hz, and 4000 Hz) in one ear and mild to moderately severe SNHL (ranging from 31 dB HL up to 55 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz) in the other ear, with a difference of at least 15 dB HL in PTA between ears;

D. Individual has had a one (1) month trial wearing a Contra Lateral Routing of Signal (CROS) hearing aid and has not shown any benefit;

E. Physician attestation of the willingness of the individual or family to undergo an extended program of auditory rehabilitation;

F. None of the following contraindications for cochlear implants are present:

1. Cochlear aplasia (absence of cochlear development);

2. Deafness due to lesions of the eighth cranial (acoustic) nerve or central auditory pathway;

3. Infection of the external or middle ear (e.g., otitis media) or other active aural disease processes.

Hybrid Cochlear Implants

III. Unilateral cochlear implantation with a device that includes the hearing aid integrated into the external sound processor (e.g., the Nucleus Hybrid L24 Cochlear Implant System) is considered **medically appropriate** when **ALL** of the following criteria are met:

A. Individual is five (5) years of age or older (Refer to Regulatory section);

B. Individual meets **BOTH** of the of the following criteria:

1. One ear has severe to profound SNHL (defined as a PTA of > 80 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz); **and**

2. In the contralateral ear, normal or near normal hearing (defined as a PTA of ≤ 30 dB HL at 500 Hz, 1000 Hz, 2000 Hz and 4000 Hz).

C. There has been limited benefit from an appropriately fit unilateral hearing aid (defined as a score of less than or equal to 5% on a Consonant Nucleus Consonant [CNC] word test);

D. For individuals between five (5) years and 18 years of age, insufficient functional access to sound in the ear to be implanted must be determined by aided speech perception test scores of 5% or less on developmentally appropriate monosyllabic word lists when tested in the ear to be implanted alone;

E. Physician attestation of the willingness of the individual or family to undergo an extended program of auditory rehabilitation;

F. None of the following contraindications for cochlear implants are present:

1. Cochlear aplasia (absence of cochlear development);
2. Deafness due to lesions of the eighth cranial (acoustic) nerve or central auditory pathway;
3. Infection of the external or middle ear (e.g., otitis media) or other active aural disease processes.

Auditory Brainstem Implants

IV. Auditory brainstem implants are **medically appropriate** when **ALL** of the following criteria are met:

A. The implant is approved by the U.S. Food and Drug Administration (FDA) (Refer to Regulatory section) for the individual's age;

B. Individual has neurofibromatosis type 2;

C. Individual is rendered deaf due to bilateral resection or treatment of neurofibromas of the auditory nerve.

Device Repair

V. Repair of a medically necessary Cochlear Implant or Auditory Brainstem Implant or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** of the following:

1. date of device implantation/initiation;
2. manufacturer warranty information, if applicable;
3. attestation that the individual has been compliant with the use of device and will continue to benefit from the use of device;

B. The device is no longer functioning adequately; and **BOTH** of the following criteria are met:

1. inadequate function interferes with activities of daily living; **and**
2. repair is expected to make the equipment fully functional (as defined by manufacturer).

VI. Repair of equipment damaged due to individuals neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

Device Replacement

VII. Replacement of a medically necessary Cochlear Implant or Auditory Brainstem Implant or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

A. The device is no longer functioning adequately and has been determined to be non-repairable or the cost of the repair is in excess of the replacement cost;

B. There is documentation that a change in the individual's condition makes the present unit non-functional and improvement is expected with a replacement unit.

VIII. The replacement of a properly functioning Cochlear Implant or Auditory Brainstem Implant, its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing.

IX. The replacement of equipment damaged or lost due to individual's neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

X. Accessories or components for a Cochlear Implant or Auditory Brainstem Implant that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

2.01.27 Evoked Potentials

7.01.77 Implantable Bone Conduction Hearing Aids

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Cochlear implants and auditory brainstem implants are prosthetic devices. Coverage for prosthetic devices is contract dependent.

II. A post cochlear implant rehabilitation program is essential to achieve benefit from the cochlear implant. The rehabilitation program includes development of skills in understanding running speech, recognition of consonants and vowels, and tests of speech perception ability.

DESCRIPTION

The American Speech-Language-Hearing Association (ASHA, n.d.) defines hearing loss (HL) within its practice portal. Available from: Hearing Loss in Adults [Accessed 2026 Jan 09].

HL refers to an audiologic diagnosis of hearing thresholds outside the range of typical hearing, and can be described by variation in type, degree, and configuration.

The three basic types of HL are:

- Sensorineural hearing loss (SNHL): cochlear (sensory) or vestibulocochlear nerve/CN VIII (neural) auditory dysfunction.
- Conductive hearing loss: a problem conducting sound waves through the outer ear canal, tympanic membrane, or middle ear (ossicles).
- Mixed hearing loss: the result of damage to conductive pathways of the outer or middle ear and to the nerves or sensory hair cells of the inner ear.

HL can be bilateral or unilateral, symmetrical (degree and configuration of HL are the same in each ear) or asymmetrical, progressive or sudden in onset, fluctuating or stable, and present at birth or acquired. The degree of HL refers to level of severity, and is measured in decibels in hearing level, or dB HL. The degree of HL can have significant implications for an individual (e.g., limiting the ability to understand speech in background noise, decreasing the enjoyment of music, impacting overall quality of life).

The most widely accepted degree of hearing loss system utilized in the audiology field (ASHA, n.d.) is as follows:

- Normal: -10 to 15 dB HL
- Slight: 16 to 25 dB HL
- Mild: 26 to 40 dB HL
- Moderate: 41 to 55 dB HL
- Moderately severe: 56 to 70 dB HL
- Severe: 71 to 90 dB HL
- Profound: ≥ 91 dB HL

The World Health Organization (2024) identifies several causes of HL that span across the lifespan, and often occur during critical periods of life, including the following:

<u>Prenatal Period</u>

- genetic factors including hereditary and non-hereditary HL
- intrauterine infections, such as rubella and cytomegalovirus infection

<u>Perinatal Period</u>

- birth asphyxia
- hyperbilirubinemia
- low-birth weight
- other perinatal morbidities and their management

<u>Childhood and Adolescence</u>

- chronic suppurative otitis media

- chronic nonsuppurative otitis media
- meningitis and other infections

Adulthood and Older Age

- chronic diseases
- smoking
- otosclerosis
- age-related sensorineural degeneration
- sudden SNHL

Factors Across the Life Span

- cerumen impaction
- trauma to the ear or head
- loud noise/loud sounds
- ototoxic medicines
- work related ototoxic chemicals
- nutritional deficiencies
- viral infections and other ear conditions
- delayed onset or progressive genetic HL

The Minimum Speech Test Battery (MSTB) for adults has been utilized to guide clinicians for cochlear implant candidacy and document post-operative speech recognition performance. The MSTB was recently revised (MSTB-Version 3) (Dunn 2024) to include the minimum battery of tests that could be utilized to provide a comprehensive assessment, which include unaided audiometric testing, hearing aid verification, functional outcomes using The Cochlear Implant Quality of Life tool (CIQOL 10), the Speech, Spatial and Qualities of Hearing Scale (SSQ-12), a Tinnitus handicap inventory when significant tinnitus is reported, and an aided speech test battery. The aided speech test battery includes the following:

- CNC Monosyllabic word test evaluating each ear separately in the best-aided condition using a list of 50-words given at different decibels to determine the better versus poorer ear to assist in the determination of which ear should be implanted.
- AzBio Sentence Test: reviews a list of words at different decibels with differing signal to noise ratios of the ear to be implanted to represent the best-aided condition.

Post-operatively, audiologic rehabilitation is recommended to help individuals understand their HL type and regain skills that they may have lost.

Technologies for the treatment of HL are dependent on the cause and severity and can include assistive listening and alerting devices, hearing aids, cochlear implants, and middle ear implants.

Hearing aids amplify sound to allow detection by damaged ears. Cochlear implants differ in that they don't amplify, rather, they directly stimulate the auditory nerve, bypassing the damaged portions of the ear altogether. The auditory nerve recognizes the signals as sound. Hearing through a cochlear implant is different from normal hearing and takes time to learn or relearn. However, it allows many people to recognize warning signals, understand other sounds in the environment, and understand speech in person or over the telephone. (National Institute on Deafness and Other Communication Disorders 2024)

Cochlear Implants (Unilateral and Bilateral) for Bilateral Sensorineural Hearing Loss (SNHL)

The basic structure of a cochlear implant includes both external and internal components. The external components include a microphone, an external sound processor, and an external transmitter. The internal components are implanted surgically and include an internal receiver implanted within the temporal bone and an electrode array that extends from the receiver into the cochlea through a surgically created opening in the round window of the middle ear. Sounds picked up by the microphone are carried to the external sound processor, which transforms sound into coded signals that are then transmitted transcutaneously to the implanted internal receiver. The receiver converts the incoming signals into electrical impulses that are then conveyed to the electrode array, ultimately resulting in stimulation of the auditory nerve. Cochlear implants can worsen low-frequency hearing sensitivity (the ability to still hear low-pitched sounds) because although the inner ear is being stimulated to restore higher frequency hearing, it results in a reduced ability to perceive low-frequency sound when compared to natural hearing.

Bilateral cochlear implants are utilized for patients who meet the criteria for unilateral cochlear implant, when it has been determined that a unilateral cochlear implant plus a hearing aid in the contralateral ear will not result in a binaural benefit (e.g., patients with HL of such magnitude that a hearing aid will not produce the required amplification). The benefits of bilateral cochlear implants are to improve understanding of speech in noise, localization of sounds, and speech intelligibility. Bilateral implantation may be performed independently with separate implants and speech processors in each ear, or with a single processor. Bilateral cochlear implantation may be done sequentially or simultaneously.

Unilateral Cochlear Implants for Single-Sided Deafness (SSD) and Asymmetric Hearing Loss (AHL)

AHL is when an individual has profound HL in one ear and mild to moderately severe HL in the hearing ear. The ear with the profound loss can be completely ineffective or not usable for hearing, making it unlikely the individual will benefit from an appropriately fit bilateral hearing aid. HL that only affects one ear is known as SSD, or unilateral hearing loss (UHL). The degree of impairment in the contralateral ear can range from mild to profound.

SSD occurs in both adults and children. Those with SSD experience poorer spatial hearing abilities and diminished speech understanding in the presence of competing noise when compared to listeners with normal hearing bilaterally. Historically, clinical recommendations for adults with SSD were to remain in an unaided condition or listen with a hearing technology that reroutes the acoustic signal from the impaired ear to the normal hearing ear (e.g., bone conduction device or contralateral routing of the signal [CROS] hearing aid). Given the limitations of these options, cochlear implant of the impaired ear for stimulation of both auditory pathways aims to improve performance on spatial

hearing tasks, including sound source localization and speech understanding in spatially separated noise (Dillon 2022).

Hybrid Cochlear Implant

Hybrid devices incorporate both a hearing aid and the external sound processor of a cochlear implant. They are indicated for individuals who have high-frequency SNHL with preserved low-frequency hearing sensitivity (the ability to still hear low-pitched sounds even when experiencing significant hearing loss in higher frequencies). Candidates for a hybrid device have too much residual hearing to receive a traditional cochlear implant, yet not enough hearing to benefit from using a hearing aid.

Hybrid cochlear implant electrodes are shorter and are inserted to a depth that are proposed to preserve residual low-frequency hearing that is generally lost through the use of traditional cochlear implants. The developer of the Nuclear 24 Hybrid Implant System, Cochlear (Lone Tree, Colorado), describes the hybrid mechanism of action as the following: 1) Sound processor microphones pick up the sound and convert it into digital information, 2) The acoustic component amplifies low frequency sound and sends it down the ear canal through the normal hearing pathway, 3)The high frequency information is transferred via the coil to the implant under the skin, 4)The implant sends electrical signals down the electrode into the cochlea where the hearing nerve fibers pick up the electrical signals and are combined with the amplified sounds, 5)The electrical signals are then sent to the brain to interpret the sound.

Auditory Brainstem Implant

Auditory brainstem implants are devices designed to restore some hearing in patients with neurofibromatosis type II. Neurofibromatosis type II is a genetic disorder that causes a growth of tumors. Individuals with this condition can have complete hearing loss due to the bilateral removal of the characteristic neurofibromas involving the auditory nerve. The device consists of an externally worn speech processor that provides auditory information to an electrical signal, which is transferred to a receiver/stimulator that is implanted in the temporal bone. The receiver stimulator is attached to an electrode array that is implanted on the surface of the cochlear nerve in the brainstem, thus bypassing the inner ear and auditory nerve. The electrode stimulates multiple sites on the cochlear nucleus, which is then processed normally by the brain.

SUPPORTIVE LITERATURE

Cochlear Implants (Unilateral and Bilateral) for Bilateral Sensorineural Hearing Loss (SNHL)

Cochlear implants, unilateral and bilateral, for adults and children with bilateral SNHL are a well-established intervention. Published studies show consistent improvement in speech reception, especially in noise, and in sound localization with bilateral devices (Baron 2018; McRacken 2018; Gaylor 2013; Crathorne 2012; Bond 2009).

Unilateral Cochlear implants for Single-Sided Deafness (SSD) or Asymmetric Hearing Loss (AHL)

For individuals who have SSD who receive a cochlear implant(s), the evidence includes small open-label RCTs, a feasibility study, prospective and retrospective studies reporting within-subjects comparisons, and systematic reviews of observational studies. Individuals with SSD have the inability

to process input from both ears, and this inability to provide a complete auditory picture negatively impacts the localization of sound, speech perception, and quality of life. Studies have been limited by population size, and heterogeneity, but several of the studies report positive outcomes for improved sound localization, speech perception in both quiet and noise, tinnitus suppression, and improved quality of life when compared to the use of Contralateral Routing of Signal and bone anchored hearing aids in specific individuals. Because of this, the use of cochlear implants for the treatment of SSD is supported by national professional society guidelines (Refer to Professional Societies Section).

In 2017, Sladen and colleagues retrospectively reviewed prospectively collected data of short-term (six-month) follow-up for 23 adults and children with single-sided deafness from a variety of mechanisms who received a cochlear implant. In the implanted ear, consonant-nucleus-consonant (CNC) word recognition improved significantly from preimplantation to three months post activation (p=0.001). However, for AzBio sentence understanding in noise (+5 dB signal-to-noise), there was no significant improvement from preimplantation to six months post activation.

Marx and colleagues aimed to assess the outcomes of cochlear implants (CI) and other treatment options in SSD or AHL on quality of life in a prospective study published in 2021. Performances for speech-in-noise recognition and localization were measured as secondary outcomes. The study included both an observational cohort of SSD/AHL who were treated using contralateral routing of the signal hearing aids (CROS) or bone-anchored systems (BAHS) or individuals who declined all treatments, and a randomized controlled trial was performed on subjects treated by cochlear implantation after failed CROS or BAHS trials. Those individuals were treated with two trials of CROS and BAHSs on headband and were then allowed to choose from the four treatment options (abstention, CROS, BAHS, or CI). Those that selected CI were then randomized into two arms, CI versus initial observation (n=51). Follow up was conducted at six months and demonstrated quality-of-life outcomes as significantly better in the CI arm versus observation, particularly in patients with associated severe tinnitus. No significant effect of the CI was found on binaural hearing results. The study was limited by the small sample size included within the RCT, and a short follow up timeframe to capture the longer-term effects of the CI on binaural hearing.

Peters et al (2021) randomized 120 adults with single-sided deafness (median duration, 1.8 years) into three treatment groups for the "Cochlear Implantation for siNGLE-sided deafness" (CINGLE) trial: cochlear implant (n=29); first bone-conduction devices, then CROS (n=45); and first CROS, then bone-conduction devices (n=46). Patients with a maximum 30 dB HL in the best ear and a minimum 70 dB HL in the poor ear with duration of single-sided deafness between three months and 10 years were eligible for inclusion. After the initial cross-over period, 25 patients were allocated to bone-conduction devices, 34 patients were allocated to CROS, and 26 patients preferred no treatment. Seven patients did not receive their allocated treatment. For the primary outcome, speech perception in noise from the front, a statistically significant improvement was noted for the cochlear implant group at three and six months compared to baseline. At three months follow-up, the cochlear implant group performed significantly better than all other groups. At six months, the cochlear implant group performed significantly better than the bone-conduction devices and no treatment groups, but no significant difference was observed between the cochlear implant group and the CROS group. Sound localization improved in the cochlear implant group only. All treatment groups improved on disease-specific quality of life compared to baseline. The study was limited by small sample size, device

heterogeneity, loss to follow-up, and lack of allocation concealment. Study follow-up through five years is ongoing.

Dillon et al (2022) conducted a systematic review of the published literature on outcomes of cochlear implant use for auditory abilities, tinnitus perception, and quality of life. The review included 42 articles published between January 2008 and September 2021. Studies were screened by two independent reviewers based on title and abstracts. Each article was assessed for the level of evidence and categorized based on the reported outcome data. Of nine studies that were included in the assessment for speech recognition in quiet (n= 307), 100% of adults implanted with a CI had an improvement. Of the studies that evaluated outcomes for speech recognition in noise (n=256), 96% experienced improvements when the target speech was presented from the CI ear, with masking configuration presented from the normal hearing ear (13 studies noted with significant improvements).

Park et al (2022) conducted a review of the literature and subsequently developed guidelines for the clinical assessment and management of cochlear implants in children with SSD, endorsed by the American Cochlear Implant Alliance Task Force (Refer to Professional Society Section). The guidelines recommend:

- Assurance of an accurate diagnosis of nerve deficiency through 3D-MRI of the internal auditory canals;
- Cochlear implants should be considered a priority for children who are at risk of HL progression in the better hearing ear, as well as children with SSD due to bacterial meningitis;
- Children with longer lengths of deafness may experience fewer benefits and should be appropriately counseled;
- Cochlear implant evaluation is recommended for children with a unilateral three frequency PTA of > 60 dB HL or an aided speech intelligibility score <0.65 as these children are not likely to receive adequate benefit from traditional amplification;
- Trials with rerouting devices are not recommended for children seeking binaural hearing as these devices are not able to provide the brain with bilateral input and the trial could delay a time-sensitive procedure;
- Counseling for families considering cochlear implants should include information about developmental disadvantages of SSD, the advantage of implantation at a younger age, the importance of post implant listening therapy, and reasonable expectations;
- The most appropriate post-activation test batteries and timeframes;
- Technique to utilize for evaluating audibility in the sound field;
- Device programming considerations.

The authors emphasized that this is a rapidly evolving field and readers should keep abreast of the literature and current research outcomes.

Oh et al (2023) published a systematic review and meta-analysis of 50 studies, including prospective and retrospective observational studies and case series, evaluating cochlear implantation in adults

(n=674) with SSD. Pooled outcomes indicated improved scores in speech perception, localization, tinnitus, and quality of life. Study interpretation was limited by small sample sizes and heterogeneity in reported outcomes and follow-up durations.

Piva de Freitas et al (2025) published a systematic review and meta-analysis to evaluate how children with single-sided deafness (SSD) feel about their quality of life (QoL) after receiving a cochlear implant (CI). The study compares the experiences based on when the hearing loss began, and the feedback received (child vs. parent). The study also assesses the ease of use of the device as related to the when the hearing loss started. There were 187 children included in the study all under the age of 18 with unilateral severe to profound hearing loss and normal contralateral hearing. The results showed that children with congenital SSD who received a CI demonstrated a statistically significant improvement in QoL, as reported by the patient and their parents. This analysis is limited by its smaller sample size and lack of generalizability. Additionally, each included study of the meta-analysis utilized different QoL assessment tools which made direct comparisons difficult. Overall, significant improvements in QoL were reported by both children with SSD and their parents, after having a CI implanted. Larger study populations and extended follow-up are needed to validate the study findings.

Hybrid Cochlear Implant

Lenarz et al (2013) reported on results of a prospective multicenter European study evaluating the Nucleus Hybrid L24 system. The study enrolled 66 adults with bilateral severe-to-profound high-frequency HL to investigate the preservation of residual hearing the performance benefits (e.g., speech recognition, sound quality, and quality of life) up to one-year post-implantation. The group median increase in air-conduction thresholds in the implanted ear for test frequencies 125-1000 Hz was less than 15 dB across the population, both immediately and one year post-operatively. At one year postoperatively, 89% of the patients were still using the Hybrid processor, 65% of subjects had significant gains in speech recognition in quiet, and 73% had significant gains in noisy environments. Compared with the cochlear implant hearing alone, residual hearing significantly increased speech recognition scores. The authors concluded that useful residual hearing was conserved in 88% of subjects, and speech perception was significantly improved over pre-operative hearing aids, as was sound quality and quality of life. Study limitations include short-term follow-up, small patient population, and fewer number of subjects still using the hybrid processor at the one-year mark.

The pivotal trial results for the Cochlear Nucleus Hybrid L24 were published by Roland et al in January 2016. A prospective, single-arm, repeated measures, single-arm, multicenter, nonrandomized study undertaken to evaluate the safety and efficacy of acoustic and electric sound processing for individuals with significant residual low-frequency hearing and severe-to-profound high-frequency SNHL. Fifty (50) individuals aged 18 years and older, with low-frequency hearing and severe high-frequency loss were implanted with the Cochlear Nucleus Hybrid L24 implant at 10 investigational sites. Significant mean improvements were observed for co-primary endpoints: consonant-nucleus-consonant words and AzBio sentences in noise 96% of subjects performed equal or better on speech in quiet and 90% in noise. 82% of subjects showed improved performance on speech in quiet and 74% in noise. Self-assessments were positive, corroborating speech perception results. 65 adverse events involving 34 of the 50 subjects were reported. The type and frequency of events were consistent with those reported in cochlear implantation (e.g., electrode open or short

circuits, postoperative dizziness, changes in tinnitus) or other mastoid operations; no unanticipated adverse events were reported. The authors concluded the Nucleus Hybrid System provides significant improvements in speech intelligibility in quiet and noise for individuals with severe high-frequency loss and some low-frequency hearing and expands indications to hearing-impaired individuals who perform poorly with amplification due to bilateral high-frequency HL and who previously were not implant candidates. However, they also noted additional longer-term follow-up for safety and study of the device in larger and diverse subgroups is important.

Five-year outcomes for the pivotal trial were reported by Roland et al (2018). The results of three related clinical studies compiled to provide outcome data after one, three and five years of implant use in a group of subjects who presented with preoperative high-frequency HL and were implanted with a Nucleus Hybrid L24 (Cochlear Ltd., Sydney, Australia) cochlear implant. The authors concluded the results demonstrate long-term success and benefits significantly better than those in the preoperative best-aided condition. The level of evidence given to these studies was 2b.

A final outcomes study by the same authors was reported by Gantz et al in April 2016. A total of 87 subjects received a Nucleus Hybrid S8 Cochlear Implant in their poorer ear. Speech perception in quiet (CNC words) and in noise (Bamford-Kowal-Bench Sentences-In-Noise [BKB-SIN]) were collected pre- and postoperatively at three, six, and 12 months. Subjective questionnaire data using the Abbreviated Profile for Hearing Aid Benefit (APHAB) were also collected. Some level of hearing preservation was accomplished in 98% subjects, with 90% maintaining a functional low-frequency pure-tone average (LFPTA) at initial activation. By 12 months, five subjects had total HL, and 80% of the subjects maintained functional hearing. CNC words demonstrated that 82.5% and 87.5% of subjects had significant improvements in the hybrid and combined conditions, respectively. Results also indicated that, as long as subjects maintained at least a severe LFPTA, there was significant improvement in speech understanding. Furthermore, all subjects reported positive improvements in hearing in three of the four subscales of the APHAB. Most experienced a progressive loss of acoustic hearing in the implant ear. The authors concluded that the concept of hybrid speech processing has significant advantages for subjects with residual low-frequency hearing. The Nucleus Hybrid S8 provided improved word understanding in quiet and noise, and there appeared to be stability of the residual hearing after initial activation of the device. They also stated that the reasons for loss of hearing after activation of the implant and acoustic amplification required more research.

In 2024, Reinhart and colleagues conducted a prospective multi-center clinical trial (NCT02379819) to assess the safety and effectiveness of a hybrid cochlear implant for delivering electric-acoustic stimulation (EAS) in patients with low- frequency acoustic hearing and severe-to-profound high-frequency HL. The study enrolled 52 adults, who were newly implanted with the hybrid cochlear implant. Post implant, testing included unaided and aided audiometric thresholds, speech perception (CNC words in Quiet and AzBio sentences +5 dB SNR), as well as patient reported outcomes using the Speech, Spatial and Qualities of Hearing Scale with a follow up timeframe of up to five years. Functionally aidable hearing, defined as low-frequency PTA (125–500 Hz) <80 dB HL, was maintained for 77% of patients through one year, with 66.7% maintaining through five years. Speech perception was significantly improved at all postoperative timepoints compared with preoperative performance with hearing aid(s), and patient-reported outcomes indicated significantly improved subjective speech understanding, spatial hearing, and sound quality. Participants with preserved acoustic hearing using

EAS reported significantly higher subjective spatial hearing and sound quality than participants with electric-only hearing in the implanted ear. The results replicated the outcomes reported in the pivotal trial (Roland 2016).

Auditory Brainstem Implant

Studies have shown that, while the use of an auditory brainstem implant is associated with a very modest improvement in hearing, this level of improvement is considered significant in this group of patients who have no other treatment options (Otto et al 2008; Ontario Health 2020).

The evidence on auditory brainstem implants in nontumor patients includes case series and systematic reviews. A 2014 systematic review (Merkus et al) suggested that auditory brainstem implants might improve outcomes in bilateral complete cochlear and inner ear aplasia. Recent research includes studies of children who are deaf but would not benefit from a cochlear implant. Hearing in this age group is critical for language development, and the auditory brainstem implants have potential to substantially improve health outcomes. However, studies of early (now obsolete) auditory brainstem implants found a high rate of failure in children and high rates of adverse events in adults. Evidence from ongoing studies assessing newer device models is needed to evaluate efficacy and durability in patients with nontumor indications.

PROFESSIONAL GUIDELINE(S)

Cochlear Implants for Bilateral SNHL

In April 2021, the American Academy of Otolaryngology–Head and Neck Surgery (AAO-HNS) revised the position statement on cochlear implants to endorse unilateral and bilateral cochlear implantation as appropriate treatment for adults and children over nine months of age with moderate to profound HL who have failed a trial with appropriately fit hearing aids.

In July 2021 (revised September 2021), AAO-HNS issued a new position statement specifically addressing cochlear implant candidacy for children with bilateral SNHL. The position reconfirms that cochlear implantation should be considered for children with bilateral sensorineural HL who are not making expected progress despite appropriately fit amplification.

Unilateral Cochlear Implants for Single-sided Deafness (SSD)/Unilateral Hearing Loss (SSD/UHL)

In 2022, the American Cochlear Implant Alliance Task Force published guidelines on the assessment and management of adult cochlear implantation for SSD (Dillon 2022). The guidance recommendations were based on expert consensus and systematic review of the current literature. The task force concluded that although further research investigating the patient and device variables that may influence the performance of adult cochlear implant users with SSD, cochlear implantation is an effective treatment option for adults with SSD. Noted potential contraindications include advanced cochlear ossification, severe labyrinthine dysplasia, and cochlear nerve aplasia; however, advanced age is not a contraindication. Prolonged duration of deafness combined with congenital SSD onset may result in limited cochlear implantation outcomes.

In April 2023, the AAO-HNS issued two new position statements endorsing cochlear implantation for

cases of single sided deafness (asymmetric or unilateral sensory HL) for adult patients and children. Adults with asymmetric or unilateral sensory HL struggle with speech perception in noise and sound source localization due to loss of binaural cues. They also experience disabling tinnitus and reduced quality of life and quality of hearing, stating that cochlear implants restore binaural hearing and markedly improve sound localization, speech perception in noise, reduces or eliminates tinnitus, and improves quality of life and hearing.

The AAO-HNS recommends that select children with unilateral SNHL, as early as nine months of age, should undergo cochlear implantation as soon as HL and appropriate anatomy is verified to avoid missing a developmental window that permits integration of binaural cues. Specifically indicating that children with unilateral SNHL also experience problems with sound localization, speech perception in noise, and increased auditory effort due to loss of binaural cues. Restoration of true binaural hearing can only be accomplished with a cochlear implant, and use of a cochlear implant has demonstrated marked improvements in localization, speech perception in noise and auditory effort.

The American Speech-Language Hearing Association (ASHA) publishes Evidence Maps to summarize published Clinical Practice Guidelines. Strong recommendations were made based upon guidelines published by the Brazilian Society of Otology Task Force for individuals with SSD (Tsuji 2025) and include the following:

- CIs are the most effective treatment to restore useful hearing in profound deafness in individuals with SSD. CIs are the only option to restore binaural hearing for this population. (Strong Recommendation; Low-Quality Evidence)
- CIs can restore binaural hearing and produce significant improvements in speech perception, spatial localization of sound, tinnitus control, and overall quality of life. (Strong Recommendation; Moderate-Quality Evidence)
- "In children with SSD due to congenital cytomegalovirus, CI is more appropriate due to the increased risk of contralateral hearing deterioration over time." (Strong Recommendation; Low-Quality Evidence)
- Family counseling should be conducted prior to the use of CI in cases of SSD in order to adjust expectations and conduct therapy. (Strong Recommendation; Moderate-Quality Evidence)
- "Adult patients with SSD undergoing ipsilateral CI have statistically significant improvements in speech perception, tinnitus reduction, sound localization, and quality of life." (Strong Recommendation; Moderate-Quality Evidence)
- In cases of sporadic vestibular schwannoma (VS), CI is a treatment option for SSD. This is especially true in the presence of disabling tinnitus and preserved cochlear nerve function. (Strong Recommendation; Low-Quality Evidence)

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) has approved several cochlear implants for commercial use in the United States. Cochlear implants are Class III devices, and therefore, FDA approval is device specific to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices. [accessed 2026 Jan 09]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Jan 09]

In 2002, the FDA issued an alert stating that children with cochlear implants were at greater risk of developing bacterial meningitis caused by streptococcus pneumoniae than children in the general population. Their investigation showed that cochlear implants with electrode positioners were associated with greater risk of developing meningitis than implants without positioners. The only model with a positioner was withdrawn from the market in July 2002. In 2006, an alert was issued discussing results of a two-year follow-up of the children identified in the earlier investigation. To decrease the risk of meningitis, the FDA recommends: adherence to the CDC vaccination guidelines, early recognition of the signs of meningitis, prompt diagnosis and treatment of middle ear infections, and consideration of the use of prophylactic antibiotics perioperatively.

In October 2007, the FDA issued a Public Health Notification: Importance of Vaccination in Cochlear Implant Recipients, and Advice for Patients with Cochlear Implants: New Information on Meningitis Risk. Both reminded of the increased, life-threatening risk of bacterial meningitis in cochlear implant recipients, especially those with a positioner, and the importance of full vaccination of those recipients, as two patients had recently died from infection, and neither one was fully vaccinated.

Hybrid Cochlear Implant

The Nucleus Hybrid L24 Cochlear Implant System (Cochlear Americas) received FDA approval on March 20, 2014, through the premarket approval (PMA) process (P130016). The implant was intended for unilateral use in patients aged 18 years and older who have residual low-frequency hearing sensitivity and severe-to-profound high-frequency SNHL, and who obtain limited benefit from an appropriately fitted bilateral hearing aid.

In 2022, the Nucleus Hybrid L24 received expanded approval for single-sided deafness or unilateral HL in adults and children aged five or older (P970051/S205). According to the FDA's summary of safety and effectiveness data, approval was based on unpublished data in 42 adults from a feasibility study (n=10) and real-world data from two cochlear implantation centers (n=32). Study interpretation is limited by small sample size in adult subjects only, unclear rationale for the efficacy threshold, and missing data. The FDA has required Cochlear Americas to conduct a post marketing study to continue to assess the safety and efficacy of the implant in a new enrollment cohort of adults and children.

The MED-EL Cochlear Implant System combined with electrical stimulation and acoustic amplification (EAS) received FDA approval in September 2016 (P000025/S084) and was indicated for partially deaf individuals aged 18 years and older who have residual hearing sensitivity in the low frequencies sloping to a severe/profound SNHL in the mid to high frequencies, and who obtain minimal benefit from conventional acoustic amplification. The FDA expanded the indication for the MED-EL Cochlear Implant System in July 2019 (P000025/S104) to include individuals aged five years and older with SSD or AHL who have profound sensorineural hearing loss in one ear and normal hearing or mild SNHL in the other ear.

Auditory Brainstem Implant

The Nucleus 24 Auditory Brainstem Implant System (Cochlear Corporation) is the only device that has received approval by the FDA (2016) for auditory brainstem implantation. The device is indicated for individuals 12 years of age and older who have been diagnosed with neurofibromatosis type II.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
69930	Cochlear device implantation, with or without mastoidectomy
92601	Diagnostic analysis of cochlear implant, patient younger than 7 years of age; with programming
92602	subsequent reprogramming
92603	Diagnostic analysis of cochlear implant, age 7 years or older; with programming
92604	subsequent reprogramming
92605	Evaluation for prescription of non-speech-generating augmentative and alternative communication device, face-to-face with the patient; first hour
92618	each additional 30 minutes (List separately in addition to code for primary procedure)
92640	Diagnostic analysis with programming of auditory brain stem implant, per hour

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HCPCS Codes

Code	Description
L8614	Cochlear device, includes all internal and external components
L8615 - L8619	Replacement components of cochlear implant device/system (code range)

Code	Description
L8621 - L8624	Replacement batteries used with cochlear implant device/system (code range)
L8625	External recharging system for battery for use with cochlear implant or auditory osseointegrated device, replacement only, each
L8627	Cochlear implant, external speech processor, component, replacement
L8628	Cochlear implant, external controller component, replacement
L8629	Transmitting coil and cable, integrated, for use with cochlear implant device, replacement
S2235	Implantation of auditory brainstem implant

ICD10 Codes

Code	Description
H90.3 - H90.8	Conductive and sensorineural hearing loss (code range)
H90.A2-H90.A32	Mixed conductive and sensorineural hearing loss (code range)
H91.3	Deaf nonspeaking, not elsewhere classified
H93.3x1-H93.3x9	Disorders of acoustic nerve (code range)
Q85.02	Neurofibromatosis, type 2
Z96.21	Cochlear implant status

REFERENCES

Agency for Healthcare Research and Quality [Internet]. Technology assessment. Effectiveness of cochlear implants in adults with sensorineural hearing loss [2011 Apr 11; corrected 2011 Jun 17; accessed 2026 Jan 12] Available from: http://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id80TA.pdf

American Academy of Audiology [Internet]. Clinical practice guideline: cochlear implants. [2019 Jul; accessed 2026 Jan 20] Available from: https://www.audiology.org/wp-content/uploads/2021/05/CochlearImplantPracticeGuidelines.pdf

American Academy of Otolaryngology-Head and Neck Surgery [Internet]. Position statement: cochlear implant candidacy for children with bilateral sensorineural hearing loss. [Adopted 2021 Jul; Revised 2021 Sep 23; accessed 2026 Jan 15] Available from: https://www.entnet.org/resource/position-statement-cochlear-implant-candidacy-children-bilateral-sensorineural-hearing-loss/

American Academy of Otolaryngology-Head and Neck Surgery [Internet]. Position statement: cochlear implant for single sided deafness in adults. [2023 Apr 25;accessed 2026 Jan 12] Available from: https://www.entnet.org/resource/position-statement-cochlear-implantation-for-single-sided-deafness-in-adults/

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) [Internet]. Position statement: cochlear implants. 1982 Jul 10[Revised 2021 Apr 05; accessed 2026 Jan 27] Available from: Position Statement: Cochlear Implants - American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)

American Academy of Otolaryngology-Head and Neck Surgery [Internet]. Position statement: pediatric cochlear implantation candidacy. [2020 April 5; accessed 2026 Jan 12] Available from: https://www.entnet.org/resource/position-statement-pediatric-cochlear-implantation-candidacy/

American Speech-Language-Hearing Association (ASHA). Practice portal clinical topics: cochlear implants, hearing loss adults, and hearing loss childhood. [accessed 2026 Jan 12] Available from: https://www.asha.org/practice-portal/clinical-topics/

Baron S, et al. Sequential bilateral cochlear implants in children and adolescents: outcomes and prognostic factors. Eur Ann Otorhinolaryngol Head Neck Dis. 2019 Apr;136(2):69-73. PMID 30314876

Basura G, et al.; Aural Rehabilitation Clinical Practice Guideline Development Panel. American Speech-Language-Hearing Association clinical practice guideline on aural rehabilitation for adults with hearing loss. Am J Audiolo. 2023 Mar;32:1-51.

Benchetrit L, et al. Cochlear implantation in children with single-sided deafness: a systematic review and meta-analysis. JAMA Otolaryngol Head Neck Surg. 2021 Jan 01;147(1):58-69.

Bond M, et al. Effectiveness of multi-channel unilateral cochlear implants for profoundly deaf children: a systematic review. Clin Otolaryngol. 2009 Jun;34(3):199-211. PMID 19531168

Bond M, et al. The effectiveness and cost-effectiveness of cochlear implants for severe to profound deafness in children and adults: a systematic review and economic model. Health Technol Assess. 2009 Sep;13(44):1-330. PMID 19799825

Crathorne L, et al. A systematic review of the effectiveness and cost-effectiveness of bilateral multichannel cochlear implants in adults with severe-to-profound hearing loss. Clin Otolaryngol. 2012 Oct; 37(5): 342-54. PMID 22928754

Dillon MT, et al.; endorsed by the American Academy of Audiology. [Internet]. American Cochlear Implant Alliance Task Force guidelines for clinical assessment and management of adult cochlear implantation for single-sided deafness. Ear & Hearing. 2022 Aug;43:1605-1619 [accessed 2026 Jan 12] Available from: https://www.audiology.org/practice-guideline/american-cochlear-implant-alliance-task-force-guidelines-for-clinical-assessment-and-management-of-adult-cochlear-implantation-for-

single-sided-deafness/

Dunn CC, et al. A consensus to revise the minimum speech test battery–Version 3. AJA. 2024 Sep;33:624-647.

Gantz BJ, et al. Multicenter clinical trial of the Nucleus Hybrid S8 cochlear implant: Final outcomes. Laryngoscope.2016 Apr;126(4):962-73.

Gaylor JM, et al. Cochlear implantation in adults: a systematic review and meta-analysis. JAMA Otolaryngol Head Neck Surg. 2013 Mar;139(3):265-72. PMID 23429927

Karltorp E, et al. Cochlear implants before 9 months of age led to more natural spoken language development without increased surgical risks. Acta Paediatr. 2020 Feb;109(2):332-341.

Lenarz T, et al. European multi-centre study of the Nucleus Hybrid L24 cochlear implant. Int J Audiol. 2013 Dec;52(12):838-48.

Marx M, et al. Cochlear implantation and other treatments in single-sided deafness and asymmetric hearing loss: results of a national multicenter study including a randomized controlled trial. Audiol Neurootol. 2021 Mar 31;26(6)414-424.

McRackan TR, et al. Meta-analysis of cochlear implantation outcomes evaluated with general health-related patient-reported outcome measures. Otol Neurotol 2018 Jan;39(1):29-36.

McRackan TR, et al. Meta-analysis of quality-of-life improvement after cochlear implantation and associations with speech recognition abilities. Laryngoscope 2018 Apr; 128(4):982-990.

Merkus P, et al. Indications and contraindications of auditory brain stem implants: systematic review and illustrative cases. Eur Arch Otorhinolaryngol. 2014 Jan; 271(1): 3-13.

National Institute for Health and Care Excellence (NICE) [Internet]. Cochlear implants for children and adults with severe to profound deafness. Technology appraisal guideline (TA566) [2019 Mar; accessed 2026 Jan 12] Available from: https://www.nice.org.uk/guidance/ta566

National Institute on Deafness and Other Communication Disorders [Internet]. Cochlear Implants, NIH Publication No. 00-4798 [2016 Feb; updated 2024 Jun 13; accessed 2026 Jan 12] Available from: What Are Cochlear Implants for Hearing? | NIDCD.

Oh SJ, et al. Cochlear implantation in adults with single-sided deafness: a systematic review and meta-analysis. Otolaryngol Head Neck Surg. 2023 Jan 26;168(2):109-250.

Ontario Health (Quality). Auditory brainstem implantation for adults with neurofibromatosis 2 or severe inner ear abnormalities: final recommendations. Ont Health Technol Assess Ser. 2020 Mar;20(4):1-85.

Otto SR, et al. Audiologic outcomes with the penetrating electrode auditory brainstem implant. Otol Neurotol 2008 Dec;29(8):1147-54.

Park LR, et al; endorsed by the American Academy of Audiology. American Cochlear Implant Alliance Task Force guidelines for clinical assessment and management of cochlear implantation in children with single-sided deafness. Ear & Hearing. 2022 Mar;43:255-267.

Peters JPM, et al. Short-term outcomes of cochlear implantation for single-sided deafness compared

to bone conduction devices and contralateral routing of sound hearing aids-results of a randomized controlled trial (CINGLE-trial). PLoS One. 2021 Oct 13;16(10)e0257447.

Piva de Freitas P, et al. Quality of life in children with unilateral hearing loss undergoing cochlear implantation: A systematic review and meta-analysis. Braz J Otorhinolaryngol. 2025 Sep-Oct;91(5):101628.

Poncet-Wallet C, et al. Prospective multicentric follow-up study of cochlear implantation in adults with single-sided deafness: tinnitus and audiological outcomes. Otol Neurotol. 2020 Apr;41(4):458-466.

Reinhart P, et al. Hybrid cochlear implant outcomes and improving outcomes with electric-acoustic stimulation. Otol & Neuro. 2024 Dec;45(10):p e749-e755.

Roland JT Jr, et al; Multicenter Clinical Trial Group. United States multicenter clinical trial of the cochlear nucleus hybrid implant system. Laryngoscope. 2016 Jan;126(1):175-81.

Roland JT Jr, et al. Long-term outcomes of cochlear implantation in patients with high-frequency hearing loss. Laryngoscope. 2018 Aug; 128(8):1939-1945.

Sladen DP, et al. Cochlear implantation for single-sided deafness: A multicenter study. Laryngoscope. 2017 Jan;127(1):223-228.

Thompson NJ, et al. Subjective benefits of bimodal listening in cochlear implant recipients with asymmetric hearing loss. Otolaryngol Head Neck Surg. 2020 Mar 17:194599820911716.

Tsuji RK, et al. Brazilian Society of Otology task force-single sided deafness-recommendations based on strength of evidence. Braz J Otorhinolaryngology. 2025 Jan-Feb;91(1):1-24.

U.S. Food and Drug Administration [Internet]. Med-El Cochlear Implant System–P000025/S104. [2019 Jul; accessed 2026 Jan 12] Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf/P000025S104A.pdf

U.S. Food and Drug Administration [Internet]. Nucleus 24 Cochlear Implant System – P970051/S172. 2020 Mar; accessed 2026 Jan 12] Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf/P970051S172A.pdf

U.S. Food and Drug Administration [Internet]. Premarket Approval: COMBI 40+ Cochlear Implant System (Med-EL)– P000025. [2021 Aug; accessed 2026 Jan 12] Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000025

U.S. Food and Drug Administration [Internet]. Premarket Approval: HiResolution Bionic Ear System – P960058. [2023 Jun; accessed 2026 Jan 27] Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P960058

U.S. Food and Drug Administration [Internet]. Premarket Approval: Med-El Cochlear Implant System with combine electrical stimulation and acoustic (ESA) amplification–P000025/S084. 2016 Sept; accessed 2026 Jan 12] Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P000025S084

U.S. Food and Drug Administration [Internet]. Premarket Approval: Neuro Cochlear Implant System – P200021. [2021 Jun; accessed 2026 Jan 27] Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P200021

U.S. Food and Drug Administration [Internet]. Premarket Approval: Nucleus 24 Cochlear Implant System – P970051/S205. 2022 Jan; accessed 2026 Jan 12] Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P970051S205

U.S. Food and Drug Administration [Internet]. Premarket Approval: Nucleus Hybrid L24 Cochlear Implant System - P130016. [2014 Mar; accessed 2026 Jan 27] Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130016

Warner-Czyz AD, et al.; endorsed by the American Academy of Audiology. American Cochlear Implant Alliance Task Force guidelines for determining cochlear implant candidacy in children. Ear & Hearing. 2022 Mar;43:268-282.

Wilkinson EP, et al. Initial results of a safety and feasibility study of auditory brainstem implantation in congenitally deaf children. Otol Neurotol. 2017;38(2):212-220.

World Health Organization [Internet]. Fact sheets, deafness and hearing loss. 2024 Feb 2; accessed 2026 Jan 12] Available from: Deafness and hearing loss

Zeitler DM, et al.; endorsed by the American Academy of Audiology. American Cochlear Implant Alliance Task Force: recommendations for determining cochlear implant candidacy in adults. Laryngoscope. 2023 Jul;00:1-14.

SEARCH TERMS

Hearing implant, Advanced Bionics HiResolution Bionic Ear System (HiRes 90k), Cochlear Nucleus 5, Med El Maestro (Sonata or Pulsar), Cochlear Implant Single-Unit Audio Processor

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Cochlear Implantation (NCD 50.3) [accessed 2026 Jan 15]

Auditory brainstem implants are not addressed in National or Regional Medicare coverage determinations or policies. Please refer to the Medicare Benefit Policy Manual [Last updated 2025 Jun 06; accessed 2026 Jan 15] Available from: Medicare Benefit Policy Manual Chapter 16-Section 100

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New:09/07 **Revised**:07/08, 07/09, 01/10, 07/10, 07/11, 07/13, 07/14, 07/15, 07/16, 07/17, 01/18, 11/19, 07/20, 7/21, 11/22, 11/25 **Reviewed**:07/12, 07/18, 07/19, 7/22, 7/23, 7/24, 1/25, 5/26	
Date	**Summary of Changes**
6/1/2026	Annual update, policy intent unchanged.
1/1/2026	Transitioned Cochlear Implant policy, 1370/20.000446 to Lifetime HealthCare Companies policy template.
9/26/2022	Revised criteria for hearing test scores from 40% correct to 60% correct. Added exception in Policy Considerations that members may be approved for coverage if not meeting policy criteria but enrolled in an FDA-approved category B investigational device exemption clinical trial.
8/1/2021	Under exclusion section: removed hybrid cochlear implant/hearing. Under Position Statement: added criteria for a hybrid cochlear implant/hearing aid.
11/1/2020	Removed coverage information for small group/individual plans in its entirety from Product Variations section as coverage is no different than commercial coverage addressed in application section of policy.
1/1/2020	Moved all coverage criteria from Medicare section to the Application section. Added coverage criteria for Small Group Individual Plans to CDPHP Product Variations section.

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

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POLICY NAME: CONCURRENT REVIEW

POLICY EFFECTIVE DATE:	8/1/2023
Policy Control #:	1370/20.000174
Next Annual Review:	July, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

DESCRIPTION

Inpatient concurrent review is an ongoing assessment to determine medical necessity of the care provided and appropriateness of the clinical setting during an enrollee's confinement in a hospital, skilled nursing, or rehabilitation facility.

CDPHP utilizes state and nationally published guidelines to assist with all determinations regarding admission and appropriateness of continued stay to facilitate the coordination of discharge planning and to research alternate levels of care.

Coverage determinations for inpatient behavioral health services are made in a manner consistent with accepted medical practices and Federal and State behavioral health parity laws.

The concurrent review process for behavioral health services includes application of criteria that are no more stringent than criteria used in the review of medical services and the review process itself is comparable to and no more stringent than the process for reviewing medical services.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

- Review Process for Resource Coordination, 1370/20.000213.

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POLICY NAME: CONCURRENT REVIEW

- CDPHP Concurrent Review Guideline, 1370/20.000497

POSITION STATEMENT

The CDPHP concurrent review process includes the following elements:

- The utilization of InterQual guidelines and a set of well-defined resource coordination medical policies.
- The utilization of LOCADTR-3 patient placement tool for substance use disorder treatment
- The utilization of InterQual medical necessity criteria for mental health services, along with case review in accordance with the NYS Office of Mental Health Guiding Principles.
- Obtaining necessary information from facility staff (designated UM department), physicians, and other members of the health care team regarding the clinical status, progress, and care being provided to enrollees.
- Identifying continuing care needs early in the inpatient stay to facilitate discharge to the appropriate setting.
- Assessing the ongoing provision of medical services and treatment to determine benefit coverage.
- Notifying practitioners, providers, and the enrollee or designee of coverage determinations in the appropriate manner and timeframe.
- Identifying enrollees for referral to covered specialty programs, including CDPHP Care Management Program, Chronic Condition Management, Behavioral Health Care Management, Enhanced Primary Care (EPC) Program, and Readmission Avoidance Program (RAD).

Concurrent review may be conducted daily, as deemed appropriate, on all CDPHP enrollees who are identified as inpatient to include, but not limited to the following:

- Planned admissions to hospitals
- Emergent/urgent admissions to hospitals
- Admission to skilled nursing facilities
- Admission to rehabilitation facilities
- Out-of-area admissions

Admission to a Participating OASAS-Licensed Facility

Coverage for inpatient admission for substance use disorder treatment at an OASAS-licensed facility that participates in the CDPHP network is not subject to preauthorization. Coverage will be subject to concurrent review on day 29 of the inpatient admission if the OASAS-licensed facility notifies CDPHP of both the admission and the initial treatment plan within two business days of admission. The entire stay may be reviewed, including the initial 28-day period, to determine whether the admission and treatment is medically necessary. Care for members discharged prior to day 29 will be reviewed retrospectively. Facilities are required to notify CDPHP of discharge within 24 hours of the discharge date and retrospective review may begin

when CDPHP is notified of the discharge. The facilities must hold members harmless for any denial of stay based upon retrospective review. Applies to member contracts issued or renewed on or after 1/1/17. Most self-insured and Medicare Advantage products are excluded from this consideration and will follow standard prior authorization requirements.

Inpatient Mental Health Admissions for Children under age 18

Coverage for inpatient admission to a participating facility within New York State, for the treatment of a mental health condition, for children under age is not subject to preauthorization. Coverage determinations are rendered when a member meets one or more predefined clinical or quality triggers, in accordance with the New York State Office of Mental Health's Guiding Principles for the utilization review process for mental health treatment. If a trigger is met, coverage will be subject to concurrent review on day 15 of the inpatient admission if the facility notifies CDPHP of both the admission and the initial treatment plan within two business days of admission. The entire stay may be reviewed, including the initial 14-day period, to determine whether the admission and treatment is medically necessary. In the event that a trigger is met, care for members discharged prior to day 15 will be reviewed retrospectively. Facilities are required to notify CDPHP of discharge within 24 hours of the discharge date and retrospective review may begin when CDPHP is notified of the discharge. Most self-insured- and Medicare Advantage products are excluded from this consideration and will follow standard prior authorization requirements. Applies to members under age 18 at the time of their hospitalization. When no trigger for utilization review it met, concurrent review does not occur. The member's care is assigned to a clinician for care coordination purposes.

Inpatient Mental Health Admissions

Prior authorization is not required for emergent admissions to inpatient mental health levels of care and concurrent review, using the InterQual guidelines, and is completed only when one or more specific clinical or quality triggers are met.

POLICY CONSIDERATIONS

Concurrent review is conducted by the resource coordination staff via telephonic review.

The utilization reviewer or behavioral health inpatient care manager facilitates appropriate use of medical and community resources to improve quality of care and maintain cost effectiveness.

When the utilization reviewer or behavioral health inpatient care manager has any question of medical necessity or inappropriate resource utilization, the case is reviewed with a CDPHP medical director.

After careful review, including contact with the attending physician as necessary, denial determinations may be rendered by a medical director.

POLICY NAME: CONCURRENT REVIEW

In those cases of denial of continued stay, the denial process is instituted.

- The attending physician, enrollee or designee, and the inpatient facility are notified and correspondence signed by the medical director is sent directly by fax and/or mail to the enrollee or designee, physician, and facility.
- If the enrollee is to be liable, the enrollee or designee is notified verbally as well as with written notification.
- All correspondence includes appeal rights.

Assessment of medical necessity for all substance use disorder treatment that is provided within New York state at facilities licensed by the Office of Alcoholism and Substance Abuse Services ("OASAS") is done in compliance with Chapter 41 of the Laws of 2014; New York Insurance Law Article 49; New York Public Health Law Article 49, using the Level of Care for Alcohol and Drug Treatment Referral ("LOCADTR") tool, which has been approved for such use by the Commissioner of OASAS in consultation with the Commissioner of Health and the Superintendent of Financial Services.

Assessment of medical necessity for all inpatient mental health treatment that is provided within New York State is done in compliance with Chapter 57 of the Laws of 2019, Insurance Law § 4902 and Public Health Law § 4902.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy except admission to OASAS-licensed facility. However, in the event of a denial for continued stay, the physician who is responsible for the enrollee's hospital care must concur.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy, in addition to the following: • LOCADTR 3 is utilized exclusively for all substance use disorder level of care decisions. • Decisions related to authorization of continued stay for behavioral health diagnosis will be made by licensed behavioral health professionals with at least three (3) years of clinical experience in behavioral health. • All behavioral health decision makers have clinical expertise in treating enrollee's condition, stratified by age. • Behavioral health denials are conducted by a peer with credentials at least equal to that of the recommending clinician.

	• For all inpatient behavioral health treatment denials, review will be completed by: ➢ A physician board certified in general psychiatry for inpatient psychiatric treatment. ➢ A physician board certified in child and adolescent psychiatry for inpatient psychiatric treatment for enrollees aged 18 and under. ➢ A physician certified in addiction treatment for inpatient substance use disorder treatment.

SOURCES

1. CDPHP Technology Assessment Team
2. Managed Care Law
3. Federal Register, Vol. 63, No. 123, Friday, June 26,1998, Rules and Regulations §422.620(b)
4. Federal Registry, Vol 71. No 227, Medicare Program: Notification of Hospital Discharge Appeal Rights; Final Rule, https://www.govinfo.gov/content/pkg/FR-2006-11-27/html/E6-20131.htm
5. National Committee on Quality Assurance (NCQA) Standards and Guidelines.
6. Guiding Principles for the Review and Approval of Clinical Review Criteria for Mental Health Services, NYS OMH; October 2019

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POLICY APPROVAL DATES

New:	04/98
Revised:	03/99, 10/99, 10/02, 09/03, 10/03, 09/04, 05/05, 09/06, 07/09, 07/11, 07/12, 7/14, 07/15, 05/16, 07/16, 11/16, 01/17, 07/17, 07/19, 05/20, 11/20, 7/22, 7/23
Reviewed:	05/00, 04/06, 09/07, 07/08, 07/10, 07/13, 07/18, 7/21, 7/24, 7/25, 7/26

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POLICY NAME: CONCURRENT REVIEW

POLICY HISTORY

Effective Date	Update
8/1/2023	Added InterQual to first bullet under Policy Statement.
8/1/2022	Updated statement for concurrent reviews to indicate they are done telephonically only in Policy Considerations section. Replaced LOCUS/CALOCUS with InterQual for mental health services in Position Statement. Updated criteria for Inpatient Mental Health Admissions for Children under 18 and Inpatient Mental Health Admissions.
1/1/2021	Policy updated in response to regulatory requirements issued by NYS Office of Mental Health (OMH).
1/1/2020	Added new sections for Admission to OASAS-Licensed Facility and Inpatient Mental Health Admissions for Children Under 18.

This Resource Coordination Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI) and Capital District Physicians' Healthcare Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: CONCURRENT REVIEW GUIDELINE

POLICY EFFECTIVE DATE:	5/1/2022
Policy Control #:	1370/20.000497
Next Annual Review:	May, 2027

The following guideline outlines those services that require concurrent review. All services outlined in this guideline are subject to medical necessity and benefit availability as defined in the enrollee's contract and/or employer-sponsored Summary Plan Description (SPD) and Benefit Design Document (BDD). Coverage of a service is subject to the member's eligibility, specific contract benefits, and CDPHP® medical/behavioral health policy. Requests for a service that do not meet criteria outlined in a CDPHP policy, or for an extension of services beyond what has been approved by CDPHP, should be directed to the resource coordination (RC) department at (518) 641-4100/1-800-274-2332. Inquiries regarding behavioral health services should be directed to the behavioral health (BH) department at (518) 641-3600/1-888-320-9584.

The **provider** is responsible for seeking prior authorization for services indicated within this guideline for the following CDPHP products: HMO, Medicare Choices HMO, Select Plan/HARP, and Child Health Plus. The **member** is responsible for seeking authorization for such services for the following CDPHP UBI products: PPO and HDPPO (in- and out-of-network), and EPO and HDEPO.

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POLICY NAME: CONCURRENT REVIEW GUIDELINE

Policy Reference/ Type of Service Requiring Concurrent Review	Contact Department	HMO	UBI PPO/HDPPO Network Benefits:		UBI EPO/ HDEPO	UBI Small Group	Select Plan/ HARP	Child Health Plus	Medicare Advantage		
			In	Out					HMO	PPO Network Benefits In	PPO Network Benefits Out
Ambulatory Mental Health Programs for Adults, 1370/20.000488	BH										
Assertive Community Treatment		N/A	N/A	N/A	N/A	N/A	No	N/A	N/A	N/A	N/A
Continuing Day Treatment		N/A	N/A	N/A	N/A	N/A	No	N/A	N/A	N/A	N/A
Personalized Recovery Oriented Services (PROS): Active Rehabilitation		N/A	N/A	N/A	N/A	N/A	No	N/A	N/A	N/A	N/A

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Policy Reference/ Type of Service Requiring Concurrent Review	Contact Department	HMO	UBI PPO/HDPPO Network Benefits:		UBI EPO/ HDEPO	UBI Small Group	Select Plan/ HARP	Child Health Plus	Medicare Advantage		
			In	Out					HMO	PPO Network Benefits In	PPO Network Benefits Out
Home Health Care/TeleHomecare/ Personal Care/Personal Emergency Response System: 1370/20.000048 Home care for the following services: Personal Care Services (PCS), Consumer Directed Personal Assistance (CDPA), and Personal Emergency Response System (PERS)	RC	N/A	N/A	N/A	N/A	N/A	Yes	N/A	N/A	N/A	N/A
Inpatient Continued Stay/Concurrent Review, 1370/20.000174 • Medical	RC	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
• Behavioral Health	BH	Yes*	Yes*	Yes	Yes*	Yes*	Yes*	Yes*	Yes	Yes	No

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Policy Reference/ Type of Service Requiring Concurrent Review	Contact Department	HMO	UBI PPO/HDPPO Network Benefits:		UBI EPO/ HDEPO	UBI Small Group	Select Plan/ HARP	Child Health Plus	Medicare Advantage		
									HMO	PPO Network Benefits	
			In	Out						In	Out
*Special conditions apply											
Inpatient Detoxification: Medically Supervised Level of Care, 1370/20.000475 *Special conditions apply	BH	Yes*	Yes*	Yes	Yes*	Yes*	Yes*	Yes*	Yes	Yes	No
Intensive Outpatient Programs *(Psychiatric):* 1370/20.00045	BH	No	No	No	No	No	N/A	N/A	No	No	No
Intensive Outpatient Programs *(Substance Use Disorder):* 1370/20.00045	BH	No	No	No	No	No	No	No	No	No	No
Partial Hospitalization Programs *(Psychiatric):* 1370/20.00045	BH	No	No	No	No	No	No	N/A	No	No	No

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POLICY NAME: CONCURRENT REVIEW GUIDELINE

Policy Reference/ Type of Service Requiring Concurrent Review	Contact Department	HMO	UBI PPO/HDPPO Network Benefits:		UBI EPO/ HDEPO	UBI Small Group	Select Plan/ HARP	Child Health Plus	Medicare Advantage		
			In	Out					HMO	PPO Network Benefits In	PPO Network Benefits Out
Partial Hospitalization Programs/ Day Rehabilitation *(Substance Use Disorder):* 1370/20.00045	BH	No	No	No	No	No	No	N/A	No	No	No
Residential Treatment Facilities for Mental Health and Substance Abuse, 1370/20.000482 *Special conditions apply	BH	Yes*	Yes*	Yes	Yes*	Yes*	Yes* (N/A for mental health)	N/A	N/A	N/A	N/A

*Special conditions apply for behavioral health admissions, as outlined in corresponding policies noted above.

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POLICY NAME: CONCURRENT REVIEW GUIDELINE

SOURCES

1. Transition of Behavioral Health Benefit into Medicaid Managed Care and Health and Recovery Program Implementation, October 2015, NYS DOH OMH OASAS
2. Memorandum: Guidance for the Implementation of Coverage and Utilization Review Changes Pursuant to Chapters 69 and 71 of the laws of 2016.
3. Member contract language

POLICY APPROVAL DATES

New: 05/16

Reviewed: 5/23, 5/24, 5/25, 5/26

Revised: 01/17, 05/17, 05/18, 09/18, 05/19, 01/20, 05/20, 5/21, 9/21, 5/22

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

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POLICY NAME: CONCURRENT REVIEW GUIDELINE

Effective Date	Update
5/1/2022	Removed neuropsychological and psychological testing from grid as there is no longer a prior authorization for these services.
10/1/2021	Removed "Mental Health Services" from the Home Health Care section as there is no concurrent review of these services.
6/01/2021	Updated Inpatient Detoxification for the Medicare PPO line of business to reflect no prior authorization required for out-of-network services.
1/1/2020	The following two sections are updated to reflect an increase in number of allowed visits from 6 to 12 prior to medical necessity review: Neuropsychological Testing and Psychological Testing. Removed Behavioral Health Home and Community Based Services from the guideline as concurrent review no longer performed.

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MEDICAL POLICY

Medical Policy Title	**Continuous Glucose Monitoring Systems/External Insulin Pump Therapy for Diabetes**
Policy Number	**1.01.30**
Current Effective Date	**September 1, 2026**
Next Review Date	**December 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Initial Request for External Insulin Pump Therapy (HCPCS: E0784)*

A. External insulin pumps are **medically appropriate** for individuals with diabetes requiring insulin when **ALL** the following criteria are met:

1. On a program of multiple daily injections of insulin (at least three (3) per day);
2. Require frequent self-adjustments of insulin dose for at least three (3) months prior to initiation of the insulin pump;
3. Performs self-testing of glucose an average of at least three (3) times per day one (1) month prior to initiation of the insulin pump or has been using a continuous glucose monitor (CGM);
4. Completed a comprehensive diabetes education program;
5. Diabetes is poorly controlled despite best practices (please refer to Policy Guideline II).

B. External insulin pumps are **medically appropriate** for women with gestational diabetes when **BOTH** of the following criteria are met:

1. Require three (3) or more insulin injections per day;
2. Diabetes cannot be controlled by intermittent dosing.

*Disposable external insulin infusion pumps (e.g., OmniPod Insulin Management System/Omnipod Dash, V-Go transdermal insulin delivery device) are considered acceptable alternatives to standard insulin infusion pumps.

II. Replacement External Insulin Pump

A. Replacement of an external insulin pump is **medically appropriate** when the following criteria are met:

1. The external insulin pump has been previously approved by the Health Plan, or the external insulin pump was in use prior to the effective date of the member's coverage with the Health Plan; **and**
2. The pump has exceeded its warranty (warranty period for insulin pumps: four (4) years)

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and the pump is malfunctioning; **or**

3. The request is for a child in need of a larger insulin reservoir.

B. Replacement of an external insulin pump is **not medically necessary** for the following indications including, but not limited to:

1. Slight damage to the pump (e.g., scratched screen);
2. Damage does not cause the pump to malfunction; **or**
3. Replacement request is driven by an advancement in technology.

III. Initial Request for Continuous Glucose Monitoring System (CGMS) (HCPCS: A9276, A9277, A9278, E2102, E2103, A4238, A4239)

A. Continuous glucose monitoring (CGM) devices are **medically appropriate** for individuals with a diagnosis of diabetes mellitus (i.e., Type 1, Type 2, other specific types of diabetes, gestational diabetes) whose age is consistent with U.S. Food and Drug Administration (FDA) indications for the specific CGM device.

B. Implantable sensors (e.g., Eversense, Senseonics) are **medically appropriate** for individuals with diabetes who meet the following criteria:

1. Age is consistent with U.S. Food and Drug Administration (FDA) indications for the specific CGM device; and have **ANY** of the following:
   a. Physical disability, such as an impairment in vision, hearing, or dexterity;
   b. A severe sensitivity to adhesives or plastics used in transcutaneous CGM components; **or**
   c. Any significant condition or situation requiring vibration alerts (e.g., individual lives alone and requires additional alarms to increase awareness of highs or lows).

IV. Professional Glucose Monitoring (three (3) to seven (7) days) (CPT: 95249, 95250, 95251)

A. Professional Glucose Monitoring is **medically appropriate** for **EITHER** of the following indications:

1. Diabetes is poorly controlled despite current evidence of best practices; **and**
   a. Has demonstrated compliance with recommended medical regimens; **or**
2. For individuals with a diagnosis of diabetes mellitus (i.e., Type 1, Type 2, other specific types of diabetes, gestational diabetes) who
   a. Are pregnant or about to become pregnant; **and**
   b. Who cannot meet recommended targets for control of diabetes in pregnancy.

V. Replacement of a CGM Device Transmitter (HCPCS: A9277, E2102)

A. Replacement of a CGM transmitter is **medically appropriate** when the following criteria

are met:

1. The transmitter or receiver is out of warranty (Warranty Period for CGM: One Year); **and**
2. The CGM device has been previously approved by the Health Plan; **or**
3. The CGM device was in use prior to the effective date of the member's coverage with the Health Plan.

VI. Replacement of a CGM Sensor (HCPCS: A4238, A4239 A9276, E2103)

A. Replacement of a CGM sensor is **medically appropriate** when **EITHER** of the following criteria are met:

1. CGM device has been previously approved by the Health Plan; **or**
2. CGM device was in use prior to the effective date of the member's coverage with the Health Plan.

VII. Initial Request for a Combined External Insulin Pump and CGM Device (Artificial Pancreas) (HCPCS: E0784 and A9276, A9277, A9278)

A. External insulin pumps and CGM devices consisting of sensor-augmented insulin pump therapy with a low glucose threshold suspend feature and a continuous glucose monitor, are considered **medically appropriate** when criteria for an external insulin pump **AND** a CGM device have been met.

VIII. Replacement of a Combined External Insulin Pump and CGM~~S~~ Device (Artificial Pancreas):

A. Replacement of an external insulin pump and CGM device is **medically appropriate** when **BOTH** of the following criteria are met:

1. The combined external insulin pump and CGM device has been previously approved by the Health Plan or the combined external insulin pump and CGM device was in use prior to the effective date of the member's coverage with the Health Plan; **and**
2. The combined external insulin pump and CGM device's transmitter or receiver are out of warranty and the insulin pump is malfunctioning.

RELATED POLICIES

Resource Coordination Policies:

Durable Medical Equipment, Prosthetics/Orthotics & Medical Supplies, 1550/20.000509

POLICY GUIDELINE(S)

I. Evidence of poorly controlled diabetes may include, but are not limited to, the following:

A. Hemoglobin A1c (HbA1c) greater than 7% within the last four (4) months;

B. History of recurring hypoglycemia (blood glucose levels low enough to put the individual or

others at risk;

C. Wide fluctuations in blood glucose before mealtime;

D. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL; or

E. History of severe glycemic excursions.

II. Improvement in control of the disease may be evidenced by, among other indications, **ANY** of the following:

A. HbA1c within therapeutic range;

B. Fewer episodes of hyperglycemia or hypoglycemia; or

C. More time spent in range (avoidance of either high or low glucose values).

III. The individual is liable for any non-medical accessories or add-ons of basic external insulin pump models.

IV. Replacement of purchased equipment that is damaged due to individual neglect, theft, or abuse; or replacement when another available coverage source is an option (e.g., homeowners, rental, auto, or liability insurance, etc.) is **ineligible for coverage**.

DESCRIPTION

Continuous Glucose Monitoring (CGM) Devices

CGM devices are used by diabetic individuals to supplement, not replace, blood glucose information obtained using standard fingerstick glucose meters and test strips. These devices are placed subcutaneously and automatically measure and track interstitial glucose and produce trends in glucose measurements throughout the day which may allow for tighter glucose control and a subsequent decrease in complications from diabetes. Most of today's CGM systems are built with active alarms to alert the user of hypoglycemia, which they may not have been aware of otherwise. Additionally, as an added safety mechanism, many CGM systems have the capability to share data between the individual, clinicians, and caregivers.

The CGM device consists of a sensor, transmitter, and receiver. The sensor is usually changed every three to fourteen days. The warranties for the transmitters range from three months to one year, depending on the type of device.

There are two forms of CGM systems available for personal use. Real-time CGM (rtCGM) devices automatically transmit data to a receiver and/or smartphone of a person with diabetes, and isCGM, also historically known as "flash" CGM, which requires a person to "swipe" the receiver and/or smartphone close to the sensor to obtain current and historical glucose data.

External Insulin Pumps/Continuous Subcutaneous Insulin Infusion (CSII) Systems

CSIIs are the traditional insulin pumps, using tubing to deliver insulin from the machine through a cannula. They can be used by Type 1 (T1) and Type 2 (T2) patients who require precise dosing

through flexible basal-bolus therapy. Injection sites are rotated every 24-72 hours. The primary benefit of the CSII is reduced injection burden, but additionally, they are discreet and are compatible with CGMs.

Sensor Augmented Pumps (SAPs)

Sensor-augmented pumps (SAPs), also known as hybrid closed-loop systems, include an insulin pump, a continuous glucose monitor (CGM), and an algorithm that automatically pauses insulin delivery when the user's glucose level is low or predicted to drop within the next 30 minutes. These devices have been shown to significantly reduce hypoglycemia, particularly overnight. SAPs have been replaced by automated insulin delivery (AID) systems, which demonstrate even better outcomes. However, AID systems can still operate in low-glucose or predictive low-glucose suspension modes, similar to SAPs.

Automated Insulin Delivery (AID) Systems

Like SAPs, AID systems consist of an insulin pump, a CGM, and an algorithm. These devices are now preferred over non-automated pumps and multi-dose injections for T1 diabetics. Examples include the iLet Bionic Pancreas System, the MiniMed 780G System, and the Omnipod 5, which was recently approved for use in T2 diabetes who are 18 years of age and older (SmartAdjust AID software, with the Omnipod 5 tubeless pump and Dexcom CGM).The algorithm uses CGM data to adjust insulin dosing by modifying preprogrammed basal rates or delivering microdoses of insulin every five minutes based on CGM readings. These systems require manual entry of carbohydrate amounts to assist with prandial dose calculations but also allow adjustments for physical activity.

Patch Pumps

Newer to the market, these are tubeless CSII, with automation, meant for T1 and T2 diabetics that can be treated with bolus only dosing because they are non-programmable. They reduce the injection burden in that they can be worn up to 3 days, and are simple to operate, but they do not have compatibility with CGMs.

The V-Go (Zealand Pharma) and Omnipod DASH (Insulet) are both disposable, tubeless insulin delivery systems that are indicated for T1 or T2 diabetics who require insulin. These systems deliver a pre-set basal rate and on demand boluses via a mechanical button or touchscreen controller (that is not disposable). Each is worn for 24 -72 hours, after which, is removed and a new device is needed to be attached. It does not work with a CGM.

SUPPORTIVE LITERATURE

Wada et al (2020) conducted a 24-week, multicenter, open-label, randomized (1:1) parallel-group study to evaluate the effects of flash glucose monitoring (FGM) versus conventional self-monitoring of blood glucose (SMBG) on glycemic control in patients with non–insulin-treated T2 diabetes. Participants (FGM: n = 49; SMBG: n = 51) used their assigned device for 12 weeks (FGM group received a FreeStyle Libre from Abbott Diabetes Care; SMBG group received a FreeStyle Precision Neo, also from Abbott Diabetes Care). The primary outcome was the change in HbA1c between

groups, analyzed using an analysis of covariance model that included baseline values and group as covariates. All participants and investigators were blinded to sensor glucose measurements during the baseline period. Additionally, the SMBG group was blinded again for the final two weeks of the 12-week intervention. At baseline, mean HbA1c levels were 7.83% in the FGM group and 7.84% in the SMBG group. At 12 weeks, both groups showed reductions (FGM: –0.43%; SMBG: –0.30%; $P \leq 0.001$). However, at 24 weeks, a significant decrease from baseline persisted in the FGM group but not in the SMBG group (FGM: –0.46%, $P < 0.001$; SMBG: –0.17%, $P = 0.124$). HbA1c reductions were significant using both ANCOVA and linear mixed model methods. The authors concluded that FGM use in non–insulin-treated patients may help maintain good glycemic control even after discontinuation of glucose measurement.

Isganaitis et al (2021) assessed the effectiveness and safety of closed loop control (CLC) insulin delivery systems in adolescents and young adults with type 1 diabetes. A sub analysis was conducted on data from a six-month multi center randomized trial. Participants aged 14 through 24 with type 1 diabetes were randomly assigned (2:1) to CLC (tandem control-IQ) or sensor augmented pump (SAP). The mean age of the 63 participants was 17 years, with a mean baseline HbA1c of 8.1%. All 63 participants completed the trial. CLC significantly increased the time in range (TIR) compared to SAP (13% increase with CLC versus 1% decrease with SAP). CLC reduced time > 180mg/dl and time < 70 mg/dl. There were no significant differences in HbA1c levels between the groups. The closed-loop system was active 89% of the time. There was one case of diabetic ketoacidosis that occurred in the CLC group. Researchers concluded that CLC used for six months was substantial and improve TIR and reduce hypoglycemia in adolescents and young adults with type 1 diabetes.

Grace and Salyer (2022) investigated the relevance of commonly used criteria for rtCGM in patients with T2 diabetes who were receiving less intensive therapy, specifically, fewer than three insulin injections per day and a history of blood glucose testing four times daily. This prospective, interventional, single-arm study included 38 patients and analyzed changes in HbA1c, average glucose, glycemic variability (percent coefficient of variation), and the percentage of TIR (70–180 mg/dL), below range (TBR; < 70 mg/dL, < 54 mg/dL), and above range (TAR; >180 mg/dL). Secondary outcomes included changes in body weight and body mass index (BMI). Participants included in the analysis had T2 diabetes, HbA1c > 7.5%, and were treated with basal insulin, non-insulin injectable antidiabetic medications, oral antidiabetic medications, and/or diet and exercise. Screening occurred at baseline, with follow-up clinic visits at three and six months. A significant reduction in mean HbA1c was observed from baseline to three months (10.1% ± 1.8% to 7.3% ± 1.3%, $P < 0.001$) and at six months (10.1% ± 1.8% to 7.1% ± 1.2%, $P < 0.001$). Increases in TIR and reductions in TAR were noted across all groups, although no significant changes in glycemic variability were identified. All participants maintained TBR targets throughout the study period. Additional reductions were observed in weight (103.5 ± 18.2 kg to 100.3 ± 18.6 kg, $P = 0.002$) and BMI (35.6 ± 7.4 to 34.5 ± 6.3, $P = 0.002$). The authors concluded that, despite the study's single-arm design and short duration, intensive insulin therapy requirements and frequent monitoring criteria for CGM coverage are not relevant. They recommend expanding access to CGM for patients with type 2 diabetes who are treated with less intensive therapies.

Beck et al (2023) conducted a meta-analysis of randomized controlled trial (RCT) outcomes on the effects of the hybrid closed loop Control-IQ technology (Control-IQ) in subgroups based on baseline characteristics such as race and ethnicity, social economic status (SES), pre-study insulin delivery modalities (pump or multiple daily injections) and baseline glycemic control. Data were pooled and analyzed from three RCTs comparing Control-IQ to a Control group using CGM in 369 participants with T1 diabetes from age 2 to 72 years old. TIR 70–180 mg/dL in the Control-IQ group (n = 256) increased from 57% – 17% at baseline to 70% – 11% during follow-up, and in the Control group (n = 113) was 56% – 15% and 57% – 14%, respectively (adjusted treatment group difference = 11.5%, 95% confidence interval +9.7% to +13.2%, P < 0.001), an increase of 2.8 h/day on average. Significant reductions in mean glucose, hyperglycemia metrics, hypoglycemic metrics, and HbA1c were also observed. A statistically similar beneficial treatment effect on time in range 70–180 mg/dL was observed across the full age range regardless of race-ethnicity, household income, pre-study continuous glucose monitor use, or pre-study insulin delivery method. Participants with the highest baseline HbA1c levels showed the greatest improvements in TIR and HbA1c. The pooled analysis of Control-IQ RCTs demonstrated the beneficial effect of Control-IQ in T1 diabetes across a broad spectrum of participant characteristics (e.g., racial-ethnic minority, lower SES, lack of pre-study insulin pump experience, and high HbA1c levels). The most benefit was observed in participants with the worst baseline glycemic control in whom the auto-bolus feature of the Control-IQ algorithm has substantial impact. No subgroups were identified that did not benefit from Control-IQ, hybrid-closed loop technology. The investigators strongly suggested its use for all youth and adults with T1 diabetes.

Uhl et al (2024) conducted a systematic review and meta-analysis of RCTs on CGM for the management of T2 diabetes in adults ≥ 18 years older. Objective measures consisted of HbA1c, TIR, hyperglycemia, and hypoglycemia. Findings included 14 randomized trials with 825 individuals using real time CGMs (rtCGM) and 822 using flash CGM. The use of CGM showed modest but statistically significant HbA1c reduction levels of about 0.32%. Separate analysis for each device showed similar HbA1c reductions. Both rtCGM and flash CGMs led to a modest but significant decline in HbA1c for T2 individuals.

Gupta et al (2024) investigated the effect of short-term application of rt and isCGMS in individuals with T1D. They measured HbA1c levels over a period of 3 months. T1 diabetic individuals were randomized into three groups in a ratio of 1:1:2, Group A (rtCGMS for 2 weeks initially, followed by isCGMS for 2 weeks at 3 months), Group B (isCGMS for 2 weeks initially followed by rtCGMS for 2 weeks at 3 months) and Group C (only self-monitoring of blood glucose), respectively. The HbA1c was measured at baseline, 3, and 6 months. Out of a total 68 T1 diabetic individuals, HbA1c decreased significantly in groups A and B at 6 months compared to the baseline, but not in group C. HbA1c was significantly lower in Group A compared to Group C at 3 and 6 months. Fructosamine levels significantly decreased in Group B before and after cross-over. Switching from isCGMS to rtCGMS led to significant improvement in glycemic variability indices. Authors concluded that intermittent application of CGMS for 2 weeks improves short- and long-term blood glucose control in T1 diabetes.

PROFESSIONAL GUIDELINE(S)

The American Diabetes Association (ADA) Professional Practice Committee published an updated Standards in Medical Care in Diabetes 2025, with a chapter dedicated to diabetes in technology, acknowledging the rapid evolution and complexity of new devices that can improve the lives and health of people with diabetes, but can be barriers to implementation for not just people with diabetes, but for their care partners and their dedicated health care team.

The ADA published 32 recommendations in the report, which consistently stated throughout that device selection should be made based on the individual's circumstances, preferences, skill level, and needs. The recommendations include, but are not limited to the following:

1. "Diabetes devices should be offered to people with diabetes (A);
2. Initiation of continuous glucose monitoring (CGM) should be offered to people with type 1 diabetes early in the disease, even at time of diagnosis (A);
3. When prescribing a device, ensure that people with diabetes and caregivers receive initial and ongoing education and training, either in person, or remotely, and ongoing evaluation of technique, results, and the ability to utilize data, including uploading or sharing data (if applicable) to monitor and adjust therapy (C);
4. People with diabetes who have been using CGM, continuous subcutaneous insulin infusion and/or automated insulin delivery (AID) for diabetes management should have continued access across third-party payors regardless of age or A1C levels (E);
5. Recommend early initiation, including at diagnosis, of CGM, CSII, and AID depending on a person's or caregiver's preferences (C);
6. People who are taking insulin and using BGM should be encouraged to check their blood glucose levels when appropriate based on their insulin therapy. This may include checking when fasting, prior to meals and snacks, after meals, at bedtime, in the middle of the night, prior to, during, and after exercise when hypoglycemia is suspected, after treating low blood glucose levels until they are normoglycemic, when hyperglycemia is suspected, and prior to and while performing critical tasks such as driving (B);
7. Although BGM in people on noninsulin therapies has not consistently shown clinically significant reductions in A1C levels, it may be helpful when modifying meal plans, physical activity plans, and/or medications (particularly medications that can cause hypoglycemia) in conjunction with a treatment adjustment program (E);
8. Recommend real-time CGM (rtCGM) (A) or intermittently scanned CGM (isCGM) (B) for diabetes management to youth (C) and adults (B) with diabetes on any type of insulin therapy.
9. Consider using rtCGM or isCGM in adults with type 2 diabetes treated with glucose-lowering medications other than insulin to achieve and maintain individualized glycemic

goals (B).

10. CGM can help achieve glycemic goals (e.g., time in range and time above range) (A) and A1C goal (B) in type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy;
11. In circumstances when consistent use of CGM is not feasible, consider periodic use of personal or professional CGM to adjust medication and/or lifestyle (C);
12. Skin reactions, either due to irritation or allergy, should be assessed and addressed to aid in successful use of devices (E);
13. AID systems should be the preferred insulin delivery method to improve glycemic outcomes and reduce hypoglycemia and disparities in youth and adults with type 1 diabetes and other types of insulin-deficient diabetes who are capable of using the device (either by themselves or with a caregiver) (A);
14. Insulin pump therapy, preferably with CGM, should be offered for diabetes management to youth and adults on multi-dose insulin with type 2 diabetes who can use the device safely (either by themselves or with a caregiver) (A)."

The ADA addresses insulin delivery systems in Chapter 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes- 2025, and includes insulin patches as a proper administration technique, stating that selection of method of administration will depend on a variety of individual-specific factors and needs, cost and coverage, and individual preferences.

In 2025, the Endocrine Society and European Society of Endocrinology published a joint clinical practice guideline regarding preexisting diabetes and pregnancy, which includes, but is not limited to the following:

- Despite being limited direct evidence of superiority of CGM use, it may offer a potential advantage over SBMG in certain subgroups of preexisting T2 diabetes, and therefore pregnant individuals with T2 diabetes should be considered for either CGM or SMBG.
- The standard of care pregnancy glucose targets of fasting < 95mg/dl (5.3mmol/L), one-hour post prandial < 140mg/dl (7.8 mmol/L), two-hour post prandial < 120 md/dl (6.7mmoL) should be used rather than a single CGM target in individuals with pre-existing diabetes mellitus.

The Management of Individuals with Diabetes at High Risk for Hypoglycemia Endocrine Society Clinical Practice Guideline was published by McCall and colleagues in 2022. The recommendations include:

- CGM is preferred over SMBG for patients with T1 diabetes receiving multiple daily injections;
- rtCGM and algorithm-driven insulin pumps should be utilized for adults and children with T1 diabetes, instead of multiple daily injections and SMBG;
- rtCGM is suggested for outpatients with T2 diabetes who take insulin and/or sulfonylureas and

are at risk for hypoglycemia.

The American Association of Clinical Endocrinology (AACE) Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons with Diabetes Mellitus was published by Grunberger G et al in 2021. AACE addresses the following:

- The glucose metrics to be utilized in clinical practice to assess glycemic status;
- Identification of those who would benefit from diabetes technologies, including but not limited to CGM use for all individuals with problematic hypoglycemia, CGM may be recommended for women with gestational diabetes mellitus who are not on insulin therapy and also that CGM may be recommended for individuals with T2 diabetes who are treated with less intensive insulin therapy (Grade B);
- The most efficient approach to interpreting continuous glucose monitoring data;
- Diagnostic/professional CGM considerations;
- Insulin delivery techniques;
- Safety considerations for the use of diabetes technology including CGMs, insulin delivery devices, integrated devices, open-source automatic insulin-dosing systems not approved by the U.S. Food and Drug Administration;
- The implementation of diabetes technologies to clinical practice.

The National Institute for Health and Care Excellence (NICE) guidelines on diagnosis and management of type 1 diabetes in adults (2022) made the following recommendation:

- "Offer adults with type I diabetes a choice of real-time continuous glucose monitoring (rtCGM) or intermittently scanned continuous glucose monitoring (isCGM, commonly referred to as "flash"), based on their individual preferences, needs, characteristics, and the functionality of the devices available."

A 2017 steering committee made up of representatives from the American Association of Clinical Endocrinologists, the American Association of Diabetes Educators, the American Diabetes Association, the Endocrine Society, JDRF International, The Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society, and the T1D Exchange formed a decision-making group for the Type 1 Diabetes Outcomes Program (Agiostratidou et al). Their goal was to develop a consensus on definitions for hypoglycemia, hyperglycemia, time in range, diabetic ketoacidosis, and patient-reported outcomes. While their decisions were informed via input from researchers, industry, and people with diabetes, they relied on published evidence, their own clinical expertise, and advisory committee feedback.

The above identified steering committee defined three levels of hypoglycemia:

- Level 1 hypoglycemia was defined as a measurable glucose concentration of less than 70 mg/dL (3.9 mmol/L) but greater than or equal to 54 mg/dL (3.0 mmol/L), which "can alert a person to take action," In those without diabetes, a blood sugar of 70 mg/dL (3.9 mmol/L) is

known as low blood sugar. Blood glucose levels at less than 70 mg/dL (3.9 mmol/L) are relevant and "clinically important," despite a lack of severe symptoms.

- Level 2 hypoglycemia was defined as a measurable glucose concentration of less than 54 mg/dL (3.0 mmol/L), which requires immediate action. At this stage, "neurogenic and neuroglycopenic hypoglycemic symptoms begin to occur, ultimately leading to brain dysfunction at levels less than 50 mg/dL (2.8 mmol/L)." At this level, symptoms like behavioral changes, visual changes, seizure, and loss of consciousness occur due to "central nervous system neuronal glucose deprivation."
- Level 3 hypoglycemia was defined as "a severe event characterized by altered mental and/or physical status requiring assistance." At this level, a person's symptoms are such that they require help from others. For some, this level may occur during the a forementioned level 1 or 2 for hypoglycemia.

REGULATORY STATUS

The New York State Insurance Laws require a medical expense indemnity corporation or a health service corporation which provides medical coverage that includes coverage for physician services in a physician's office and every policy which provides major medical or similar comprehensive type coverage to include coverage of certain equipment and supplies for the treatment of diabetes when recommended or prescribed by a physician or other licensed health care provider. Additionally, coverage must include diabetes self-management education, limited to visits medically necessary upon the diagnosis of diabetes, where a physician diagnoses a significant change in the patient's symptoms or conditions which necessitate changes in a patient's self-management, or where reeducation or refresher education is necessary.

The U.S. Food and Drug Administration (FDA) regulates CGMS and external insulin pumps as medical devices. All CGMS and external insulin pumps including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Nov 11]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 Nov 11]

I. Examples of FDA approved external insulin pumps include, but are not limited to the following:

Brand Name	Manufacturer
MiniMed 770G with SmartGuard technology	Medtronic
MiniMed 780G System	Medtronic

Omnipod	Insulet Corp.
CeQur Simplicity	CeQur
iLet Bionic Pancreas System	Beta Bionics
Omnipod 5	Insulet Corp.
Omnipod Dash	Insulet Corp.
t:slim X2 Insulin Pump with Control-IQ	Tandem Diabetes Care
twist	Sequel
V-Go	Zealand Pharma

II. Examples of FDA approved CGM devices include, but are not limited to:

Brand Name	Manufacturer	Approved for:	Sensor	Transmitter	Receiver
DexCom G6	DexCom, Inc.	Individuals ≥ two (2) years (not for use in pregnant women, people on dialysis, or critically ill patients)	Three per 30 days	Four per 360 days	One per year
DexCom G7	DexCom, Inc.	Individuals ≥ two (2) years (can be worn during pregnancy for all types of diabetes)	Combined Sensor and transmitter Three per 30 days	N/A	One per year (Optional)
Guardian Connect System	Medtronic Diabetes	Individuals ≥ 14 years	Four per 30 days	One per year	NA
Guardian Sensor 3 with Guardian Link 3 transmitter	Medtronic Diabetes	Individuals > 2 with Medtronic 770G system, 7+ with Medtronic	7 days	Rechargeable	N/A

		670G system			
FreeStyle Libre 2 system	Abbott Diabetes Care	Individuals ≥ four (4) years	Two per 28 days	N/A	One per one year
FreeStyle Libre 14 Day System	Abbott Diabetes Care	Individuals ≥ 18 years (not for use in pregnant women)	Two per 28 days	N/A	One per one year
FreeStyle Libre 3	Abbott Diabetes Care	Children, adolescents, and adults ≥ two (2) years	Two per 28 days	N/A	One per year
FreeStyle Libre 3 Plus	Abbott Diabetes Care	Individuals ≥ 4 years	Two per 28 days	N/A	One per year
Eversense	Senseonics Holdings, Inc.	Individuals ≥ 18 years	One per 90 days	One per year	NA
Eversense E3	Senseonics Holdings, Inc.	Individuals ≥ 18 years	One per 180 days	One per year	NA

III. Examples of FDA approved external insulin pump/continuous glucose monitoring systems include, but are not limited to:

Brand Name	Manufacturer	Approved for:
Minimed 630G System	Medtronic	Individuals ≥ seven (7) years
Minimed 770G System	Medtronic	Individuals ≥ two (2) years
Minimed 780G System	Medtronic	Children and adults with type 1 diabetes Type 2 insulin treated diabetics ≥ 18 years
T-slim with Control-IQ technology/Dexcom G6	Tandem Diabetes Care, Inc.	Individuals ≥ six (6) years
iLet Bionic Pancreas	Beta Bionics	Individuals ≥ 6 years of age

		with type 1 diabetes

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
0447T	Removal of implantable interstitial glucose sensor from subcutaneous glucose sensor from subcutaneous pocket via incision
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation

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HCPCS Codes

Code	Description
A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week
A4230	Infusion set for external insulin pump, non-needle cannula type
A4231	Infusion set for external insulin pump, needle type
A4232	Syringe with needle for external insulin pump, sterile, 3 cc
A4238	Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system (CGM)
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system (CGM)
E0784	External ambulatory infusion pump, insulin
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing (e.g., Dexcom Continuous Glucose Monitoring System and the Tandem T:Slim)
E2102	Adjunctive, nonimplanted continuous glucose monitor (CGM) or receiver
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver (CGM)
S1030	Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use cpt code)
S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use cpt code)

Code	Description
S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system
S1036	Transmitter; external, for use with artificial pancreas device system
S1037	Receiver (monitor); external, for use with artificial pancreas device system
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)

ICD10 Codes

Code	Description
E10.10-E10.9	Type 1 diabetes mellitus (code range)
E11.00-E11.9	Type 2 diabetes mellitus (code range)
E13.00-E13.9	Other specified diabetes mellitus (code range)
E79.0	Hyperuricemia without signs of inflammatory arthritis and tophaceous disease
O24.011-O24.019	Pre-existing diabetes mellitus, type 1, in pregnancy (code range)
O24.03	Pre-existing diabetes mellitus, type 1, in the puerperium
O24.111-O24.119	Pre-existing diabetes mellitus, type 2, in pregnancy (code range)
O24.13	Pre-existing diabetes mellitus, type 2, in the puerperium
O24.311-O24.33	Unspecified pre-existing diabetes mellitus in pregnancy, childbirth and the puerperium (code range)
O24.410-O24.439	Gestational diabetes mellitus in pregnancy (code range)
O24.811-O24.819	Other pre-existing diabetes mellitus in pregnancy (code range)
O24.83	Other pre-existing diabetes mellitus in the puerperium

Code	Description
O24.911-O24.93	Unspecified diabetes mellitus in pregnancy, childbirth and the puerperium (code range)
O99.810-O99.815	Abnormal glucose complicating pregnancy, childbirth and the puerperium (code range)
P70.2	Neonatal diabetes mellitus
R73.01-R73.9	Elevated blood glucose level (code range)

REFERENCES

Agiostratidou G, et al. Standardizing clinically meaningful outcome measures beyond HbA1c for type 1 diabetes: a consensus report of the American Association of Clinical Endocrinologists, The American Association of Diabetes Educators, the American Diabetes Association, the Endocrine Society, JKRF International, the Leona M. and Harry B. Helmsley Charitable Trust, the Pediatric Endocrine Society and the T1D Exchange. Diabetes Care. 2017 Dec;40(12)1622-1630.

American Diabetes Association (ADA) Professional Practice Committee. 7. Diabetes technology: standards of care in diabetes-2025. Diabetes Care 2025;48 (Suppl. 1):S146-S166.

Bailey CJ and Gavin JR III. Flash continuous glucose monitoring: a summary review of recent real-world evidence. Clin Diabetes. 2021 Jan;39(1):64-71.

Battelino T, et al. Clinical targets for continuous glucose monitoring data interpretation: recommendations from the International Consensus on Time in Range. Diabetes Care. 2019 Aug; 42(8):1593-1603.

Beck RW, et al. Validation of time in range as an outcome measure for diabetes clinical trials. Diabetes Care. 2019 Mar;42(3):400-405.

Beck RW, et al. A meta-analysis of randomized trial outcomes for the t:slim X2 insulin pump with control-IQ technology in youth and adults from age 2 to 72. Diabetes Technol Ther. 2023 May;25(5):329-342.

Bergenstahl RM et al. Threshold-based insulin-pump interruption for reduction of hypoglycemia. NEJM. 2013 Jul 18;369(3):224-32.

Bergenstahl RM , et al. Effectiveness of sensor-augmented insulin-pump therapy in type 1 diabetes. NEJM. 2010 Jul 22;363(4):311-20.

Bloomgarden ZT. American Diabetes Association 60th scientific sessions 2000. Glucose tolerance, diabetes and cancer, glycemic control, monitoring, and related topics. Diabetes Care. 2001 Apr;24(4):779–84.

Chehregosh H, et al. A view beyond HbA1c: role of continuous glucose monitoring. Diabetes Ther. 2019;10:853-863.

Cowart K. A review of the first long-term implantable continuous glucose monitoring system available in the United States. J Diabetes Sci Technol. 2021 Jan;15(1):160-166.

Cowart K, et al. Continuous glucose monitoring in persons with type 2 diabetes not using insulin. Expert Rev Med Devices 2021 Nov;18(11):1049-1055.

Deiss D, et al. Clinical practice recommendations on the routine use of Eversense, the first long-term implantable continuous glucose monitoring system. Diabetes Technol Ther. 2019;21:254-64.

ElSayed NA, et al. On behalf of the American diabetes association. introduction and methodology: standards of care in diabetes-2023. Diabetes Care. 2023 Jan 1;46(Suppl 1):S1-S4.

Gilbert TR, et al. Change in hemoglobin A1c and quality of life with real-time continuous glucose monitoring use by people with insulin-treated diabetes in the landmark study. Diabetes Technology & Therapeutics. 2021 Mar;23(S1):S35-S39.

Grace T and Slayer J. Use of real-time continuous glucose monitoring improves glycemic control and other clinical outcomes in type 2 diabetes patients treated with less intensive therapy. Diabetes Technol Ther. 2022; 24(1):26-31.

Grunberger G, et al. American Association of Clinical Endocrinology (AACE) clinical practice guideline: the use of advanced technology in the management of persons with diabetes mellitus. Endocrine Practice. 2021 May 28; 27(2021):505-537.

Gupta A, et al. Impact of short-term application of continuous glucose monitoring system(CGMS) on long-term glycemic profile in adolescents and adults with type 1 diabetes mellitus: An open-label randomized control cross over study. Diabetes Res Clin Pract. 2024 Apr;210:111610.

Isganaitis E, et al. Closed-loop insulin therapy improves glycemic control in adolescents and young adults: outcomes from the International Diabetes Closed-Loop Trial. Diabetes Technol Ther. 2021 May;23(5):342-349.

Kamble S, et al. Cost-effectiveness of sensor-augmented pump therapy in adults with type 1 diabetes in the United States. Value Health. 2012 Jul-Aug;15(5):632-8.

Kruger KD, et al. A multicenter randomized trial evaluating the insulin-only configuration of the bionic pancreas in adults with type 1 diabetes. Diabetes Technol Ther. 2022 Oct;24(10):697-711.

Laffel LM, et al. Effect of continuous glucose monitoring on glycemic control in adolescents and young adults with type 1 diabetes: a randomized clinical trial. JAMA. 2020 Jun 16;323(23)2388-2396.

Ly TT, et al. Effect of sensor-augmented insulin pump therapy and automated insulin suspension vs standard insulin pump therapy on hypoglycemia in patients with type 1diabetes a randomized clinical trial. JAMA. 2013;310(12):1240-7.

McCall AL, et al. [Internet] Management of individuals with diabetes at high risk for hypoglycemia: an

Endocrine Society Clinical Practice Guideline. JCEM. 2023 March [accessed 2025 Nov 14]. Available from: High Risk for Hypoglycemia Guideline Resources | Endocrine Society

Misso ML, et al. Continuous subcutaneous insulin infusion (CSII) versus multiple insulin injections for type 1 diabetes mellitus. Cochrane Database Syst Rev. 2010 Jan 20(1):CD005103.

Nally L, et al. Safety and glycemic outcomes of the MiniMed 780G system with a disposable all-in one sensor. Diabetes Technol Ther. 2025 Aug 18. doi: 10.1177/15209156251368928. Online ahead of print.

National Institute for Health and Care Excellence guideline. [Internet]. Type 1 diabetes in adults: diagnosis and management. 2015 Aug 26. [updated 2022 Aug 15; accessed 2025 Nov 14]. Available from: www.nice.org.uk/guidance/ng17

New York State Consolidated Insurance Law. [Internet]. Article 43. § 4303. [accessed 2025 Nov 24]. Available from: https://www.nysenate.gov/legislation/laws/ISC/4303#:~:text=Insurance%20%28ISC%29%20CHAPTER%2028%2C%20ARTICLE%2043%20%C2%A7%204303.,performed%20in%20hospital%20facilities%20prior%20to%20scheduled%20surgery

Pratley RE, et al. Effect of continuous glucose monitoring on hypoglycemia in older adults with type 1 diabetes: a randomized clinical trial. JAMA. 2020 Jun 16;232(23):2397-2406.

Reznik Y, et al. Insulin pump treatment compared with multiple daily injections for treatment of type 2 diabetes (OpT2mise): a randomised open-label controlled trial. Lancet. 2014 Oct;384.

Reznik Y. Continuous subcutaneous insulin infusion (CSII) using an external insulin pump for the treatment of type 2 diabetes. Diabetes Metab. 2010 Dec;36 (6 Pt 1):415-421.

Tweden K, et al., Longitudinal analysis of real-world performance of an implantable continuous glucose sensor over multiple sensor insertion and removal cycles. Diabetes Technol Ther. 2020 May;22(5):422-427.

Uhl S, et al. Effectiveness of continuous glucose monitoring on metrics of glycemic control in Type 2 diabetes mellitus: a systematic review and meta-analysis of randomized controlled trials. J Clin Endocrinol Metab. 2024 Mar 15;109(4):1119-1131.

Wada E, et al. Flash glucose monitoring helps achieve better glycemic control than conventional self-monitoring of blood glucose in non-insulin-treated type 2 diabetes: a randomized controlled trial. BMJ Open Diab Res Care. 2020 Jun 09;8:1-8.

Ware J, et al. Randomized trial of closed-loop control in very young children with Type 1 diabetes. N Engl J Med. 2022;386(3):209-219.

Wyckoff JA, et al. Preexisting diabetes in pregnancy: an Endocrine Society and European Society of Endocrinology joint clinical practice guideline. Eur J Endocrinol. 2025 Jun 30;193(1):G1-G48.

Willi SM, et al. Benefits of continuous subcutaneous insulin infusion in children with type 1 diabetes. J Pediatr. 2003 Dec;143(6):796-801.

Zucchini S, et al. Comparison between sensor-augmented insulin therapy and continuous subcutaneous insulin infusion or multiple daily injections in everyday life: 3-day analysis of glucose patterns and sensor accuracy in children. Diabetes Technol Ther. 2011 Dec;13(2):1187-93.

SEARCH TERMS

CGMS, Continuous glucose monitor, CGM, DexCom STS, Freestyle Navigator, Interstitial glucose monitoring, MiniMed CGMS System Gold, MiniMed Guardian Real-Time, MiniMed Paradigm Revel Real-Time system, DexCom G5, Wrist glucose monitor, Continuous subcutaneous insulin infusion, CSII, Insulin pump therapy.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Infusion Pumps (280.14) [accessed 2025 Nov 18]

LCD - Glucose Monitors (L33822) [accessed 2025 Nov 18]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 05/09

Revised: 01/11, 05/11, 09/11, 03/12, 05/12, 01/14, 07/14, 01/15, 05/15, 05/16, 05/17, 11/17, 01/18, 03/18, 07/18, 09/18, 11/18, 05/19, 11/19, 03/20, 01/21, 03/21, 7/21, 5/22, 5/23, 5/24, 5/26

Reviewed: 05/10, 05/13, 05/14, 05/15, 05/20, 5/25

Date	Summary of Changes
9/1/2026	• Transitioned External Ambulatory Insulin Infusion Pump policy, 1370/20.000457 to Lifetime HealthCare Companies policy template and also added CGM criteria from Diabetic Services Policy 1370/20.000047.

6/1/2024	• Removed V-Go from the exclusions section and added as an acceptable alternative to a standard insulin infusion pump. • Under Medicaid, added V-Go as an allowance to the disposable insulin pump verbiage.
6/1/2023	• Under the position statement: removed the values for "hypoglycemia" and "wide fluctuations in blood glucose before mealtime" criteria. • Under Medicaid: removed value for "hypoglycemia" criteria.
6/1/2022	• Changed required visit timeframe for patients with an external insulin infusion pump from every three months to every six months.
7/1/2021	• Per DOH guidelines, updated criteria for insulin infusion pumps for Select Plan/HARP.
5/01/2021* *No change to effective date	• Under Policy Considerations: removed 2 statements: 1. Combined/integrated insulin pump/continuous glucose monitoring systems (S1034, S1035, S1036, S1037) are considered nonstandard equipment and will be considered for coverage only for individuals meeting the medical-necessity criteria for a personal glucose monitoring system (these codes are addressed in the Diabetic Services policy) 2. The interpretation and reporting (95251) of data from a patient-owned continuous glucose monitor may be reported once every 30 days (statement is being moved to the Diabetic Services policy under Continuous Glucose Monitors. • Under Medicare: removed reference to Continuous Glucose Monitors as they are addressed in the Diabetic Services policy.
5/1/2021	• Updated paragraph in the Policy Considerations section in regards to coverage of personal CGM's as coverage is now available for Diabetes type I and type II.

11/13/2019	• Added Omnipod Dash to the list of covered programmable disposable external insulin infusion pumps to the Policy Considerations section as covered for all LOB. • Removed exclusion for non-coverage of Omnipod from the Select Plan section as it is now covered for all LOB. • Added compliance with usage of a therapeutic continuous glucose monitor as an alternative to the requirement for glucose self-testing.
11/13/2019 Effective date of policy remains the same	• Added statement to Select Plan section to address coverage of Omnipod/Omnipod Dash as an acceptable alternative to an external ambulatory insulin infusion pump.

MEDICAL POLICY

Medical Policy Title	**Continuous Positive Airway Pressure (CPAP) and Auto-Adjusting Positive Airway Pressure (APAP) Devices**
Policy Number	**1.01.06**
Current Effective Date	**January 1, 2027**
Next Review Date	**June 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Initial 90-day Trial

Continuous Positive Airway Pressure and Auto-Adjusting Devices

I. Continuous positive airway pressure (CPAP) and auto-adjusting positive airway pressure (APAP) devices are considered **medically appropriate** for **ANY** of the following indications:

   A. Adults with obstructive sleep apnea (OSA) who meet **ONE** of the following indications:

      1. Polysomnography (PSG) or home sleep testing (HST) results documenting an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) of > 5 (five), and < 15 respiratory events per hour and **ONE** of the following associated symptoms:

         a. Symptoms of OSA (e.g., excessive daytime sleepiness, impaired cognition, insomnia); **or**

         b. Documented cardiovascular diseases, including hypertension, ischemic heart disease, or history of stroke; **or**

      2. PSG or HST results document an AHI or RDI of ≥ 15 respiratory events per hour.

   B. Children < 18 years with OSA who meet **ONE** of the following indications: (Please note that a 90-day continuation review is not required for pediatric members.)

      1. Failure of adenotonsillectomy to relieve OSA symptoms;

      2. A contraindication to surgical intervention; **or**

      3. For whom a nonsurgical approach is strongly preferred; **and**

      4. **Either** of the following criteria:

         a. PSG results documenting an AHI or RDI of ≥ 5 and exhibits OSA symptoms; **or**

         b. PSG results demonstrated an AHI or RDI within normal ranges and the individual exhibits OSA symptoms (e.g., excessive daytime sleepiness, impaired cognition, insomnia) **and ONE** of the following:

i. The child exhibits episodes of hypercarbia based on end-tidal CO_2 measurements > 53 mm Hg; **or**

ii. The end-tidal CO_2 is > 50 mmHg for 10 to 24% of the sleep time.

Continuation of Use (Past 90-day Trial)

II. Continuation of coverage after the 90-day trial is **medically appropriate** when **BOTH** of the following have been demonstrated.

A. Improved AHI and symptom resolution during trial; **and**

B. Compliance has been demonstrated (e.g., defined by using the device for 70% of the nights, for four (4) or more hours per 24-hour period, during a consecutive 30-day period).

III. CPAP is **not medically necessary** for the treatment of snoring without accompanying OSA.

Durable Medical Equipment (DME) Repair

IV. Repair of a medically necessary CPAP or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** the following:

1. Date of DME initiation;
2. Manufacturer warranty information, if applicable;
3. Attestation that the patient has been compliant with the use of the DME and will continue to benefit from the use of the DME;

B. The DME is no longer functioning adequately; and **BOTH** of the following criteria are met:

1. Inadequate function interferes with activities of daily living; and
2. Repair is expected to make the equipment fully functional (as defined by manufacturer).

V. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

DME Replacement

VI. Replacement of a medically necessary CPAP or components not under warranty will be considered **medically appropriate** when **ALL** of the following criteria are met:

A. For positive pressure devices proof of compliance needs to be documented (refer to continuation of coverage after 90-day trial).

B. **Either** of the Following:

1. The DME is no longer functioning adequately and has been determined to be non-repairable, or the cost of the repair is in excess of the replacement cost;
2. There is documentation that a change in the patient's condition makes the present unit

non-functional and improvement is expected with a replacement unit.

VII. The replacement of a properly functioning CPAP, its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or to make the DME more aesthetically pleasing;

VIII. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

IX. Accessories or components for CPAP that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

1.01.57 Home Non-Invasive Positive Pressure Ventilation (NIPPV) devices for Respiratory Insufficiency and Failure

2.01.28 Sleep Studies

7.01.41 Surgical Management of Sleep Disorders

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Individuals who do not meet the criteria for continuation of coverage during the initial 90 day trial are eligible to re-qualify for a CPAP device, but must have a clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to CPAP therapy (e.g., documentation of failure of symptoms to resolve or improper fit of device, and re-education of the individuals regarding proper use of the equipment or re-fitting of masks).

II. CPAP with expiratory relief or APAP are options for patients who cannot tolerate the high constant air pressure associated with CPAP but wish to continue treatment for OSA.

III. Supplemental oxygen or humidification can be added to positive pressure devices to increase oxygen saturation and decrease vasomotor rhinitis.

IV. Coverage is allowed for a one-month rental when the CPAP device is malfunctioning and out of warranty, (and not associated with a manufacturer recall) while the device is being repaired.

V. The monitoring feature/device, stand-alone or integrated, any type, including all accessories, components, and electronics, not otherwise classified (HCPCS: A9279) is considered inclusive to the positive airway pressure device.

VI. Devices used to clean or sanitize CPAP devices are considered a convenience item and are **ineligible for coverage** (e.g., SoClean, SoClean 2 Go).

DESCRIPTION

Sleep Apnea

Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing during sleep. These interruptions called apnea can occur hundreds of times per night which can lead to fragmented sleep and decreased oxygen levels resulting in daytime fatigue, cardiovascular problems, and other health issues.

Obstructive Sleep Apnea (OSA)

Obstructive sleep apnea (OSA) is a sleep-related breathing disorder caused by upper-airway obstruction, most often from relaxed throat muscles during sleep. In adults, OSA involves recurrent episodes of complete or partial upper airway blockage lasting more than 10 seconds and is commonly linked to obesity, male sex, aging, and anatomical factors. Symptoms include loud snoring, witnessed apneas, gasping, excessive daytime sleepiness, and hypertension, and diagnosis requires polysomnography or home sleep testing with evidence of clinical impairment. Untreated adult OSA increases the risk of hypertension, heart failure, atrial fibrillation, other arrhythmias, and nonalcoholic fatty liver disease.

Pediatric OSA, typically caused by enlarged tonsils and adenoids, is defined by prolonged partial obstruction or intermittent complete obstruction lasting at least two respiratory cycles and may present with snoring, breathing pauses, restless sleep, behavioral issues, or poor growth. If left untreated, children may experience growth abnormalities, neurologic problems, or cor pulmonale. Polysomnography (PSG) is the preferred diagnostic tool, although normative AHI/RDI values for children are not well established. Adenotonsillectomy is first-line therapy for pediatric OSA, while persistent cases or those with contraindications may require CPAP, observation, medications, or additional airway surgery. Obstructive hypoventilation (OH), a related condition in children, may present with normal AHI but episodes of hypercarbia indicated by elevated end-tidal CO_2.

Central Apneas

Central sleep apnea is defined as the cessation of airflow through the nose and mouth for at least 10 seconds with no respiratory effort noted. The cessation in breathing can be caused by problems involving brain mechanisms, or an obstructive component. Approximately 4% of individuals undergoing PSG in a sleep laboratory are diagnosed with central sleep apnea, making this an uncommon condition.

Mixed Apneas

Mixed sleep apnea is a combination of obstructive and central sleep apnea. Not only does the patient have an obstruction in the airway, but the patient may have a neurological dysfunction or cardiopulmonary as well that contributes to the central apnea component.

Continuous Positive Airway Pressure (CPAP)

CPAP is the gold standard treatment option for adults with documented OSA. The symptoms associated with OSA, such as excessive daytime sleepiness, impaired cognition, and mood disorders

are reduced or eliminated with the consistent use of CPAP. CPAP is not indicated in individuals with simple snoring that is not associated with pauses in respirations. Treatment recommendations for OSA are based primarily on the RDI or the AHI, the severity of the presenting symptoms, and the existence and severity of co-morbid conditions.

CPAP provides constant pressure throughout the respiratory cycle by raising the intraluminal upper airway pressure above the positive critical transmural pressure of the pharynx or hypopharynx. The pressure is delivered by a flow generator through either nasal mask or modified nasal prongs to keep the upper airway patent resulting in adequate ventilation and arterial oxygenation. The pressure used is determined individually, with a range of 3 to 20 cm water.

Auto- or Self-Titrating Positive Airway Pressure (APAP)

Auto- or self-titrating positive airway pressure, or APAP, systems utilize an algorithm that uses a pressure transducer and microprocessor to monitor the airway for vibration patterns and then makes air pressure adjustments based on the incidence of apnea or absence of vibration. APAP devices are also referred to as demand positive airway pressure devices (DPAP).

CPAP with expiratory relief (e.g., C- Flex technology Respironics, Inc., Murrysville, PA) is designed to provide pressure relief during expiration, while maintaining optimal pneumatic splinting for effective therapy. CPAP with expiratory relief technology monitors the patient's airflow during expiration and reduces expiratory pressure proportional to expiratory flow. CPAP with C-Flex technology can increase compliance in those patients who find it difficult or uncomfortable to breathe out against the continuous positive pressure. This technology can be applied to CPAP, BPAP and APAP devices.

Most PAP machines now contain a data card that can record and transmit daily use rates of the device. In addition, most PAP machines can also be equipped with a modem (either wired or wireless) that is capable of transmitting data daily to a manufacturer-owned database. The ability to detect disturbances in a variety of measures, including air flow, amount of time used, and mask leak, is also included in most commercially available PAP machines.

SUPPORTIVE LITERATURE

Sanchez-de la-Torre et al (2023) conducted a systematic review and meta-analysis of individual participant data (IPD) from three randomized controlled trials (RCT, Sleep Apnea Cardiovascular Endpoints (SAVE), Impact of Sleep Apnea Syndrome in Acute Coronary Syndrome (ISAACC) and Randomized Intervention with CPAP in Coronary Artery Disease and Sleep Apnea (RICCADSAO) to assess whether adherence to CPAP therapy reduces the risk of major adverse cardiac and cerebrovascular events (MACCEs) in individuals with OSA and established cardiovascular disease. The study included 4186 adults with cardiovascular disease and OSA. The primary outcome was the first MACCEs. Statistical analysis included one stage and two stage IPD meta-analysis as well as on treatment analysis using marginal structural models to assess the effects of CPAP adherence. A total of 691 MACCEs (16.5%) were observed, the CPAP group had 349 and the no CPAP group 342. The main outcome intention- to-treat analysis did not show a significant difference in MACCEs between the CPAP and the no CPAP group. The on-treatment analysis revealed good adherence to CPAP (≥ 4 hours per day) was associated with a reduced risk of MAACEs reoccurrence. Adherence to CPAP was

associated with reduced MACCE recurrent risks suggesting that treatment adherence is a key factor in secondary cardiovascular prevention in individuals with OSA.

Patil et al (2019) conducted a systematic review and meta-analysis of 184 studies to evaluate the effectiveness of PAP therapy for adults with OSA. CPAP significantly reduced AHI by 23 events/hour versus no treatment—an 86% reduction from 32.7 to 4.1 events/hour. CPAP also improved daytime sleepiness by 2.4 points in symptomatic patients and showed clinically meaningful benefits for sleep-related quality of life, blood pressure, and motor vehicle crash risk. Observational evidence suggested reductions in cardiovascular events and mortality, though RCTs did not confirm these outcomes. No major differences were found among CPAP, APAP, and BiPAP for individual clinical outcomes, supporting CPAP as first-line therapy unless not tolerated. Home-based versus in-lab APAP initiation showed comparable results. Education, behavioral interventions, and telemonitoring improved adherence. Nasal masks enhanced adherence and reduced AHI more effectively than oronasal masks. Humidification reduced side effects without improving adherence or outcomes. Overall, CPAP reliably reduces OSA severity, improves sleepiness, and lowers blood pressure, particularly in symptomatic or hypertensive adults. Benefits for asymptomatic individuals and long-term cardiovascular outcomes remain uncertain.

Wang et al (2019) conducted a systematic review to assess the effectiveness of home noninvasive NIPPV (home mechanical ventilation (HMV), BiPAP, or CPAP devices) in adults with chronic respiratory failure. Sixty-eight (68) studies evaluating 53,733 patients were included. In patients with COPD, home BiPAP (compared to no device) was associated with lower mortality, decreased need for intubations and hospital admissions, but no change in quality of life. In patients with COPD, HMV (compared individually with BiPAP, CPAP, or no device) was associated with fewer hospital admissions. In patients with thoracic restrictive diseases, HMV (compared to no device) was associated with lower mortality. In patients with neuromuscular diseases, home BiPAP (compared to no device) was associated with lower mortality and better quality of life. In patients with obesity hypoventilation syndrome, home HMV/BiPAP (compared to no device) was associated with lower mortality. Current evidence was not available to assess the comparative effectiveness of many device capabilities on patient outcomes. Criteria to initiate home NIPPV and home respiratory services varied and were not validated in comparative studies.

PROFESSIONAL GUIDELINE(S)

The 2021 National Institute for Health and Care Excellence (NICE) Clinical Guidelines for Diagnosis and Management of Obstructive Sleep Apnea/Hypopnea Syndrome (OASAHS), Obesity Hypoventilation Syndrome (OHS) and Chronic Obstructive Pulmonary Disease with OSAHS (COPD-OSAHS overlap syndrome) in people over 16 years of age.

- Offering fixed-level CPAP in those with mild OSA when symptoms affect quality of life (QOL) and usual daytime activities if lifestyle changes alone have been unsuccessful or are considered inappropriate.
- APAP as an alternative to fixed-level CPAP in those unable to tolerate CPAP.

- In individuals who cannot tolerate or refuse CPAP, they recommend offering a customized mandibular advancement device.
- In individuals with moderate to severe OSA, CPAP is recommended as a treatment option, with APAP offered as an alternative in those unable to tolerate CPAP.
- A customized mandibular advancement device may be used if an individual refuses PAP or is unable to tolerate PAP.
- A positional modifier may be considered for those with mild to moderate positional OSA if other treatments are unsuitable or not tolerated, but this should not be a first-line treatment option.
- The European Respiratory Society (ERS) and the American Thoracic Society (ATS) Clinical Recommendation for non-invasive ventilation (NIV) in Adults with Acute Respiratory Failure (ARF) (Rochwerg 2017). Bilevel NIV for individuals with ARF leading to acute or acute-on-chronic respiratory acidosis (pH <7.35) due to COPD exacerbation. (Strong recommendation, high certainty of evidence.)
- Either bilevel NIV or CPAP for individuals with ARF due to cardiogenic pulmonary oedema. (Strong recommendation, moderate certainty of evidence.
- Early NIV for immunocompromised individuals ARF. (Conditional recommendation, moderate certainty of evidence.)
- Due to the uncertainty of evidence ERS/ATS is unable to offer a recommendation on the use of NIV for de novo ARF.
- NIV for individuals with post-operative ARF. (Conditional recommendation, moderate certainty of evidence.)
- NIV to dyspneic individuals for palliation in the setting of terminal cancer or other terminal conditions. (Conditional recommendation, moderate certainty of evidence.)
- NIV should not be used in the treatment of patients with established post-extubation respiratory failure. (Conditional recommendation, low certainty of evidence.

The American Academy of Pediatrics Clinical Guidelines for the Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome (OSAS) (2012).

- All children/adolescents should be screened for snoring.
- Polysomnography should be performed in children/adolescents with snoring and symptoms/signs of OSAS; if polysomnography is not available, then alternative diagnostic tests or referral to a specialist for more extensive evaluation may be considered.
- Adenotonsillectomy is recommended as the first-line treatment of patients with adenotonsillar hypertrophy.
    - High-risk patients should be monitored as inpatients postoperatively.
    - Patients should be reevaluated postoperatively to determine whether further treatment is

required. Objective testing should be performed in patients who are high risk or have persistent symptoms/signs of OSAS after therapy.

- Continuous positive airway pressure is recommended as treatment if adenotonsillectomy is not performed or if OSAS persists postoperatively.

- Weight loss is recommended in addition to other therapy in patients who are overweight or obese.
- Intranasal corticosteroids are an option for children with mild OSAS in whom adenotonsillectomy is contraindicated or for mild postoperative OSAS.

American Academy of Sleep Medicine (ASSM 2008) Clinical Guidelines for the Manual Titration of Positive Airway Pressure in Patient with OSA.

- Pre-Titration Preparation: All candidates should receive PAP education, hands-on demonstration, careful mask fitting, and acclimatization. (Standard)
- Transition to BiPAP: If a patient is uncomfortable or intolerant of high CPAP pressures, or obstructive respiratory events continue at 15 cm H2O, switch the patient to BiPAP. (Consensus)
- Repeat Titration Study: Consider repeating a titration if the initial titration was not optimal/good and, for split-night studies, fails to meet AASM criteria. (Consensus)

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates PAP devices as medical devices. All PAP devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Feb 13]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2026 Feb 13]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
94660	Continuous positive airway pressure ventilation (CPAP), initiation and management

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HCPCS Codes

Code	Description
A7027-A7039	Accessories/supplies, code range for positive pressure airway devices (code range)
A7044-A7046	Accessories/supplies, code range for positive pressure airway devices (code range)
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified
E0561	Humidifier, nonheated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device
E0601	Continuous airway pressure (CPAP) device

ICD10 Codes

Code	Description
E66.2	Morbid (severe) obesity with alveolar hypoventilation
G47.00	Insomnia, unspecified
G47.10	Hypersomnia, unspecified
G47.20	Circadian rhythm sleep disorder, unspecified type
G47.8	Other sleep disorders
G47.9	Sleep disorder, unspecified
I50.9	Heart failure, unspecified
J39.8	Other specified diseases of upper respiratory tract
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.9	Chronic obstructive pulmonary disease, unspecified

Code	Description
J95.2	Acute pulmonary insufficiency following nonthoracic surgery
J96.00-J96.02	Acute respiratory failure (code range)
J96.10-J96.12	Chronic respiratory failure (code range)
J96.20-J96.22	Acute and chronic respiratory failure (code range)
J96.90-J96.92	Respiratory failure, unspecified, unspecified whether with hypoxia or hypercapnia (code range)
J98.4	Other disorders of lung
J98.8	Other specified respiratory disorders

REFERENCES

Alajmi M, et al. Impact of continuous positive airway pressure therapy on blood pressure in patients with obstructive sleep apnea hypopnea: a meta-analysis of randomized controlled trials. Lung 2007 Mar-Apr;185(2):67-72.

American Academy of Otolaryngology Head and Neck Surgery [Internet]. Position statement: treatment of obstructive sleep apnea. [accessed 2026 Feb 13]. Available from: Position Statement: Treatment of Obstructive Sleep Apnea - American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)

American Academy of Pediatrics [Internet]. Clinical practice guideline: diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics 2002;109(4):704-712. [accessed 2026 Feb 13]. Available from: https://publications.aap.org/pediatrics/article/130/3/576/30284/Diagnosis-and-Management-of-Childhood-Obstructive?autologincheck=redirected

American Academy of Sleep Medicine. Practice parameters for the use of auto-titrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea. Sleep 2002;25(2):143-147.

Benjafield Adam V, et al. Estimation of the global prevalence and burden of obstructive sleep apnoea: a literature-based analysis. The Lancet Respiratory Medicine 2019 Aug;7(8): 687–698.

Chang H-P, et al. Obstructive sleep apnea treatment in adults. The Kaohsiung Journal of Medical Sciences 2019 Sept: 7-12.

Cistulli P, et al. Short-term CPAP adherence in obstructive sleep apnea: a big data analysis using real world data. Sleep Medicine 2019 Jul;59:114-116.

Downey R, et al. Nasal continuous positive airway pressure use in children with obstructive sleep apnea younger than 2 years of age. Chest 2000 Jun;117(6):1608-1612.

Hady KK, et al. Positive airway pressure therapy for pediatric obstructive sleep apnea. Children 2021 Nov;8(11):979.

Johnson K, Johnson D. In reference to positive airway pressure titration task force of the American Academy of Sleep Medicine. Clinical guidelines for the manual titration of positive airway pressure in patients with obstructive sleep apnea. Journal of Clinical Sleep Medicine 2008;4:157-171. J Clin Sleep Med. 2008 Dec 15;4(6):610.

Kushida CA, et al. Positive Airway Pressure Titration Task Force; American Academy of Sleep Medicine. Clinical guidelines for the manual titration of positive airway pressure in patients with obstructive sleep apnea. J Clin Sleep Med. 2008 Apr 15;4(2):157-71.

Macrea M, et al. Long-term noninvasive ventilation in chronic stable hypercapnic chronic obstructive pulmonary disease: an official American Thoracic Society clinical practice guideline. Am J Respir Crit Care Med 2020 Aug 15;202(4):e74-e87.

Marcus CL, et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics. 2012 Sep;130(3):576-84.

National Institute for Health and Care Excellence [Internet]. Obstructive sleep apnea/hypopnea syndrome and obesity hypoventilation syndrome in over 16s. Published Aug 2021. [accessed 2026 Feb 13]. Available from: https://www.nice.org.uk/guidance/NG202

Patil SP, et al. Treatment of adult obstructive sleep apnea with positive airway pressure: an American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med 2019 Feb 15;15(2):335-343.

Rochwerg B, et al. Official ERS/ATS clinical practice guidelines: noninvasive ventilation for acute respiratory failure. Eur Respir J. 2017 Aug 31;50(2):1602426.

Sánchez-de-la-Torre M, et al. Adherence to CPAP treatment and the risk of recurrent cardiovascular events: a meta-analysis. JAMA. 2023 Oct 3;330(13):1255-1265.

Strohl, Kingman. Obstructive sleep apnea. Merck Manual 2020 Sept.

Wang Z, et al. Noninvasive positive pressure ventilation in the home. Rockville (MD): Agency for Healthcare Research and Quality (US); 2019 Mar 14. PMID: 32101390.

Weiss MR, et al. Defining the patterns of pap adherence in pediatric obstructive sleep apnea: a clustering analysis using real world data. Journal of Clinical Sleep Medicine 2020 May;17 (5):1005-1013.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Respiratory Assist Devices (LCD L33800) [accessed 2026 Feb 13]

Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (LCD L33718)

[accessed 2026 Feb 13]

Durable Medical Equipment Reference List (NCD 280.1) [accessed 2026 Feb 13]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: CORONARY FRACTIONAL FLOW RESERVE USING COMPUTED TOMOGRAPHY (FFR-ct)

POLICY EFFECTIVE DATE:	11/1/2024
Policy Control #:	1370/20.000511
Next Annual Review:	November, 2026

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

75580, 0523T

DESCRIPTIONS

Fractional flow reserve (FFR) measurement involves determining the ratio between the maximum achievable blood flow in a diseased coronary artery and the theoretical maximum flow in a normal coronary artery. An FFR of 1.0 is widely accepted as normal. An FFR lower than 0.75-0.80 is generally considered to be associated with myocardial ischemia (MI).

FFR is easily measured during routine coronary angiography by using a pressure wire to calculate the ratio between coronary pressure distal to a coronary artery stenosis and aortic pressure under conditions of maximum myocardial hyperemia. This ratio represents the potential decrease in coronary flow distal to the coronary stenosis.

Coronary computed tomography angiography (CCTA) is a noninvasive imaging modality designed to be an alternative to invasive cardiac angiography (cardiac catheterization) for diagnosing coronary artery disease (CAD) by visualizing the blood flow in arterial and venous vessels.

Computed tomography (CT)-based Fractional flow reserve (FFR-ct) computations are used to evaluate the functional severity of coronary artery stenoses, with FFRs derived from outflow

boundary conditions based on conventional morphology generally agreeing with those based on positron-emission tomography (PET) conditions. FFR-ct uses simulated pressure, velocity and blood flow information generated from static CCTA images to determine the fraction of maximal coronary blood flow that can be achieved in a restricted artery.

RELATED POLICIES/DOCUMENTS

Resource Coordination:

Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT) Coronary Plaque Analysis (AI-CPA), 1370/20.000523

POSITION STATEMENT

CDPHP will cover Computed Tomography-based Fractional Flow Reserve Technology (FFR-ct) that is FDA-approved for patients who meet **one** of the following criteria:

- Intermediate risk* patients with acute or stable chest pain and no known coronary artery disease, with coronary artery stenosis of 40-90% in proximal or middle coronary artery on Coronary Computed Tomography Angiography (CCTA);

OR

- Intermediate risk with acute chest pain and known non-obstructive (< 50%) coronary artery stenosis of 40-90% in a proximal or middle segment on CCTA;

OR

- Stable nonobstructive coronary artery (< 50%) disease with persistent ischemia related symptoms despite maximally tolerated medical therapy requiring further testing, and ≥ 40-90% stenosis on CCTA

Fractional flow reserve technology will not be covered in conjunction with stress testing unless FFR-ct was not high quality, and an alternative study is needed.

*Intermediate and high-risk is as defined in the 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain

The patient's medical record must include **all** the following information:

- The clinical findings that led to the initial performance of the CCTA, and the CCTA must be fully reviewed before the performance of FFR-ct. (as evidenced by the submission of the Coronary Computed Tomographic Angiography Report)
- Description of symptoms consistent with stable ischemic heart disease.
- Body mass index

POLICY NAME: CORONARY FRACTIONAL FLOW RESERVE USING COMPUTED TOMOGRAPHY (FFR-ct)

- Fractional Flow Reserve analysis report

POLICY CONSIDERATIONS

This service should be performed in patients with stable coronary symptoms. It should not be performed until after the base study (CCTA) has been completed and interpreted.

If higher grade stenoses (i.e., greater than 90%) are present, this study is not medically necessary, as the patient should proceed to catheterization. Similarly, low-grade stenoses (less than 30%) do not require additional confirmatory data.

This should be performed as an alternative to stress testing. If extensive plaque is present, a high quality CCTA is unlikely and stress testing is preferred.

EXCLUSIONS

Intraprocedural coronary fractional flow reserve (FFR) with 3D functional mapping of color-coded FFR values for the coronary tree, derived from coronary angiogram data, for real-time review and interpretation of possible atherosclerotic stenosis(es) intervention (0523T).

FFR-ct will not be covered for the following clinical circumstances:

- Prior placement of prosthetic valves
- Prior placement of grafts in coronary bypass surgery
- Suspicion of acute coronary syndrome (where MI or unstable angina have not been ruled out)
- Intracoronary metallic stent
- Status post-heart transplantation
- Recent MI (30 days or less)
- Prior pacemaker or defibrillator lead placement
- Newly diagnosed systolic heart failure, with no prior left heart catheterization
- Left main coronary artery disease with Intermediated Coronary Stenosis (lumen reduction less than or equal to 40%)
- Non-obstructing stenosis (< 50% of all major epicardial vessels) on CTA or catheterization in the past twelve months, in the absence of a new symptom complex.
- If turnaround times may impact prompt clinical care decisions

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: CORONARY FRACTIONAL FLOW RESERVE USING COMPUTED TOMOGRAPHY (FFR-ct)

MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. Other payers
2. Medicare LCD L39075, Non-Invasive Fractional Flow Reserve(FFR) for Stable Ischemic Heart Disease https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39075&ver=7&keyword=fractional%20flow&keywordType=starts&areaId=s65&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1
3. Fractional Flow Reserve (FFR) Measurement Updated: Dec 30, 2019 Author: Eiman Jahangir, MD, FACC.
4. Gulati M, Levy PD, Mukherjee D, et al. 2021 AHA/ACC/ASE/CHEST/SAEM/SCCT/SCMR Guideline for the Evaluation and Diagnosis of Chest Pain: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. 2021:CIR.0000000000001030.

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POLICY APPROVAL DATES

New: 7/23

Revised: 1/24, 7/24, 11/24, 3/26

Reviewed: 11/25

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: CORONARY FRACTIONAL FLOW RESERVE USING COMPUTED TOMOGRAPHY (FFR-ct)

Effective Date	Update
3/1/2026	No change to policy criteria. Added new policy Artificial Intelligence Enabled CT Based Quantitative Coronary Topography (AI-QCT) Coronary Plaque Analysis (AI-CPA) in the related policies section.
11/1/2024 *No change to effective date of policy	Updated criteria in the position statement and removed a few conditions from the exclusions section.
11/1/2024	Added code 0523T to exclusions.
1/1/2024	Deleted termed codes 0501T-0504T and replaced with new code 75580.
8/1/2023	New

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MEDICAL POLICY

Medical Policy Title	**Cosmetic and Reconstructive Procedures**
Policy Number	**7.01.11**
Current Effective Date	**January 1, 2027**
Next Review Date	**September 2027**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

This policy does not address criteria related to gender affirming surgeries/procedures. Refer to the Related Policies section below for policy reference.

Reconstructive Procedures

I. A procedure is considered reconstructive and **medically appropriate** when **ALL** of the following are met:

   A. **ONE** (1) of the following definitions of functional deficit is documented:

      1. Pain or other physical deficit that interferes with activities of daily living; **or**
      2. Impaired physical activity;

   B. **ONE** (1) of the following definitions of reconstruction is documented:

      1. The procedure is performed to correct structures of the body affected by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease that have resulted in the functional deficit;
      2. Reconstructive procedures incidental to or following surgery to treat an accidental injury, infection, or other disease of the part of the body involved, that correct the functional deficit; **or**
      3. The procedure is intended to correct a congenital disease or anomaly of a child that has resulted in the functional deficit; **and**

   C. Indication specific criteria are met below:

      1. Acne procedures (10040, 11900, 11901)

         a. Intralesional injection of painful acne cysts

         b. Surgical drainage of painful acne lesions (acne surgery)

         For comedone extraction or chemical exfoliation, refer to Policy Statement II

         For cryotherapy (e.g., carbon dioxide [CO2] slush, liquid nitrogen), refer to Policy Statement III

         Related CMP #8.01.21 Light and Laser Therapies for Dermatologic Conditions

2. Actinic keratoses
    a. The use of surgical or medical treatment methods, including, but not limited to cryosurgery, curettage, and excision

    Related CMP #8.01.21 Light and Laser Therapies for Dermatologic Conditions

3. Benign skin lesions, including skin tag removal (11200-11201, 11300-11313, 1140-11474, 17110-17111):
    a. Treatment is required due to bleeding, pain, recent changes in physical appearance (e.g., color, size), obstruction of an orifice, clinically restricts eye function, or exposure to frequent irritation.

    For any other indication, refer to Policy Statement II.

4. Breast procedures: augmentation with implant (19325), correction of asymmetry, grafting of autologous fat or tissue (15769, 15771-15772), mastopexy/breast lift (19316), nipple tattooing (11920, 11921, 11922) when **EITHER** of the following criteria are met:
    a. A significant functional deficit is documented; **or**
    b. When performed during or after surgical mastectomy, including partial mastectomy (e.g., lumpectomy, segmentectomy, quadrantectomy) for benign or malignant disease as required under applicable law.

    For any other indication, refer to Policy Statement II.

    Related CMP #10.01.01 Breast Reconstruction Surgery and Prophylactic Breast Cancer Risk-Reducing Mastectomy

    Related CMP #7.01.39 Reduction Mammaplasty (Mammoplasty) for female breast reduction.

    Related criteria InterQual, Reduction Mammaplasty, Male for male mastectomy for gynecomastia.

5. Congenital chest wall deformity surgical correction (21740, 21742, 21743):
    a. Pectus excavatum:
        i. Haller index is 3.25 or greater;
        ii. **ONE** (1) of the following criteria documenting functional impairment are met:
            a) Cardiac impairment including but not limited to conduction abnormalities, cardiac displacement, reduced cardiac output;
            b) Pulmonary impairment as evidenced by paradoxical respirations or pulmonary function tests (PFTs) demonstrating restrictive or obstructive lung capacity; **or**

c) Exercise intolerance as demonstrated by cardiopulmonary exercise testing (CPET) results that are below the predicted values; (See Policy Guidelines).

b. Pectus carinatum or Poland syndrome:

i. **ONE** (1) of the following criteria documenting functional impairment are met:

a) Cardiac impairment including but not limited to conduction abnormalities, cardiac displacement, reduced cardiac output;

b) Pulmonary impairment as evidenced by paradoxical respirations or pulmonary function tests (PFTs) demonstrating restrictive or obstructive lung capacity; **or**

c) Exercise intolerance as demonstrated by cardiopulmonary exercise testing (CPET) results that are below the predicted values; (See Policy Guidelines).

6. Dermabrasion (15780, 15781, 15782, 15783)

a. When the documented functional deficit results from a traumatic injury, previous surgery, or burn.

For any other indication, refer to Policy Statement II.

7. Ear or body piercing repair (12001, 12011, 12051)

a. Repair, immediately post-injury, of traumatic laceration

For any other indication, refer to Policy Statement II.

8. Hemangioma treatment (17106, 17107, 17108)

a. Treatment of hemangioma(s), including laser therapy, when a functional deficit (e.g., bleeding, ulceration, affecting a vital structure [e.g., nose, eyes, lips]) is documented.

9. Hyperhidrosis

a. Surgical treatments including endoscopic transthoracic sympathicotomy/ sympathectomy (ETS), sympathectomy (radial artery, ulnar artery, superficial palmar arch), video assisted thoracic sympathectomy (VATS), and surgical excision of axillary sweat glands (32664, 64821, 64822, 64823, 97033) when **BOTH** of the following criteria are met:

i. Documentation of **ONE** of the following:

a) a medical complication such as skin breakdown with secondary infections (e.g., folliculitis or cellulitis requiring treatment with systemic antibiotics, or fissuring or cracking); **or**

b) documented significant biopsychosocial functional impairments (e.g., agoraphobia requiring mental health intervention); **and**

ii. Documentation supporting inability to tolerate or failure of **ALL** the following conservative therapies:

a) Topical aluminum chloride or other extra-strength antiperspirants are ineffective or result in a severe rash;

b) Patient is unresponsive or unable to tolerate pharmacotherapy prescribed for excessive sweating; **and**

c) For treatment of primary focal axillary hyperhidrosis only: Patient has failed to adequately respond to treatment with botulinum toxin A (Botox A).

For other treatments, refer to Policy Statement III.

10. Hypertrophic scar revision (e.g., burn laceration, surgical incision, and keloid) (0479T, 0480T, 11400 - 11446, 11900, 11901, 17110, 17111, 17999) when **ALL** of the following criteria are met:

a. The treatment is expected to improve the significant functional deficit (e.g., contracture, limited range of motion; **and**

b. Treatment includes **ONE** (1) of the following:

i. intralesional injection of corticosteroid or 5-fluorouracil;

ii. fractional ablative laser; **or**

iii. surgical excision.

This policy does not address adjunct radiation treatment for keloids.

Related CMP #10.01.01 Breast Reconstruction Surgery and Prophylactic Breast Cancer Risk-Reducing Mastectomy

11. Otoplasty / Pinnaplasty (69300)

a. For the treatment of congenital protruding or prominent ears when **BOTH** of the following are met:

i. a functional deficit is documented; **and**

ii. when the distance from helical rim to mastoid is greater than or equal to 2.1 centimeters (cm) (normal distance is 1.5-2.0 cm).

12. Rhytidectomy (face lift) (15824 - 15829)

a. The functional deficit is a result of facial nerve palsy

For any other indication, including glabella (frown line correction), refer to Policy Statement II.

13. Rosacea, including erythematotelangiectatic rosacea (visible dilated blood vessels [telangiectasia]) (17106-17108)

a. When **ONE** of the following treatment methods is used to treat the functional deficit (e.g., bleeding, ulceration, affecting a vital structure [e.g., nose, eyes, lips]):

i. Photoablation

ii. Laser treatment; **or**

iii. Ultraviolet light therapy.

14. Vulvectomy (56620, 56625)

a. Vulvectomy as part of surgery to treat cancer or pre-cancerous lesions (dysplasia) is considered **medically appropriate**.

For vaginal rejuvenation procedures, refer to Policy Statement II.

Cosmetic Procedures

II. Cosmetic procedures are performed to reshape structures of the body to improve a patient's appearance or self-esteem in the absence of a functional deficit.

Unless the criteria outlined in Policy Statement I are met, the following non-inclusive list of procedures are typically considered cosmetic and **not medically necessary** for **ALL** indications. A medical exception may be considered when clinical records document a significant functional deficit that cannot be adequately addressed through conservative treatments.

A. Benign skin lesions (11300-11313; 11400-11471; 17110-17111);

B. Body sculpting, non-surgical (e.g., cryolipolysis [also known as fat freezing; e.g., CoolSculpting], deoxycholic acid injection [e.g., Kybella, CPT J0591]);

C. Breast augmentation with implants (19325);

D. Breast lift (mastopexy) (19316);

E. Chemical exfoliation or peel (15788 - 15793, 17360);

F. Comedone extraction, including when combined with light/laser technology (e.g., TheraClearX);

G. Dermabrasion (15780 - 15783);

H. Grafting of autologous fat or tissue (15769 - 15772);

I. Hairplasty (hair transplant) (15775, 15776);

J. Hair removal, including for treatment of hirsutism or hypertrichosis (17380, 17999);

K. Ear or body piercing (69090);

L. Ear lobe or body piercing repair (12001, 12011, 12051);

M. Rhytidectomy, including for glabella (frown line) correction (15824 - 15829);

N. Tattooing (CPT 11920, 11921, 11922);

O. Tattoo removal (CPT 11920, 11921, 11922, 15783);

P. Vaginal rejuvenation (e.g., labiaplasty, vulvectomy) (56620, 56625);

Q. Voice lifting procedures.

III. The following procedures are considered **investigational**:

A. Cryotherapy (carbon dioxide [CO2] slush, liquid nitrogen) in the treatment of acne (17340);

B. The following treatments for hyperhidrosis: acupuncture, axillary liposuction, homeopathy, hypnosis, massage, and phytotherapy (use of extracts from natural origin as medicines);

C. Autologous epidermal cell (cultured and noncultured melanocytic) transplantation for skin repigmentation as a treatment for vitiligo (15011 – 15018, C1832).

Related CMP #8.01.21 Light and Laser Therapies for Dermatologic Conditions

RELATED POLICIES

Corporate Medical Policy

For criteria specifically related to gender affirming surgeries/procedures, refer to either:

- 7.01.84 Gender Affirming Surgery and Treatments for Commercial and Medicare Advantage Members, or
- 7.01.105 Gender Reassignment/Gender Affirming Surgery and Treatments for Medicaid and HARP Members

7.01.39 Reduction Mammaplasty

7.01.47 Varicose Vein Treatments

7.01.53 Abdominoplasty and Panniculectomy

7.01.55 Blepharoplasty with or without Levator Muscle Advancement

7.01.119 Injectable Fillers for Dermal and Laryngeal Conditions

8.01.21 Light and Laser Therapies for Dermatologic Conditions

10.01.01 Breast Reconstruction Surgery and Prophylactic Breast Cancer Risk-Reducing Mastectomy

11.01.03 Experimental or Investigational Services

Pharmacy Management Drug Policy

-09 Clinical Review Prior Authorization (CRPA) Rx

-72 Step Therapy

POLICY GUIDELINE(S)

I. Requests for procedures or services will be considered in accordance with State and Federal Law.

II. When procedures are intended to improve impaired function/functional deficit, coverage will be

considered based on adequate documentation submitted for clinical review. Documentation must be provided upon request and prior to performing the procedure. This may include objective documentation of any impairment(s), study/test results, description and duration of conservative treatments, photographs, copies of consultations, and any other pertinent information.

III. If a medical condition results from a cosmetic procedure, medically necessary services required to treat the medical condition will be eligible for coverage. Common, anticipated, side effects (e.g., nausea and vomiting that results in a prolonged hospital stay) are considered part of the cosmetic procedure and are ineligible for coverage.

IV. Normal cardiopulmonary exercise testing (CPET) results: peak oxygen content (PVO_2) > 84% predicted; ventilatory anaerobic threshold (VAT) > 40% PVO2 (40–80%); maximum heart rate (HRmax) > 90% age predicted; heart rate reserve (HRR) < 15 beats per minute; blood pressure (BP) < 220/90; O2 pulse (VO2/HR) > 80%; Ventilatory reserve (VR) MVV2VEmax > 11 liters or VEmax/MVV x 100 < 85%, respiratory rate (RR) < 60 breaths per minute; minute ventilation/carbon dioxide output ratio (VE/VCO2) at VAT < 34 (Albouaini 2007).

DESCRIPTION

Acne vulgaris is a chronic, inflammatory skin disease that primarily presents with open or closed comedones, papules, pustules, or nodules on the face or trunk and may result in pain, erythema, hyperpigmentation, or scars. Acne inversa (hidradenitis suppurativa) is a chronic follicular occlusive disease primarily affecting the axilla, waist, groin, perianal, perineal, and inframammary areas.

Actinic keratosis (AKs), also known as solar keratoses, are common, sun-induced skin lesions that are confined to the epidermis and have the potential to become a skin cancer. Various options exist for treating AKs, including cryosurgery with liquid nitrogen, topical drug therapy, and curettage. Less commonly performed treatments for AK include dermabrasion, excision, chemical peels, laser therapy, and photodynamic therapy.

Hyperhidrosis is defined as excessive sweating beyond a level required to maintain normal body temperature, in response to heat exposure or exercise. It can be classified as primary or secondary. Primary focal hyperhidrosis is idiopathic, typically involving the hands (palmar), feet (plantar), or axillae (underarms). Secondary hyperhidrosis can result from a variety of drugs (e.g., tricyclic antidepressants, selective serotonin reuptake inhibitors) or underlying diseases/conditions (e.g., febrile diseases, diabetes, menopause). Secondary hyperhidrosis is usually generalized or craniofacial sweating. Secondary gustatory hyperhidrosis is excessive sweating on ingesting highly spiced foods. Frey syndrome is an uncommon type of secondary gustatory hyperhidrosis that arises from injury to surgery near the parotid gland resulting in damage to the secretory parasympathetic fibers of the facial nerve. A variety of therapies have been investigated for primary hyperhidrosis, including topical therapy with aluminum chloride, topical anticholinergic medications, oral anticholinergic medications, iontophoresis, intradermal injections of botulinum toxin, endoscopic transthoracic sympathectomy, and surgical excision of axillary sweat glands. Treatment of secondary hyperhidrosis focuses on treatment of the underlying cause, such as discontinuing certain drugs or hormone replacement therapy as a treatment for menopausal symptoms.

Keloids and hypertrophic scars are fibroproliferative disorders that result from aberrant wound healing in predisposed individuals following trauma, inflammation, surgery, or burns. While hypertrophic scars do not exceed the margins of the original wound, keloids are characterized by continuous growth and invasion into the adjacent, healthy skin beyond the original wound boundary. Keloids are often associated with pain and itch, can be disfiguring, and impair function and quality of life. Keloids also have a marked tendency to recur when surgically excised. Although hypertrophic scars and, especially, keloids are widely perceived as difficult to treat and at high risk of recurrence, advances in the understanding of the pathophysiology of abnormal scars has led to improved therapeutic approaches and outcomes (Ogawa 2024). Numerous treatment options exist (e.g., intra-lesional corticosteroid injections, pressure therapy, cryotherapy, surgical excision followed by immediate adjunctive postoperative low dose radiation therapy. Radiation is typically indicated for recurrent keloids or those at high risk of recurrence.

Otoplasty is a surgical procedure performed to correct protruding or prominent ears, a congenital deformity that can result in social and psychological problems. Assessment of the ear includes measurement of the distance from the scalp to the helix at three points. In the normal ear, the upper third of the helix is 10-12 millimeters (mm) from the skull, the middle third is 16-18 mm from the skull, and the lobule is 20-22 mm from the mastoid and should not project beyond the upper two thirds of the ear. The ideal age for otoplasty surgery is 4 or 5, which is when the ears have become firmer and mostly stopped growing.

Pectus defects are a group of congenital conditions where the sternum is depressed back towards the spine (excavatum), protrudes forwards (carinatum) or more rarely is a mixture of both. For the majority of patients, it is well tolerated, but some patients are affected psychologically, physiologically, or both. A small number of patients have more extreme depression of their sternum that impedes their physiological reserve, which can occur when engaging in strenuous exercise (e.g., running) but can also limit moderate activity such as walking and climbing stairs. The effects can be so extreme that symptoms occur at rest or cause life-threatening compression of the major blood vessels and organs (Dunning 2024). When investigating a patient with pectus excavatum with suspected cardiac compression, cross-sectional imaging of the thorax to determine the Haller index. A Haller index of 3.25 is consistently used to determine the severe category.

Poland syndrome is a rare congenital condition that is classically characterized by absence (aplasia) of chest wall muscles on one side of the body (unilateral) and abnormally short, webbed fingers (symbrachydactyly) of the hand on the same side (ipsilateral) (National Organization for Rare Disorders 2015). Affected individuals may have variable associated features, such as underdevelopment or absence of one nipple (including the darkened area around the nipple [areola]) and/or patchy absence of hair under the arm. In females, there may be underdevelopment or absence of one breast and subcutaneous tissues. In some cases, associated skeletal abnormalities may also be present, such as underdevelopment or absence of upper ribs; elevation of the shoulder blade (Sprengel deformity); and/or shortening of the arm, with underdevelopment of the forearm bones (i.e., ulna and radius). Surgical intervention, although rarely necessary, can be indicated for reasons including paradoxical movement of the chest wall, severe rib hypoplasia and aplasia, hypoplasia or aplasia of the female breast, and cosmetic indication for men and women with chest

wall asymmetry (Tafti 2023).

Rosacea is characterized by episodic erythema, edema, papules, pustules, and telangiectasia that occur primarily on the face but also present on the scalp, ears, neck, chest, back, and occasionally rosacea may affect the eyes. Rosacea is not life-threatening, but if not treated, it may lead to persistent erythema, telangiectasias, and rhinophyma (hyperplasia and nodular swelling and congestion of the skin of the nose). While the clinical manifestations of rosacea do not usually impact the physical health status of the patient, psychological consequences from the most visually apparent symptoms (i.e., erythema, papules, pustules, telangiectasias) may impact quality of life. Rhinophyma, an end-stage form of chronic acne, has been associated with obstruction of nasal passages and basal cell carcinoma in rare, severe cases. The probability of developing nasal obstruction or basal or squamous cell carcinoma with rosacea is not sufficient to warrant the preventive removal of rhinophymatous tissue. Treatment may include pharmacologic therapy or nonpharmacologic therapies such as dermabrasion, chemical peels, surgical debulking, and electrosurgery.

Vitiligo is a disease that causes areas of skin to lose color, resulting in spots and patches of lighter skin that can develop anywhere on a person's skin (American Academy of Dermatology 2022). Vitiligo can affect eyes, mucous membranes, hair color, and melanocytes in the inner ear leading to hearing loss. When vitiligo is actively destroying cells that give a person's skin its color, the patches can itch and can be pink or tricolor (causing a zone of tan skin between a person's natural skin color and the white vitiligo). Once vitiligo is no longer active, the patches turn completely white. There is no one best treatment for vitiligo. Personal preference, the type of vitiligo, where it appears on the body, and how it's progressing also play important roles. Treatment options include cover up (makeup or self-tanner), medication (e.g., corticosteroids, tacrolimus ointment, JAK inhibitor), and light therapy. The transplantation of cultured and noncultured melanocytic cells has emerged as one of the most novel treatment alternatives and consists of obtaining melanocytic and keratinocyte cells from a donor site and then transplanting them to the diseased site. This treatment can be performed autologously using different graft harvesting methods, as well as cell preparation (Souroujon 2023).

SUPPORTIVE LITERATURE

Acne Treatment Procedures

Cryotherapy (cryoslush) treatment has insufficient published evidence to determine the safety and efficacy for the treatment of acne. A pilot clinical trial investigated the feasibility and efficacy of precision cryotherapy for acne vulgaris on a small sample of volunteers (n=20) using the TargetCool (RecensMedical Inc.) carbon dioxide-based device (Hong 2024). The authors reported a significant reduction (90.25%) in the acne lesion count by week 4, with clinical improvement indicated by the Investigator Global Assessment (IGA) scale score reduction ($p<0.001$). The erythema index (EI) showed notable improvements at weeks 1, 2, and 4. Study limitations (e.g., small size and short-term follow-up) are noted to impact the generalizability of the results.

Actinic Keratosis (AK)

There is significant evidence from prospective studies and comparative trials to support the use of cryosurgery as a readily available, rapid, and effective lesion-directed treatment for AKs. Clinically,

cryosurgery has been reported to cure between 57% and 98.8% of AKs followed up over 3 months to 8.5 years (Eisen 2021).

Steeb et al (2020) conducted a systematic review and meta-analysis assessing the efficacy and safety of chemical peels for the treatment of actinic keratosis. A total of eight (8) trials were included in the systematic review (4 RCTs, 2 non-randomized controlled trials, and 2 single-arm studies). Data analysis and interpretation of results were challenged by the presence of multiple study designs and the investigation of multiple distinct comparisons. The studies included in the review were at a high risk for selection bias because only one study clearly described the generation of a random sequence and performed allocation concealment. None of the patients in the studies were blinded; blinding of the outcome assessor was described in one study. Additionally, the chosen efficacy outcomes refer to short-term clearance rates but may not reflect long-term results. Overall, the authors concluded that additional high-quality studies and a standardization of peeling protocols were warranted in order to appropriately determine the value of chemical peeling as a treatment for actinic keratoses.

Congenital Chest Wall Deformity Correction

Zens et al (2022) acknowledge that repair of pectus excavatum has cosmetic benefits, but the physiological impacts remain controversial. A single-center analysis was conducted to characterize the relationship between the degree of pectus excavatum and cardiopulmonary dysfunction seen on cardiac magnetic resonance (CMR; n=345) imaging, cardiopulmonary exercise testing (CPET; n=261), and pulmonary function testing (PFT; n=281). The right ventricular ejection fraction (RVEF) was < 0.50 in 16% of patients, left ventricular ejection fraction (LVEF) was < 0.55 in 22%, RVEF Z-score was < -2 in 32%, and the LVEF Z-score was < -2 in 18%. CPET revealed 33% of patients had reduced aerobic fitness. PFT results were abnormal in 23.1% of patients. Adjusted analyses revealed the Haller index had significant (P<.05) inverse associations with RVEF and LVEF. The authors concluded the severity of pectus excavatum is associated with ventricular systolic dysfunction. Pectus excavatum impacts right and left ventricular systolic function and can also impact exercise tolerance. The Haller index and correction index may be the most useful predictors of impairment.

Rosacea

No randomized controlled trials (RCTs) evaluating dermabrasion, chemical peels, surgical debulking, or electrosurgery for treating rosacea were identified.

Scar Revision, Including Burn and Keloid

Walsh et al (2023) conducted an evidence-based systematic review of recent advances in keloid treatments up to November 2020. The search was limited to prospective studies (n=108) that were peer-reviewed and reported on clinical outcomes of keloid therapies. The authors concluded that current literature supports silicone gel or sheeting with corticosteroid injections as first-line therapy for keloids. Adjuvant intralesional 5-fluorouracil (5-FU), bleomycin, or verapamil can be considered, although mixed results have been reported with each. Laser therapy can be used as independent therapy for keloids or in combination with intralesional corticosteroids or topical steroids with occlusion to improve drug penetration. Excision of keloids with immediate post-excision radiation therapy is an effective option for recalcitrant lesions. There is sparse but emerging evidence on the

utilization of photodynamic therapy (PDT) in treating keloids and hypertrophic scars. Extracorporeal shockwave therapy (ESWT) as a monotherapy for keloids showed a reduction in volume, height, and appearance that was not significantly different compared to intralesional triamcinolone. Further long-term studies of the effect of ESWT would be interesting as an additional treatment modality prior to excision. Intralesional cryotherapy is recommended for smaller lesions. Laser-assisted delivery of corticosteroids and combination of different lasers for treatment of keloids are emerging treatments.

Vitiligo – Transplantation

The evidence is insufficient to determine that the procedure results in an improvement in the net health outcome.

Souroujon and colleagues (2023) aimed to address the gap in knowledge and literature on autologous cell transplant as a therapeutic approach for stable segmental vitiligo. Stating that autologous cell transplant has emerged as a promising modality for managing vitiligo, with cultured and non-cultured transplants being considered when determining the patient's treatment approach, the authors conducted a systematic review of the literature to assess the efficacy of the melanocyte and keratinocyte transplantation. Six studies were assessed (2 case reports, 3 pilot studies, 1 case series), for a total of 23 patients. Although the studies were limited by factors such as sample size, lack of data (e.g., age), and use of different technique for cell preparation, the authors concluded that autologous cell transplantation in stable segmental vitiligo holds tremendous promise as a viable alternative. Final recommendation is to further explore and thoroughly investigate the potential of cell transplantation and its associated techniques to establish comprehensive guidelines for standardizing transplantation procedures.

Lou and colleagues (2024) conducted a systematic review and meta-analysis of randomized trials to assess the efficacy and safety of autologous epidermal cell suspensions for re-epithelialization of skin lesions. The primary output measure was the healing time, and the secondary outputs were effective rate, size of donor site for treatment, size of study treatment area, operation time, pain scores, repigmentation, complications, scar scale scores and satisfaction scores. A total of 32 RCTs met inclusion criteria, for a total of 1552 patients grouped into the autologous epidermal cell suspensions group, control group, and within-subject controlled. Of these trials, stable vitiligo was studied in 12 trials (n=417 patients), with a follow-up range of 3- to 24-months. The pooled data from all included studies demonstrated that the treatment group has significantly reduced healing time ($p=0.02$), size of donor site for treatment ($p<0.001$) operation time ($p<0.001$), pain scores ($p=0.0002$), and complications ($p=0.03$). There were no significant differences in the size of study treatment area, depigmentation, scar scale scores and satisfaction scores between the two groups. Identified study limitations include a small number of studies, study bias, and varying methodological quality. Specific to stable vitiligo, the authors concluded that autologous epidermal cell suspensions present a safe and effective treatment and is potentially useful in early-stage interventions. Overall, the authors conclude that this systematic review support the potential role of autologous epidermal cell suspensions as a novel approach to the management of acute or chronic wounds, and vitiligo; however, the authors found that this intervention has minimal impact on size of treatment area, repigmentation, scar scale scores and satisfaction scores.

PROFESSIONAL GUIDELINE(S)

Acne Vulgaris

The American Academy of Dermatology (AAD) issued guidelines for the care management of acne vulgaris with 18 evidenced-based recommendations and five (5) good practice statements (Reynolds 2024). The AAD made a good practice recommendation supporting the use of intralesional corticosteroid injections as an adjuvant therapy treatment option in patients with larger acne papules or nodules. The AAD found that the available evidence is insufficient to develop a recommendation on the use of acne lesion/comedo extraction, chemical peels (including glycolic acid, trichloroacetic acid, salicylic acid, Jessner's solution, or mandelic acid), or photodynamic therapy with aminolevulinic acid for the treatment of acne.

In 2023 the National Institute for Health and Care Excellence (NICE) published updated guidelines on the management of acne vulgaris and recommends the use of intralesional corticosteroids in treating severe inflammatory cysts.

Actinic Keratosis

The American Academy of Dermatology (AAD) issued guidelines for the care management of actinic keratosis with 18 recommendations based on the best available evidence (Eisen 2021). Strong recommendations are made for using ultraviolet protection, topical imiquimod, topical 5-fluorouracil, and cryosurgery. A conditional recommendation, based on moderate evidence, was made for treatment with cryosurgery over CO2 laser ablation and for treatment with aminolevulinic acid (ALA)-red light photodynamic therapy (PDT) over 35% trichloroacetic acid (TCA) peel.

Hirsutism

In 2018, the Endocrine Society issued clinical practice guidelines for the evaluation and treatment of Hirsutism (Martin et al., 2018). The goal in assessing hirsutism is to determine the specific etiology and to provide a baseline for the patient. There are two main approaches to the management of hirsutism that may be used either individually or in combination: pharmacologic therapies that target androgen production and action, and direct hair removal methods. The Endocrine Society suggests pharmacotherapy as initial therapy. Cosmetic measures to manage hirsutism include methods that remove hair shafts from the skin surface (depilation) and those that extract hairs to above the bulb (epilation). Shaving is a popular depilation method that removes hair down to just below the surface of the skin. Chemical depilatory agents are also commonly used to dissolve the hair. Epilation methods (e.g., plucking or waxing) can cause some discomfort but are relatively safe and inexpensive. These methods do not cause an increase in hair diameter.

Hyperhidrosis

This International Hyperhidrosis Society developed five separate clinical guidelines and algorithms for treatment of hyperhidrosis (generalized as well as focal) to help guide clinicians as they determine the optimal therapeutic course. The general recommendation is to attempt more conservative therapy before resorting to invasive treatment.

The National Institute for Health and Care Excellence (NICE) issued two interventional procedures guidance recommendations for hyperhidrosis. In 2014, endoscopic thoracic sympathectomy (ETS) was recommended for primary hyperhidrosis of the upper limb only for patients suffering from severe and debilitation primary hyperhidrosis that has been refractory to other treatments. In 2017, NICE determined that the evidence on the safety and efficacy of transcutaneous microwave ablation for severe primary axillary hyperhidrosis is inadequate in quantity and quality.

Hypertrophic Scar Revision, Including Burn and Keloid

In 2019, in the absence of guidelines on the use of superficial radiation therapy (SRT) for treatment of keloids a group of qualified dermatologists issued consensus guidelines with recommendations for treatment based on published evidence (Nestor 2019). The authors reported that an enormous body of literature has demonstrated the effectiveness of SRT as an adjunctive therapy for the treatment of keloid scars that are resistant to other therapies, postsurgical treatment of keloid excision suture lines with several fractions of SRT significantly reduces keloid recurrence rates, and with three (3) post-surgical fractions. Although effective outcomes can be achieved with single doses of SRT, long-term sequelae are improved with three doses.

In 2020, an international consensus recommendation for laser treatment of traumatic scars and contractures was published (Seago 2020). The panel members are unanimous in their view that lasers are a first-line therapy in the management of traumatic scars and contractures. The lasers that target all major chromophores in the skin have demonstrated utility in the management of traumatic scars including hemoglobin (e.g., 595-nm pulsed dye laser [PDL]), pigment (e.g., 532-, 694-, 755-, and 1064-nm lasers), and tissue water (e.g., 1,540- and 1,565-nm non-ablative fractional lasers [NAFL]), 2940- and 10,600-nm ablative fractional lasers (AFL), and full- field ablative lasers. The fractional lasers, especially AFL, have the most potential to treat the entire range of clinical issues as a single modality.

- For larger traumatic injuries such as burns, over 90% of panelists would begin laser treatment within 4 months or less, and 76% within 2 months or less. Early intervention to minimize pathological scar formation and related disability is an important paradigm shift in traumatic scar treatment, and an essential potential benefit of minimally invasive laser procedures.

Ogawa et al (2022) published an updated algorithms for the treatment and prevention of hypertrophic scars and keloids. Treatment of hypertrophic scars depends on scar contracture severity: if severe, surgery is the first choice. If not, conservative therapies are indicated. Conservative therapies (e.g., gel sheets, tape fixation, topical and injected external agents, should be administered on a case-by-case basis. Keloid treatment depends on whether they are small and single or large and multiple. Small and single keloids can be treated radically by surgery with adjuvant therapy (e.g., radiotherapy) or multimodal conservative therapy. For large and multiple keloids, volume- and number-reducing surgery is a choice. Regardless of the treatment(s), patients should be followed up over the long term.

Otoplasty

According to the American Society of Plastic Surgeons (ASPS), otoplasty is a medically necessary and

reconstructive surgery when it is performed to approximate a normal appearance, even if it does not improve function (ASPA 2015).

Pectus Excavatum and Pectus Carinatum

In 2012, the American Pediatric Surgical Association (APSA) issued clinical practice guidelines with recommendation to assist pediatric surgeons and pediatricians in the evaluation and management of children with pectus carinatum.

- Without strong evidence for ideal timing of treatment, expert opinion suggests that the age for operative therapy must be individualized but is typically deferred until pubertal growth in nearly complete.
- For the compliant pectus deformity, nonoperative compressive orthotic bracing is usually an appropriate first line therapy as it does not preclude the operative option.
- Expert opinion suggests that the noncompliant chest wall deformity or significant asymmetry of the pectus carinatum deformity caused by a concomitant excavatum-type deformity may not respond to orthotic bracing.
- Open surgical reconstructive techniques are acceptable surgical options in the hands of experienced pediatric surgeons.
- Unless there is some overwhelming indication for repair, operative repair of pectus chest wall deformities is to be discouraged in children ages 5 years and younger due to the risk of disruption of normal chest wall growth with resultant chest wall restriction.

In 2024, joint specialist societies issued best practice consensus guidelines on the treatment of patients with pectus abnormalities (Dunning et al 2024), including the following recommendations:

- Patients with severe pectus excavatum with a Haller index above 3.25 and objective evidence of cardiac compression benefit physiologically from surgical intervention. (Class I, Level of Evidence B)
- Some patients who experience shortness of breath and exercise intolerance but do not fit the preceding criteria may also benefit from surgery, but other objective parameters should be used to determine the likelihood of improvement in cardiovascular performance. (Class IIb, Level of Evidence C)
- For patients with very severe pectus excavatum and evidence of symptomatic malignant arrhythmias with no other cause identified, surgical treatment is indicated to mitigate the risk of death from that arrhythmia. (Class I, Level of Evidence C)
- Surgery is indicated in patients with syncope or presyncope due to severe pectus excavatum. (Class I, Level of evidence C)
- Patients with very severe pectus excavatum and dysphagia (not otherwise explained by esophageal pathology) should benefit from surgery to relieve these symptoms. (Class IIa, Level of Evidence C)

- Bracing is a highly effective and safe conservative treatment for patients with significant pectus carinatum and must be available to all suitable patients who wish to be treated for their condition. It has fewer risks and is cheaper than an operation and still provides good outcomes. (Class I, Level of Evidence B)

Poland Syndrome (PS)

In 2020, the Italian Association of Poland Syndrome (AISP) issued consensus-based recommendation for diagnosis and medical management of Poland syndrome (Baldelli 2020). AISP reports that there are no strict guidelines or indications regarding thoracic surgery in the current literature. The mandatory feature of PS is the agenesis or hypoplasia of the pectoralis major muscle (the sterno-costal head is always affected). In most cases, PS is unilateral. Presumed bilateral PS needs a more extensive differential diagnosis. Additional diagnostic criteria are hypo/aplasia of the homolateral mammary gland and nipples, and malformations of the homolateral upper limb (limited to or more severely affecting the central rays).

- The indication for thoracic surgery is usually related to severe rib cage anomalies, either regarding anterior chest wall (pectus excavatum, carinatum or combination of both) or ribs (rib agenesis).
- Respiratory symptoms are not common in PS patients. Lack of protection of lungs and other thoracic organs due to the rib cage defect (rib agenesis) does not indicate per se thoracoplasty during childhood.

Rosacea

The National Rosacea Society's standard management options for rosacea (Thiboutot 2019) and the American Acne & Rosacea Society's update on the management of rosacea (Del Rosso 2019) do not address chemical peels or dermabrasion as treatment options for rosacea.

Vitiligo – Cellular Transplant

The international Vitiligo Task Force issued a consensus position statement, part 2, for specific treatment recommendations (Senschal 2023). Surgery should be reserved for patients with stable vitiligo and other localized and stabilized forms of vitiligo (non-segmental) after the documented failure of medical interventions. Several techniques exist, including punch grafting, suction blister grafting, non-cultured epidermal cellular grafting, and cultured epidermal cellular grafting. Each method has its pros and cons.

REGULATORY STATUS

Not Applicable

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).

- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0479T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; first 100 cm^2 or part thereof, or 1% of body surface area of infants and children
0480T	each additional 100 cm^2, or each additional 1% of body surface area of infants and children, or part thereof (List separately in addition to code for primary procedure)
10040	Acne surgery (e.g., marsupialization, opening or removal of multiple milia, comedones, cysts, pustules)
11200	Removal of skin tags, multiple fibrocutaneous tags, any area; up to and including 15 lesions
11201	each additional 10 lesions, or part thereof (List separately in addition to code for primary procedure)
11300	Shaving of epidermal or dermal lesion, single lesion, trunk, arms, or legs; lesion diameter 0.5 cm or less
11301	lesion diameter 0.6 to 1.0 cm
11302	lesion diameter 1.1 to 2.0 cm
11303	lesion diameter over 2.0 cm
11305	Shaving of epidermal or dermal lesion, single lesion, scalp, neck, hands, feet, genitalia; lesion diameter 0.5 cm or less
11306	lesion diameter 0.6 to 1.0 cm
11307	lesion diameter 1.1 to 2.0 cm
11308	lesion diameter over 2.0 cm
11310	Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane
11311	lesion diameter 0.6 to 1.0 cm
11312	lesion diameter 1.1 to 2.0 cm
11313	lesion diameter over 2.0 cm
11401 - 11406	Excision, benign lesion including margins, except skin tag (unless listed

Code	Description
	elsewhere), trunk, arms, or legs (code range)
11420 - 11426	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), scalp, neck, hands, feet, genitalia (code range)
11440 - 11446	Excision, other benign lesion including margins, except skin tag (unless listed elsewhere), face, ears, eyelids, nose, lips, mucous membrane; (code range)
11900	Injection, intralesional; up to and including 7 lesions
11901	more than 7 lesions
11920	Tattooing, intradermal introduction of insoluble opaque pigments to correct color defects of skin, including micropigmentation; 6.0 sq cm or less
11921	6.1 to 20.0 sq cm
11922	each additional 20.0 sq cm, or part thereof (List separately in addition to code for primary procedure)
12001	Simple repair of superficial wounds of scalp, neck, axillae, external genitalia, trunk and/or extremities (including hands and feet); 2.5 cm or less
12011	Simple repair of superficial wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.5 cm or less
12051	Repair, intermediate, wounds of face, ears, eyelids, nose, lips and/or mucous membranes; 2.5 cm or less
15011 (*E/I)	Harvest of skin for skin cell suspension autograft; first 25 sq cm or less (*E/I for diagnosis codes L80 Vitiligo; H02.73-H02.739; N90.8-N90.89)
15012 (*E/I)	each additional 25 sq cm or part thereof (List separately in addition to code for primary procedure) (*E/I for diagnosis codes L80 Vitiligo; H02.73-H02.739; N90.8-N90.89)
15013 (*E/I)	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin (*E/I for diagnosis codes L80 Vitiligo; H02.73-H02.739; N90.8-N90.89)
15014 (*E/I)	each additional 25 sq cm of harvested skin or part thereof (List separately in addition to code for primary procedure) (*E/I for diagnosis codes L80 Vitiligo; H02.73-H02.739; N90.8-N90.89)
15015 (*E/I)	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, trunk, arms, legs; first 480 sq cm or less (*E/I for diagnosis codes L80 Vitiligo; H02.73-H02.739; N90.8-N90.89)

Code	Description
15016 (*E/I)	each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure) (*E/I for diagnosis codes L80 Vitiligo; H02.73-H02.739; N90.8-N90.89)
15017 (*E/I)	Application of skin cell suspension autograft to wound and donor sites, including application of primary dressing, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 480 sq cm or less (*E/I for diagnosis codes L80 Vitiligo; H02.73-H02.739; N90.8-N90.89)
15018 (*E/I)	each additional 480 sq cm or part thereof (List separately in addition to code for primary procedure) (*E/I for diagnosis codes L80 Vitiligo; H02.73-H02.739; N90.8-N90.89)
15769 (NMN)	Grafting of autologous soft tissue, other, harvested by direct excision (e.g., fat, dermis, fascia)
15771 (NMN)	Grafting of autologous fat harvested by liposuction technique to trunk, breasts, scalp, arms, and/or legs; 50 cc or less injectate
15772 (NMN)	each additional 50 cc injectate, or part thereof (List separately in addition to code for primary procedure)
15775 (NMN)	Punch graft for hair transplant; 1 to 15 punch grafts
15776 (NMN)	more than 15 punch grafts
15780	Dermabrasion; total face (e.g., for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	segmental, face
15782	other than face
15783	superficial, any site (e.g., tattoo removal)
15788 (NMN)	Chemical peel, facial; epidermal
15789 (NMN)	dermal
15792 (NMN)	Chemical peel, nonfacial; epidermal
15793 (NMN)	dermal
15824	Rhytidectomy; forehead
15825	neck with platysmal tightening (platysmal flap, P-flap)
15826 (NMN)	glabellar frown lines
15828	cheek, chin, and neck

Code	Description
15829	superficial musculoaponeurotic system (SMAS) flap
17106	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); less than 10 sq cm
17107	10.0 to 50.0 sq cm
17108	over 50.0 sq cm
17110	Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; up to 14 lesions
17111	15 or more lesions
17340 (E/I)	Cryotherapy (CO2 slush, liquid N2) for acne
17360 (NMN)	Chemical exfoliation for acne (e.g., acne paste, acid)
17380 (NMN)*	Electrolysis epilation, each 30 minutes (*Unless related to gender affirming procedure requests. Refer to Related Policies section for criteria.)
17999 (*NMN)	Unlisted procedure, skin, mucous membrane, and subcutaneous tissue (*NMN when used for laser hair removal, unless related to gender affirming procedure requests. Refer to Related Policies section for criteria.)
19316	Mastopexy
19325	Breast augmentation with implant
21740	Reconstructive repair of pectus excavatum or carinatum; open
21742	minimally invasive approach (Nuss procedure), without thoracoscopy
21743	minimally invasive approach (Nuss procedure), with thoracoscopy
32664	Thoracoscopy, surgical; with thoracic sympathectomy
56620	Vulvectomy simple; partial
56625	complete
64821	Sympathectomy; radial artery
64822	ulnar artery
64823	superficial palmar arch
69090 (NMN)	Ear piercing
69300	Otoplasty, protruding ear, with or without size reduction

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HCPCS Codes

Code	Description
C1832 (*E/I)	Autograft suspension, including cell processing and application, and all system components (*E/I for diagnosis codes L80 Vitiligo; H02.73-H02.739; N90.8-N90.89)
J0591 (NMN)	Injection, deoxycholic acid, 1 mg

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

Congenital Chest Wall Deformity (pectus carinatum, pectus excavatum, Poland syndrome)

Abid I, et al. Pectus Excavatum: A Review of Diagnosis and Current Treatment Options. J Am Osteopath Assoc 2017 Feb 1;117(2):106-113.

Albouaini K, et al. Cardiopulmonary exercise testing and its application. Heart. 2007 Oct;93(10):1285-92.

American Pediatric Surgical Association [Internet]. Pectus carinatum guideline. 2012 Aug 8 [accessed 2025 Aug 8]. Available from: https://apsapedsurg.org/resources/resources/practice-guidelines/apsa-guidelines/

Baldelli I, et al. Consensus based recommendations for diagnosis and medical management of Poland syndrome (sequence). Orphanet J Rare Dis. 2020 Aug 5;15(1):201.

Dunning J, et al. The pectus care guidelines: best practice consensus guidelines from the joint specialist societies SCTS/MF/CWIG/BOA/BAPS for the treatment of patients with pectus abnormalities. Eur J Cardiothorac Surg. 2024 Jul 1;66(1):ezae166.

Tafti D and Cecava ND. Poland syndrome [Internet]. In: UpToDate, Connor RF (Ed), Wolters Kluwer. 2023 May 22 [accessed 2025 Aug 8]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK532259/

Zens TJ, et al. The severity of pectus excavatum defect is associated with impaired cardiopulmonary function. Ann Thorac Surg. 2022 Sep;114(3):1015-1021.

Hyperhidrosis

Cerfolio RJ, et al. The Society of Thoracic Surgeons expert consensus for the surgical treatment of

hyperhidrosis. Ann Thorac Surg. 2011;91(5):1642-1648.

Chudry H. The treatment of palmar hyperhidrosis - a systematic review. Int J Dermatol. 2022 Nov;61(11):1303-1310.

Del Rosso JQ, et al. Update on the management of rosacea from the American Acne & Rosacea Society (AARS). J Clin Aesthet Dermatol. 2019 Jun;12(6):17-24.

International Hyperhidrosis Society (IHHS) [Internet]. Clinical Guidelines. Axillary, facial and gustatory, palmar, plantar, generalized. [accessed 2025 Aug 8]. Available from: https://www.sweathelp.org/treatments-hcp/clinical-guidelines.html

National Institutes for Health and Care Excellence (NICE) [Internet]. Endoscopic thoracic sympathectomy for primary hyperhidrosis of the upper limb. Intervention procedures guidance [IPG487]. 2014 May 27 [accessed 2025 Aug 8] Available from: https://www.nice.org.uk/guidance/ipg487

National Institutes for Health and Care Excellence (NICE) [Internet]. Transcutaneous microwave ablation for severe primary axillary hyperhidrosis. Interventional procedures guidance [ipg601]. 2017 Dec 20 [accessed 2025 Aug 8]. Available from: https://www.nice.org.uk/guidance/ipg601

Hypertrophic Scar Revision, Including Burn and Keloid

Deflorin C, et al. Physical management of scar tissue: A systematic review and meta-analysis. J Altern Complement Med. 2020 Oct;26(10):854-865.

Nestor MS, et al. Consensus guidelines on the use of superficial radiation therapy for treating nonmelanoma skin cancers and keloids. J Clin Aesthet Dermatol. 2019 Feb;12(2):12-18. Erratum in: J Clin Aesthet Dermatol. 2019 Jun;12(6):14.

Ogawa R. Keloids and hypertrophic scars [Internet]. In: UpToDate, Connor RF (Ed), Wolters Kluwer. 2024 May 1 [accessed 2025 Aug 8]. Available from: https://www.uptodate.com/contents/keloids-and-hypertrophic-scars

Waibel JS, et al. Randomized, controlled early intervention of dynamic mode fractional ablative CO_2 laser on acute burn injuries for prevention of pathological scarring. Lasers Surg Med. 2020 Feb;52(2):117-124.

Willows BM, et al. Laser in the management of burn scars. Burns. 2017 Nov;43(7):1379-1389.

Vitiligo

American Academy of Dermatology Association [Internet]. Vitiligo. 2022 Jun 29 [accessed 2025 Aug 8]. Available from: https://www.aad.org/public/diseases/a-z/vitiligo-overview

Ju HJ, et al. Surgical interventions for patients with vitiligo: a systematic review and meta-analysis. JAMA Dermatol. 2021 Mar 1;157(3):307-316.

Seneschal J, et al. Worldwide expert recommendations for the diagnosis and management of vitiligo: position statement from the international Vitiligo Task Force-part 2: specific treatment recommendations. J Eur Acad Dermatol Venereol. 2023 Nov;37(11):2185-2195.

Souroujon AA, et al. Autologous cell transplant as a treatment for stable segmental vitiligo: A systematic review. Int J Dermatol. 2023;62(11):1324-1331.

van geel N, et al. Modified technique of autologous noncultured epidermal cell transplantation for repigmenting vitiligo: a pilot study. Dermatol Surg. 2001 Oct;27(10):873-6.

van Geel N, et al. Long-term results of noncultured epidermal cellular grafting in vitiligo, halo naevi, piebaldism and naevus depigmentosus. Br J Dermatol. 2010;163(6):1186–93.

Other Indications

American College of Obstetricians and Gynecologists [Internet]. Committee Opinion 686: Breast and labial surgery in adolescents. 2017 Jan [Reaffirmed 2020; accessed 2025 Aug 8]. Available from: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/01/breast-and-labial-surgery-in-adolescents

American College of Obstetricians and Gynecologists [Internet]. Committee Opinion 795: Elective female genital cosmetic surgery. 2007 Sept [Reaffirmed 2023; accessed 2025 Aug 8]. Available from: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/01/elective-female-genital-cosmetic-surgery

American Society of Plastic Surgeons [Internet]. ASPS recommended insurance coverage criteria for third-party payers. Ear deformity: prominent ears. 2005 Dec [reaffirmed 2015 Jun; accessed 2025 Aug 8]. Available from: https://www.plasticsurgery.org/for-medical-professionals/health-policy/recommended-insurance-coverage-criteria

Calvisi L, et al. Microbotox: A prospective evaluation of dermatological improvement in patients with mild-to-moderate acne and erythematotelangiectatic rosacea. J Cosmet Dermatol. 2022;21(9):3747-3753.

Cerfolio RJ, et al. The Society of Thoracic Surgeons expert consensus for the surgical treatment of hyperhidrosis. Ann Thorac Surg. 2011;91(5):1642-1648.

Del Rosso JQ, et al. Update on the management of rosacea from the American Acne & Rosacea Society (AARS). J Clin Aesthet Dermatol. 2019 Jun;12(6):17-24.

Eisen D, et al; American Academy of Dermatology. Focused update to the guidelines of care for the management of actinic keratosis: Executive summary. J Am Acad of Dermatol. 2022 Aug 01;87(2):373-374.e5.

Eisen D, et al. Guidelines of care for the management of actinic keratosis. J Am Acad Dermatol. 2021;85:e209-33.

Gallagher T, et al. Dermatologist use of intralesional triamcinolone in the treatment of acne. J Clin Aesthet Dermatol. 2020 Dec;13(12):41-43.

Hong JY, et al. Targeted precision cryotherapy for acne vulgaris. Skin Res Technol. 2024 Sep;30(9):e70045.

Juliandri J, et al. Global rosacea treatment guidelines and expert consensus points: The differences. J

Cosmet Dermatol. 2019 Aug;18(4):960-965.

Martin KA, et al. Evaluation and treatment of hirsutism in premenopausal women: An Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2018 Apr 1;103(4):1233-1257.

National Institutes for Health and Care Excellence (NICE) [Internet]. Acne vulgaris: management. NICE guideline [NG198]. 2021 Jun 25 [last updated 2023 Dec 07; accessed 2025 Aug 8]. Available from: https://www.nice.org.uk/guidance/ng198

National Organization for Rare Disorders [Internet]. Poland syndrome. 1987 [updated 2015 Jun 30; accessed 2025 Aug 8]. Available from: https://rarediseases.org/rare-diseases/poland-syndrome/

Reynolds RV, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2024 May;90(5):1006.e1-1006.e30. Epub 2024 Jan 30. PMID: 38300170.

Steeb T, et al. Chemical peelings for the treatment of actinic keratosis: a systematic review and meta-analysis. J Eur Acad Dermatol Venereol. 2021 Mar;35(3):641-649.

Thiboutot D, et al. Standard management options for rosacea: The 2019 update by the National Rosacea Society Expert Committee. J Am Acad Dermatol. 2020 Jun;82(6):1501-1510.

Waldman A, et al. ASDS Guidelines Task Force: consensus recommendations regarding the safety of lasers, dermabrasion, chemical peels, energy devices, and skin surgery during and after isotretinoin use. Dermatol Surg. 2017 Oct;43(10):1249-1262.

Wilkie, G and Bartz, D. Vaginal rejuvenation: a review of female genital cosmetic surgery. Obstet Gynecol Surg. 2018 May;73(5): 287-292.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Actinic Keratoses (NCA CAG-00049N) [accessed 2025 Aug 8]

Laser Procedures (NCD 140.5) [accessed 2025 Aug 8]

Treatment of Actinic Keratosis (AKs) (NCD 250.4) [accessed 2025 Aug 8]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare

coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
1/1/27	
Date	**Summary of Changes**
1/1/27	• Original effective date

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

POLICY EFFECTIVE DATE:	4/1/2026
Policy Control #:	1370/20.000071
Next Annual Review:	May, 2026

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

See Exclusions and Attachment A: Covered & Non-Covered Procedures.

See Attachment B for breast reconstruction services.

DESCRIPTIONS

Cosmetic surgery is defined as surgery performed to reshape normal structures of the body in order to improve the patient's appearance and self-esteem, or as an elective treatment for aesthetic improvement of non-disabling physical defects or problems.

Reconstructive surgery is defined as medically necessary surgery performed on an abnormal structure of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease. It is generally performed to improve function.

A surgical procedure is not considered cosmetic when such service is incidental to or follows surgery resulting from trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.

RELATED POLICIES/DOCUMENTS

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

Resource Coordination Policies:

- Abdominoplasty, Panniculectomy, & Lipectomy Services, 1370/20.000443.
- Blepharoplasty, 1370/20.000225.
- Clinical Review Preauthorization List
- Gender Dysphoria Services, 1370/20.000447.
- Non-Covered Technologies, 1370/20.000444.
- Orthognathic Surgery, 1370/20.000274.
- Reduction Mammaplasty (Mammoplasty), 7.01.39

POSITION STATEMENT

CDPHP considers a reconstructive procedure medically necessary when performed for one or more of the following indications:

- The procedure is to correct an abnormality that is incidental to or following surgery, trauma, infection, or other diseases of the involved part that has resulted in a functional impairment.
- The procedure is intended to correct a congenital anomaly of a covered dependent child that has resulted in a functional impairment.
- The procedure is performed to correct other abnormalities or anomalies, other than those stated above, that cause significant functional impairment that have not been relieved by application of all available physician-directed conservative measures.
- As required by applicable laws and mandates.

Submission of medical record documentation, from the primary care physician or treating physician, is required and must demonstrate the requested procedure meets one of the criteria stated above. In addition, documentation should include the following information:

- Documentation of the etiology of the abnormality in question.
- Any conservative treatments provided.
- Objective documentation of any functional impairment.
- Studies or tests to confirm the presence of the abnormality and the degree to which it is causing functional impairment.
- Photographs when applicable and/or upon request.
- Consultations and/or operative reports.
- Any other pertinent information to support the medical necessity of the procedure being requested.

Medical Photographs

CDPHP requires original medical photographs to be sent for review to determine the medical necessity of services. Faxed or photo-copied images will not be accepted. The CDPHP preferred method of sending original photos is through our secure provider portal at cdphp.com or by US mail. If sending through US mail, please use the following address:

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

CDPHP Utilization Review Department
6 Wellness Way
Latham, NY 12110

The submission of photographs through the portal or US Mail must include the following information:

- Patient Name (Required)
- CDPHP ID# (Required)
- Date of Birth (Required if CDPHP ID# is not available)
- A sentence stating what is attached (i.e., medical photos attached for review)

POLICY CONSIDERATIONS

Services in attachment "A" that have covered indications (not considered cosmetic) may not be inclusive of all indications for the specific service. Some indications could be considered not medically necessary or experimental/investigational and should be submitted for review prior to service being rendered to determine coverage status.

Initial evaluations for establishment of a diagnosis will be allowed.

CDPHP administers benefits for medically necessary removal of skin lesions by all acceptable methods.

- All lesion removals will be reimbursed at CDPHP fee schedule regardless of method of removal.
- All lesion removal services are subject to retrospective review.

CDPHP allows removal of benign skin lesions when symptoms or signs warrant medical intervention such as:

- Bleeding
- Intense itching
- Pain
- Change in physical appearance (i.e., reddening, pigmentary change, enlargement)
- Physical evidence of inflammation or infection (i.e., purulence, edema, oozing, erythema)
- Lesion obstructs an orifice
- Lesion clinically restricts eye function
    - Lesion restricts eyelid function
    - Lesion causes misdirection of eyelashes or eyelid
    - Lesion restricts lacrimal puncta and interferes with tear flow
    - Lesion touches globe
- Clinical uncertainty as to the likely diagnosis, particularly where malignancy is a realistic consideration based on lesion appearance

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

- Wart removals is not considered cosmetic when guidelines above are met or if any of the following clinical circumstances are present:
    - Periocular warts associated with chronic recurrent conjunctivitis thought secondary to lesion virus shedding
    - Warts showing evidence of spread from one body area to another, particularly in immunosuppressed patients or warts of recent origin in an immunocompromised patients
    - Lesions are condyloma acuminata or molluscum contagiosum
    - Cervical dysplasia that is associated with genital warts
    - Pregnancy that is associated with genital warts

Pursuant to the applicable participating provider agreement, providers ordering, or performing a non-covered cosmetic service must inform the enrollee of the non-covered status before rendering the service. CDPHP requires a written waiver specific to the service being performed; a generic waiver is not considered to be an acceptable form of enrollee consent.

- If a provider informs the enrollee prior to performing a specific service that the service is not covered, and the enrollee consents to accept liabilities for the services by signing a waiver specific to that service, the provider ***may bill*** the enrollee.
- If a provider performs a specific service without notifying the enrollee the service is not covered, or the enrollee does not consent to accept liability for the specific service, the provider ***may not bill*** the enrollee.

Services performed by aestheticians and billed by a medical provider are not considered medically necessary and are not covered.

Cosmetic procedures do not become eligible for coverage because of psychiatric and/or emotional distress. (For exceptions to this, please refer to the Gender Dysphoria Therapies policy, 1370/20.000447).

Cosmetic and reconstructive services are subject to retrospective review.

EXCLUSIONS

Non-medically necessary cosmetic services, including surgery and elective treatment for aesthetic improvement of non-disabling physical defects or problems.

Surgery for scar repair or revision only, where no functional defect is present.

Procedures performed at the time of the initial visit for cosmetic purposes will not be allowed.

The following list is not all inclusive but contains examples of procedures that are generally considered cosmetic. As such, they are not covered except when a case specific review justifies a medical exception due to documented functional impairment that cannot be addressed through conservative treatment.

- Chemical peel for treatment of skin wrinkles or uneven pigmentation (15788, 15789, 15792, 15793)
- Cryotherapy or chemical exfoliation for treatment of skin wrinkles, uneven pigmentation, or post acne scarring (17340, 17360)
- Correction of diastasis recti abdominis
- Dermabrasion for treatment of skin wrinkles, uneven skin pigmentation, acne, post-acne scarring, removal, or treatment of decorative tattoo (15780, 15781, 15782, 15783)
- Ear or body piercing (69090)
- Ear lobe repair in the absence of accidental injury
- Electrolysis for hirsutism (17380) or laser hair removal (For exceptions to this, please refer to the Gender Dysphoria Therapies policy, 1370/20.000447)
- Excision of excessive skin and subcutaneous tissue of the abdomen, thigh, leg, hip, buttock, arm, forearm or hand, submental fat pad, or other area (15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839)
- Labiaplasty or labia reduction for asymmetrical, enlarged, or hypertrophic labia minora and/or labia majora except when performed as part of initial gender reassignment surgery (15839, 56620)
- Liposuction – suction assisted lipectomy (15876, 15877, 15878, 15879)
- Lipectomy (15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839,)
- Subcutaneous injection of filling material, e.g., collagen (11950, 11951, 11952, 11954)
- Treatment of melasma (L81.0-L81.9)
- Treatment for vitiligo (L80, H02.731-H02.736, H02.739, A67.2, N90.89)
- Treatment/surgery for xanthomas or xanthelasma (H02.60-H02.66)

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. Other Payers
2. Bruhlman, Y.: Breast Reduction Improves Symptoms of macromastia and has a long-lasting effect: Annals of Plastic Surgery, Sept. 1998, 41(3), pp. 240-245.
3. Member Contract Language
4. Reduction Mammoplasty for Teenagers Workgroup
5. Public law 105-277, The Women's Health and cancer Right Act of 1998
6. American Academy of Dermatology, Guidelines of Care for Dermabrasion, Journal of

American Academy of Dermatology 1994; 31:654-7.
7. American Academy of Dermatology, Guidelines of Care for Acne Vulgaris, Journal of American Academy of Dermatology 1990: 22:676-80.
8. N.Y. Comp. Codes Rules & Regulations, Title 11, §52.16, (c) – 5.
9. Actinic Keratoses Treatment (#CAG-00049; Health Care Finance Administration: http://cms.hhs.gov/manuals/06_cim/ci35.asp#_35_10, accessed 11/02.
10. American Academy of Pediatrics, Circumcision Policy Statement (RE9850), Pediatrics, Volume 103, Number 3, 1999.
11. National Guideline Clearinghouse, National Guideline for the Management of Balanitis, August, 1999.
12. Department of Health/Department of Insurance: Memorandum Regarding New Claims Procedure for Certain Cosmetic Codes, October 21, 2005.
13. Hayes, Incorporated Medical Technology Directories, https://www.hayesinc.com/subscribers/subscriberHome.do
14. New York State Insurance Law, http://public.leginfo.state.ny.us/lawssrch.cgi?NVLWO
15. Women's Health and Cancer Rights Act, 1998. https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/whcra_factsheet.html
16. Affordable Care Act (ACA) Women's Preventive Services Guidelines, 2010. http://www.hrsa.gov/womensguidelines/
17. USPSTF recommendations for breast cancer screening, breast cancer genetic screening, and prophylactic medications, https://www.uspreventiveservicestaskforce.org/
18. New York State Department of Financial Services Insurance Circular Letter No. 2: Health Insurance Coverage for the Prevention and Treatment of Breast Cancer, July 8, 2016. https://www.dfs.ny.gov/insurance/circltr/2016/cl2016_02.htm
19. Medicare LCD L33575, Varicose Veins of the Lower Extremity. Treatment of

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POLICY APPROVAL DATES

New:	08/90
Revised:	10/92, 08/94, 01/96, 09/96, 05/97, 12/97, 10/98, 08/99, 10/99, 04/01, 09/01, 01/02,05/02, 11/02, 10/03, 02/04, 07/04, 09/04, 03/05, 04/05, 02/06, 05/06, 03/07, 06/07, 05/08, 05/09, 05/10, 05/11, 05/12, 09/12, 11/12, 05/13, 07/13, 03/14, 05/14, 05/15, 07/15, 05/16, 05/17, 09/17, 05/19, 5/21, 11/21, 11/22, 7/23, 9/23, 11/23, 1/24, 5/24, 1/25, 5/25, 9/25, 3/26
Reviewed:	12/91, 04/93, 05/12, 05/18, 05/20, 5/22, 5/23

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

ATTACHMENT A

The following table is not all-inclusive but contains examples of covered and non-covered procedures.

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
15830, 15847	Abdominoplasty, panniculectomy and lipectomy performed solely for purpose of enhancing appearance.	Refer to Resource Coordination Policy: ***Abdominoplasty, Panniculectomy, and Lipectomy Services***, **1370/20.000443.**	Yes
15786, 15787	Abrasion, lesions (e.g., keratosis, scar) repair performed solely for the purpose of enhancing appearance.	Performed due to a congenital disease or anomaly resulting in a functional impairment.	Yes
15820, 15821 15822, 15823 67900, 67901 67902, 67903 67904, 67906 67908, 67909, 67911	Blepharoplasty performed solely for purpose of enhancing appearance.	Refer to Resource Coordination Policy: ***Blepharoplasty, 1370/20.000225.***	Yes
21280, 21282	Canthopexy (revision of upper eyelid) performed solely for purpose of enhancing appearance.	Refer to Resource Coordination Policy*:* **Blepharoplasty, 1370/20.000225.**	Yes
15819	Cervicoplasty (surgery of the neck) performed solely for purpose of enhancing appearance.	Cervicoplasty when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes
54150, 54161	Circumcision performed post-newborn period without medical indication.	Circumcision performed beyond the newborn period (four weeks) for the following indications: • Circumcision delayed due to infant being premature or ill; **or** • Symptomatic urinary tract infection or evidence of reflux upon workup in infants up to one year of age; **or**	No

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
		• Significant adhesions, infection, or inflammation (balanitis). Surgical intervention for such conditions may be considered appropriate at any age; **or** • Phimosis that is non-responsive to more conservative measures (i.e., steroid creams). Surgical intervention for phimosis is considered appropriate for age groups six years of age and older. Surgery performed on age groups < 6 years may not be medically necessary as phimosis is considered physiologic in nature.	
21137, 21138 21139, 21172 21175, 21179 21180	Forehead reduction or reconstruction performed solely for purpose of enhancing appearance.	Forehead reduction and/or reconstruction when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes
21120, 21121 21122, 21123	Genioplasty (chin augmentation) performed solely for purpose of enhancing appearance.	Genioplasty when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes
19300	Gynecomastia surgery performed solely for purpose of enhancing appearance or for any indication other than presence of existing breast mass suspicious for malignancy.	Surgical treatment for the removal of an existing breast mass suspicious for malignancy or have confirmed genetic condition of Klinefelter Syndrome.	Yes
15775, 15776 15220, 15221	Hair transplant for alopecia, male pattern baldness or age-related hair thinning in women.	Hair transplant when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes
21083, 21087	Impression and custom preparation of palatal lift or nasal prosthesis for purpose of enhancing appearance.	Insertion or injection of prosthetic material for significant deformity when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
10040, 17110, 17111	Acne (L70.0-L70.9) treatment that does not meet criteria in next column.	Acne extractions/10040 as an initial treatment for severe acne will be considered medically necessary for treatment of painful inflamed cysts or pustules or when one of the below is met: • Documentation supports failure of initial medication treatments (e.g., oral contraceptive hormone therapy, antibiotics, retinoids); • Documentation supports development of side effects of initial medication treatments Comedone extractions are considered not medically necessary. For continued treatments following the initial surgery, procedure notes that identify the treatment technique being utilized and documentation of medical necessity for continued treatment will be required. Only one surgical treatment for acne will be authorized at a time. ** Severe acne treatment with laser, pulsed dye laser, PUVA, etc. (e.g., ClearLight Acne Photoclearing System, AviClear Laser System, TheraClear Acne Therapy) are considered experimental/investigational (refer to Non-Covered Technologies policy).	Yes
21270	Malar augmentation (cheek bone) performed solely for purpose of enhancing appearance.	Malar augmentation when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes
21125, 21127 21193, 21194, 21195, 21198, 21245, 21246, 21247, 21249	Mandibular augmentation or mandible or maxilla reconstruction performed solely for purpose of enhancing appearance.	Augmentation or reconstruction of the mandible or maxilla when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
69300	Otoplasty to correct lop ears, bat ears, or prominent or protruding ears without functional deficiencies.	Otoplasty when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes
21740, 21742 21743	Reconstructive repair of pectus excavatum or carinatum without functional impairment.	Surgical repair of pectus excavatum when both of the following criteria are met: Imaging studies (i.e., CT scan) confirm Haller index greater than 3.25 **and** documentation of functional impairment evidenced by one or more conditions below: • Cardiac impairment evidenced by cardiac test results (e.g., echocardiograph, cardiac MRI) that are consistent with external compression (e.g., murmurs, mitral valve prolapse, cardiac displacement or conduction abnormalities). • Pulmonary impairment evidenced by pulmonary function tests results that are consistent with moderate to severe restrictive or obstructive lung disease. • Objective evidence of exercise intolerance as demonstrated by cardiopulmonary exercise testing and exercise pulmonary function testing that are below the predicted values. Requests for coverage of repair for pectus carinatum will be reviewed on an individual case basis as it is extremely uncommon for this deformity to cause a functional and/or physiological deficit.	Yes
21181, 21182 21183, 21184	Reconstruction by contouring or following intra- and extracranial excision of a benign tumor of the cranial bones (e.g., fibrous dysplasia).	Reconstruction repair of a bony defect when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes
17106, 17107 17108	Treatment of cutaneous vascular lesions (e.g., hemangiomas, port wine stains) from which no significant improved physiologic function is achieved.	Pulse-dye laser for cutaneous vascular lesions when the lesion meets one of the following: • affecting a vital structure (e.g., nose, eyes, lips) • bleeding	Yes

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
		• painful • ulcerating	
ICD-10: L91.0	Keloid or hypertrophic scar that is asymptomatic.	Steroid injection of symptomatic keloids or hypertrophic scars or excision when there is functional impairment and failure of steroid injections, if appropriate. **If intralesional steroid injections do not improve symptoms after completion of 3-4 injections, 3-4 weeks apart, excision is considered medically necessary. If there has been no treatment for 1 year after the last intralesional injection(s), a new course of injections should be trialed before excision is performed. For adults only, who have excision of a keloid(s), radiation as an adjunctive therapy if initiated immediately following or within 72 hours following surgery. Up to a maximum of three fractionated doses are allowed. Radiation treatment as a stand-alone treatment without prior keloid excision may also be used for patients deemed not to be surgical candidates to improve subjective symptoms (e.g., pain, itching). Radiation therapy used for these indications as a monotherapy is only recommended for keloid scars and not hypertrophic scars.	No No
31570, 31571, 31574, L8607, C1878	Radiesse or Prolaryn™ used as a dermal filler (e.g., filling of vertical lip lines, corners of the mouth, and nasolabial folds; performed solely for purpose of enhancing appearance.	1. For the treatment for vocal cord insufficiency as follows: • Vocal fold paralysis resulting from: • Prior neck or chest surgery that damaged the vagus or recurrent laryngeal nerve • Complications from endotracheal intubation • Tumor invasion causing nerve damage • Blunt trauma to the neck or chest • Viral/inflammatory processes or • Degenerative neural disorders • Vocal cord paresis • Vocal cord scarring	Yes

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
		• Presblaryngitis (age related loosening of the vocal cords aka vocal cord atrophy) • Parkinson's disease 2. For management of Type 1 Laryngeal cleft when there has been a failed 3-month trial of conservative measures (i.e., thickening the consistency and viscosity of feed, feeding strategies and positioning).	
30400, 30410 30420, 30430 30435, 30450	Rhinoplasty for external nasal deformity not due to trauma or disease without functional impairment.	Rhinoplasty for external nasal deformity, in which there is a functional impairment, when incidental to or following surgery, trauma, infection, or disease, or congenital anomaly or disease of a covered dependent child. Medical documentation must include clinical to support all the following: • Relevant history of accidental or surgical trauma, congenital defect, or disease. • Prolonged obstructed nasal breathing. • Results of nasal endoscopy, CT, or other appropriate imaging that documents the degree of nasal obstruction. • Symptoms related to the nasal airway obstruction (e.g., chronic rhinosinusitis). • Obstructive symptoms that persist despite conservative treatment for 4 weeks or greater (e.g., nasal steroids, antihistamines, immunotherapy). • Photographs (frontal, lateral, and worms eye) that demonstrate an external nasal deformity. • Indication as to why septoplasty and turbinectomy alone will not resolve obstructive symptoms.	Yes
15824, 15825 15826, 15828 15829	Rhytidectomy (facelift) to diminish the aging process	Reconstructive rhytidectomy for burns.	Yes

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
36468, 36470, 36471	Sclerotherapy for telangiectasia (spider veins) as these are not associated with any physical symptoms and do not cause a functional deficit.	• Sclerotherapy as a medically necessary adjunctive treatment of symptomatic varicose and tributary veins, 3.0 mm or greater in diameter for individuals with a CEAP score of 2 or greater who are being treated or have previously been treated (ligation and stripping, radiofrequency ablation, endovenous laser ablation) for incompetence (i.e., reflux) of the greater or small saphenous veins who meet the following criteria: • Perforator veins located under an open or healed venous ulceration, • **or** • Significant or recurrent bleeding from a ruptured varicosity or venulectasia, • **or** ○ • Meets either (a) or (b and c) below: • Severe and persistent pain resulting in a significant functional impairment (e.g., impaired mobility, inability to perform household chores, or interferes with essential job functions • **or** • Significant recurrent attacks of superficial phlebitis • **and** • These have been unresponsive to non-surgical medical management for at least three months (analgesics, elevation of legs, avoidance of prolonged immobility, and use of prescription gradient support	Yes

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
		compression stockings, unless contraindicated). For additional treatments, three months' time must elapse after prior treatment to document continued symptoms and/or functional impairment despite conservative treatments. **Exception**: For Medicare Advantage: The treatments of the varicose and tributary veins will be considered medically necessary if saphenous reflux is not present or already successfully eliminated, the veins are > than 4 mm in diameter and if the patient remains symptomatic after a six-week trial of conservative therapy. The patient is considered symptomatic if any of the following signs and symptoms of significantly diseased vessels of the lower extremities are documented in the medical record: • Stasis ulcer of the lower leg, • Significant pain and significant edema that interferes with activities of daily living, • Bleeding associated with the diseased vessels of the lower extremities, • Recurrent episodes of superficial phlebitis, • Stasis dermatitis, or • Refractory dependent edema.	
ICD-10: L82.1	Seborrheic keratosis that is asymptomatic.	Destruction of seborrheic keratosis only when repeatedly irritated, inflamed, or bleeding.	No
11200, 11201	Skin tags that are asymptomatic.	Skin tag removal only when repeatedly irritated or bleeding.	No
54660	Testicular prosthesis for purpose of enhancing appearance.	Testicular prosthesis for replacement of congenitally-absent testes or testes lost due to trauma, infection, or disease, or congenital anomaly with functional impairment.	Yes

ATTACHMENT B

Below CPT codes for breast reconstruction services are allowed without a Prior Authorization following a mastectomy or partial mastectomy when billed with one of the following diagnosis codes:

- Z42.1 (Encounter for breast reconstruction following mastectomy)
- Z90.1 (Acquired absence of breast and nipple)
- Z90.10 (Acquired absence of unspecified breast and nipple)
- Z90.11 (Acquired absence of right breast and nipple)
- Z90.12 (Acquired absence of left breast and nipple)
- Z90.13 (Acquired absence of bilateral breasts and nipples)

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)
19340 19342	Breast prosthesis (implant) For cosmetic enhancement of the breast in the absence of mastectomy, or to correct congenital asymmetry without functional impairment.	
19325, 15771-15772	Augmentation of small but otherwise normal breasts.	
19350 19355 19361 19364 19367 19368 19369 19380 19396 S2066 S2067 S2068	Breast reconstruction surgery solely for enhancement of appearance.	
19316	Mastopexy (breast lift) to treat sagging of the breasts.	

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)
11920 11921 11922	Tattooing (flesh color) of the areola or for the treatment of port wine stains, hemangiomas, or birth marks.	
11960 11970 11971 19357	Tissue expander; insertion and/or replacement for purpose of enhancing appearance.	
19328 19330	Breast prosthesis (explantation). Explantation of a breast implant in an asymptomatic patient simply desiring removal. Explantation of ruptured saline implant(s) in patients who had originally undergone breast implantation for cosmetic purposes.	Explantation of a silicone or saline breast implant due to rupture*, infection, extrusion, Baker class IV contracture • *Note: Explantation of a ruptured saline breast implant is covered only for those patients who had originally undergone breast implantation for reconstructive purposes following a mastectomy or other approved reconstructive surgery. Replacement of an implant is covered only when: 1. It was originally placed following a covered mastectomy/partial mastectomy; or 2. The reason for the original implantation surgery was determined medically necessary.
19370 19371	Explantation of breast implant and capsulectomy/capsolotomy performed on an asymptomatic patient.	Explantation of breast implant with capsulectomy/capsulotomy for symptomatic capsular contracture when the following criteria are met: • Baker Class IV contracture associated with severe pain; or • Baker Class IV contracture with limited movement leading to inability to perform tasks that involve reaching or abduction.

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

Effective Date	Update
4/1/2026	Updated verbiage under acne treatment section.
1/1/2026	Under acne treatment, added comedone extractions as not medically necessary.
9/1/2025	Added additional criteria and coverage information for hypertrophic scars to keloids section.
5/1/2025 *No change to effective date for this policy	Added additional coverage criteria for Medicare Advantage for sclerotherapy.
5/1/2025* *No change to effective date for this policy	Updated requirements for submitting medical photographs.
5/1/2025	Clarified criteria for acne surgery.
9/1/2024	Added criteria for acne surgery (10040) and non-covered indications for acne treatment.
7/1/2024	Updated criteria for sclerotherapy.
3/1/2024	Added additional indication for Radiesse/Prolaryn. Added time frames for radiation treatment following keloid excision.
2/1/2024	Updated criteria for pulse dye laser (17106, 17107 17108) treatment. Removed codes 15830 and 15847 as these are addressed in policy 1370/20.000443.
1/1/2024 *No change to effective date of policy	Added "Attachment B" for breast reconstruction services and codes that will allow reconstruction without a PA. Updated keloid section to include radiation treatment.
1/1/2024	Added codes 31574, L8607 and the product Prolaryn to the Radiesse section.
11/1/2023 *No change to effective date of policy	For clarification, added the below statement to the Policy Considerations section:

	• Services in attachment "A" that have covered indications (not considered cosmetic) may not be inclusive of all indications for the specific service. Some indications could be considered not medically necessary or experimental/investigational and should be submitted for review prior to service being rendered to determine coverage status. Removed codes 21141, 21142 21143, 21145 21146, 21147, 21150, 21151 21154, 21155 21159, 21160, 21188, 21196, & 21248 from policy and PA requirement.
11/1/2023	Added criteria for benign lesion removal
12/1/22 *No change to effective date of policy	Added language to require original photographs when required
6/1/2022	No content changes. Removed Refractive Surgery/Keratoplasty, 1370/20.000257 under the related policies section. Added to refer to Gender Dysphoria Therapies policy regarding cosmetic procedures related to psychiatric and/or emotional distress.
3/1/22	Added criteria for rhinoplasty and updated verbiage to clarify that sclerotherapy for telangiectasia (spider veins) is considered cosmetic.
12/1/2021	Added the condition of Klinefelter Syndrome to the coverage allowance for gynecomastia surgery.
9/1/2021	Removed deleted CPT codes: 19324, 19366, 36469. Added replacement codes 15771 and 15772 for code 19324. Removed codes 30460 and 30462 from requiring a PA as these are related to congenital anomaly cleft palate repair, which is not cosmetic in nature. Removed from exclusions: Surgical procedures to correct refractive errors (65760, 65765, 65767, 65770, 65771, 65772, 65775, S0800, S0810)

This Resource Coordination Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI) and Capital

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

POLICY EFFECTIVE DATE:	9/1/2026
Policy Control #:	1370/20.000071
Next Annual Review:	May, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

See Exclusions and Attachment A: Covered & Non-Covered Procedures.

DESCRIPTIONS

Cosmetic surgery is defined as surgery performed to reshape normal structures of the body in order to improve the patient's appearance and self-esteem, or as an elective treatment for aesthetic improvement of non-disabling physical defects or problems.

Reconstructive surgery is defined as medically necessary surgery performed on an abnormal structure of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease. It is generally performed to improve function.

A surgical procedure is not considered cosmetic when such service is incidental to or follows surgery resulting from trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

- Abdominoplasty, Panniculectomy, & Lipectomy Services, 1370/20.000443.
- Blepharoplasty, 1370/20.000225.
- Gender Dysphoria Services, 1370/20.000447.
- Non-Covered Technologies, 1370/20.000444.
- Clinical Review Preauthorization List
- Reduction Mammaplasty (Mammoplasty), 7.01.39

POSITION STATEMENT

CDPHP considers a reconstructive procedure medically necessary when performed for one or more of the following indications:

- The procedure is to correct an abnormality that is incidental to or following surgery, trauma, infection, or other diseases of the involved part that has resulted in a functional impairment.
- The procedure is intended to correct a congenital anomaly of a covered dependent child that has resulted in a functional impairment.
- The procedure is performed to correct other abnormalities or anomalies, other than those stated above, that cause significant functional impairment that have not been relieved by application of all available physician-directed conservative measures.
- As required by applicable laws and mandates.

Submission of medical record documentation, from the primary care physician or treating physician, is required and must demonstrate the requested procedure meets one of the criteria stated above. In addition, documentation should include the following information:

- Documentation of the etiology of the abnormality in question.
- Any conservative treatments provided.
- Objective documentation of any functional impairment.
- Studies or tests to confirm the presence of the abnormality and the degree to which it is causing functional impairment.
- Photographs when applicable and/or upon request.
- Consultations and/or operative reports.
- Any other pertinent information to support the medical necessity of the procedure being requested.

Medical Photographs

CDPHP requires original medical photographs to be sent for review to determine the medical necessity of services. Faxed or photo-copied images will not be accepted. The CDPHP preferred method of sending original photos is through our secure provider portal at cdphp.com or by US mail. If sending through US mail, please use the following address:

CDPHP Utilization Review Department
6 Wellness Way

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

Latham, NY 12110

The submission of photographs through the portal or US Mail must include the following information:

- Patient Name (Required)
- CDPHP ID# (Required)
- Date of Birth (Required if CDPHP ID# is not available)
- A sentence stating what is attached (i.e., medical photos attached for review)

POLICY CONSIDERATIONS

Services in attachment "A" that have covered indications (not considered cosmetic) may not be inclusive of all indications for the specific service. Some indications could be considered not medically necessary or experimental/investigational and should be submitted for review prior to service being rendered to determine coverage status.

Initial evaluations for establishment of a diagnosis will be allowed.

CDPHP administers benefits for medically necessary removal of skin lesions by all acceptable methods.

- All lesion removals will be reimbursed at CDPHP fee schedule regardless of method of removal.
- All lesion removal services are subject to retrospective review.

CDPHP allows removal of benign skin lesions when symptoms or signs warrant medical intervention such as:

- Bleeding
- Intense itching
- Pain
- Change in physical appearance (i.e., reddening, pigmentary change, enlargement)
- Physical evidence of inflammation or infection (i.e., purulence, edema, oozing, erythema)
- Lesion obstructs an orifice
- Lesion clinically restricts eye function
    - Lesion restricts eyelid function
    - Lesion causes misdirection of eyelashes or eyelid
    - Lesion restricts lacrimal puncta and interferes with tear flow
    - Lesion touches globe
- Clinical uncertainty as to the likely diagnosis, particularly where malignancy is a realistic consideration based on lesion appearance
- Wart removals is not considered cosmetic when guidelines above are met or if any of the following clinical circumstances are present:

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

- Periocular warts associated with chronic recurrent conjunctivitis thought secondary to lesion virus shedding
- Warts showing evidence of spread from one body area to another, particularly in immunosuppressed patients or warts of recent origin in an immunocompromised patients
- Lesions are condyloma acuminata or molluscum contagiosum
- Cervical dysplasia that is associated with genital warts
- Pregnancy that is associated with genital warts

Pursuant to the applicable participating provider agreement, providers ordering, or performing a non-covered cosmetic service must inform the enrollee of the non-covered status before rendering the service. CDPHP requires a written waiver specific to the service being performed; a generic waiver is not considered to be an acceptable form of enrollee consent.

- If a provider informs the enrollee prior to performing a specific service that the service is not covered, and the enrollee consents to accept liabilities for the services by signing a waiver specific to that service, the provider ***may bill*** the enrollee.
- If a provider performs a specific service without notifying the enrollee the service is not covered, or the enrollee does not consent to accept liability for the specific service, the provider ***may not bill*** the enrollee.

Services performed by aestheticians and billed by a medical provider are not considered medically necessary and are not covered.

Cosmetic procedures do not become eligible for coverage because of psychiatric and/or emotional distress. (For exceptions to this, please refer to the Gender Dysphoria Therapies policy, 1370/20.000447).

Cosmetic and reconstructive services are subject to retrospective review.

EXCLUSIONS

Non-medically necessary cosmetic services, including surgery and elective treatment for aesthetic improvement of non-disabling physical defects or problems.

Surgery for scar repair or revision only, where no functional defect is present.

Procedures performed at the time of the initial visit for cosmetic purposes will not be allowed.

The following list is not all inclusive but contains examples of procedures that are generally considered cosmetic. As such, they are not covered except when a case specific review justifies a medical exception due to documented functional impairment that cannot be addressed through conservative treatment.

- Chemical peel for treatment of skin wrinkles or uneven pigmentation (15788, 15789,

15792, 15793)
- Cryotherapy or chemical exfoliation for treatment of skin wrinkles, uneven pigmentation, or post acne scarring (17340, 17360)
- Correction of diastasis recti abdominis
- Dermabrasion for treatment of skin wrinkles, uneven skin pigmentation, acne, post-acne scarring, removal, or treatment of decorative tattoo (15780, 15781, 15782, 15783)
- Ear or body piercing (69090)
- Ear lobe repair in the absence of accidental injury
- Electrolysis for hirsutism (17380) or laser hair removal (For exceptions to this, please refer to the Gender Dysphoria Therapies policy, 1370/20.000447)
- Excision of excessive skin and subcutaneous tissue of the abdomen, thigh, leg, hip, buttock, arm, forearm or hand, submental fat pad, or other area (15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839)
- Labiaplasty or labia reduction for asymmetrical, enlarged, or hypertrophic labia minora and/or labia majora except when performed as part of initial gender reassignment surgery (15839, 56620)
- Liposuction – suction assisted lipectomy (15876, 15877, 15878, 15879)
- Lipectomy (15832, 15833, 15834, 15835, 15836, 15837, 15838, 15839,)
- Subcutaneous injection of filling material, e.g., collagen (11950, 11951, 11952, 11954)
- Treatment of melasma (L81.0-L81.9)
- Treatment for vitiligo (L80, H02.731-H02.736, H02.739, A67.2, N90.89)
- Treatment/surgery for xanthomas or xanthelasma (H02.60-H02.66)

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. Other Payers
2. Bruhlman, Y.: Breast Reduction Improves Symptoms of macromastia and has a long-lasting effect: Annals of Plastic Surgery, Sept. 1998, 41(3), pp. 240-245.
3. Member Contract Language
4. Reduction Mammoplasty for Teenagers Workgroup
5. Public law 105-277, The Women's Health and cancer Right Act of 1998
6. American Academy of Dermatology, Guidelines of Care for Dermabrasion, Journal of American Academy of Dermatology 1994; 31:654-7.
7. American Academy of Dermatology, Guidelines of Care for Acne Vulgaris, Journal of

American Academy of Dermatology 1990: 22:676-80.
8. N.Y. Comp. Codes Rules & Regulations, Title 11, §52.16, (c) – 5.
9. Actinic Keratoses Treatment (#CAG-00049; Health Care Finance Administration: http://cms.hhs.gov/manuals/06_cim/ci35.asp#_35_10, accessed 11/02.
10. American Academy of Pediatrics, Circumcision Policy Statement (RE9850), Pediatrics, Volume 103, Number 3, 1999.
11. National Guideline Clearinghouse, National Guideline for the Management of Balanitis, August, 1999.
12. Department of Health/Department of Insurance: Memorandum Regarding New Claims Procedure for Certain Cosmetic Codes, October 21, 2005.
13. Hayes, Incorporated Medical Technology Directories, https://www.hayesinc.com/subscribers/subscriberHome.do
14. New York State Insurance Law, http://public.leginfo.state.ny.us/lawssrch.cgi?NVLWO
15. Women's Health and Cancer Rights Act, 1998. https://www.cms.gov/CCIIO/Programs-and-Initiatives/Other-Insurance-Protections/whcra_factsheet.html
16. Affordable Care Act (ACA) Women's Preventive Services Guidelines, 2010. http://www.hrsa.gov/womensguidelines/
17. USPSTF recommendations for breast cancer screening, breast cancer genetic screening, and prophylactic medications, https://www.uspreventiveservicestaskforce.org/
18. New York State Department of Financial Services Insurance Circular Letter No. 2: Health Insurance Coverage for the Prevention and Treatment of Breast Cancer, July 8, 2016. https://www.dfs.ny.gov/insurance/circltr/2016/cl2016_02.htm
19. Medicare LCD L33575, Varicose Veins of the Lower Extremity. Treatment of

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POLICY APPROVAL DATES

New:	08/90
Revised:	10/92, 08/94, 01/96, 09/96, 05/97, 12/97, 10/98, 08/99, 10/99, 04/01, 09/01, 01/02,05/02, 11/02, 10/03, 02/04, 07/04, 09/04, 03/05, 04/05, 02/06, 05/06, 03/07, 06/07, 05/08, 05/09, 05/10, 05/11, 05/12, 09/12, 11/12, 05/13, 07/13, 03/14, 05/14, 05/15, 07/15, 05/16, 05/17, 09/17, 05/19, 5/21, 11/21, 11/22, 7/23, 9/23, 11/23, 1/24, 5/24, 1/25, 5/25, 9/25, 3/26, 5/26
Reviewed:	12/91, 04/93, 05/12, 05/18, 05/20, 5/22, 5/23

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ATTACHMENT A

The following table is not all-inclusive but contains examples of covered and non-covered procedures.

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
15830, 15847	Abdominoplasty, panniculectomy and lipectomy performed solely for purpose of enhancing appearance.	Refer to Resource Coordination Policy: ***Abdominoplasty, Panniculectomy, and Lipectomy Services***, **1370/20.000443.**	Yes
15786, 15787	Abrasion, lesions (e.g., keratosis, scar) repair performed solely for the purpose of enhancing appearance.	Performed due to a congenital disease or anomaly resulting in a functional impairment.	Yes
15820, 15821 15822, 15823 67900, 67901 67902, 67903 67904, 67906 67908, 67909, 67911	Blepharoplasty performed solely for purpose of enhancing appearance.	Refer to Resource Coordination Policy: ***Blepharoplasty, 1370/20.000225.***	Yes
21280, 21282	Canthopexy (revision of upper eyelid) performed solely for purpose of enhancing appearance.	Refer to Resource Coordination Policy*:* **Blepharoplasty, 1370/20.000225.**	Yes
	Cervicoplasty (surgery of the neck) performed solely for purpose of enhancing appearance.	Cervicoplasty when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes
54150, 54161	Circumcision performed post-newborn period without medical indication.	Circumcision performed beyond the newborn period (four weeks) for the following indications: • Circumcision delayed due to infant being premature or ill; **or** • Symptomatic urinary tract infection or evidence of reflux upon workup in infants up to one year of age; **or** • Significant adhesions, infection, or inflammation (balanitis). Surgical	No

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
		intervention for such conditions may be considered appropriate at any age; **or** • Phimosis that is non-responsive to more conservative measures (i.e., steroid creams). Surgical intervention for phimosis is considered appropriate for age groups six years of age and older. Surgery performed on age groups < 6 years may not be medically necessary as phimosis is considered physiologic in nature.	
21137, 21138 21139, 21172 21175, 21179 21180	Forehead reduction or reconstruction performed solely for purpose of enhancing appearance.	Forehead reduction and/or reconstruction when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes
21120, 21121 21122, 21123	Genioplasty (chin augmentation) performed solely for purpose of enhancing appearance.	Genioplasty when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes
19300	Gynecomastia surgery performed solely for purpose of enhancing appearance or for any indication other than presence of existing breast mass suspicious for malignancy.	Surgical treatment for the removal of an existing breast mass suspicious for malignancy or have confirmed genetic condition of Klinefelter Syndrome.	Yes
15775, 15776 15220, 15221	Hair transplant for alopecia, male pattern baldness or age-related hair thinning in women.	Hair transplant when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes
21083, 21087	Impression and custom preparation of palatal lift or nasal prosthesis for purpose of enhancing appearance.	Insertion or injection of prosthetic material for significant deformity when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
10040, 17110, 17111	Acne (L70.0-L70.9) treatment that does not meet criteria in next column.	Acne extractions/10040 as an initial treatment for severe acne will be considered medically necessary for treatment of painful inflamed cysts or pustules or when one of the below is met: • Documentation supports failure of initial medication treatments (e.g., oral contraceptive hormone therapy, antibiotics, retinoids); • Documentation supports development of side effects of initial medication treatments Comedone extractions are considered not medically necessary. For continued treatments following the initial surgery, procedure notes that identify the treatment technique being utilized and documentation of medical necessity for continued treatment will be required. Only one surgical treatment for acne will be authorized at a time.	Yes
21270	Malar augmentation (cheek bone) performed solely for purpose of enhancing appearance.	Malar augmentation when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes
21125, 21127 21193, 21194, 21195, 21198, 21245, 21246, 21247, 21249	Mandibular augmentation or mandible or maxilla reconstruction performed solely for purpose of enhancing appearance.	Augmentation or reconstruction of the mandible or maxilla when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes
69300	Otoplasty to correct lop ears, bat ears, or prominent or protruding ears without functional deficiencies.	Otoplasty when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
21740, 21742 21743	Reconstructive repair of pectus excavatum or carinatum without functional impairment.	Surgical repair of pectus excavatum when both of the following criteria are met: Imaging studies (i.e., CT scan) confirm Haller index greater than 3.25 **and** documentation of functional impairment evidenced by one or more conditions below: • Cardiac impairment evidenced by cardiac test results (e.g., echocardiograph, cardiac MRI) that are consistent with external compression (e.g., murmurs, mitral valve prolapse, cardiac displacement or conduction abnormalities). • Pulmonary impairment evidenced by pulmonary function tests results that are consistent with moderate to severe restrictive or obstructive lung disease. • Objective evidence of exercise intolerance as demonstrated by cardiopulmonary exercise testing and exercise pulmonary function testing that are below the predicted values. Requests for coverage of repair for pectus carinatum will be reviewed on an individual case basis as it is extremely uncommon for this deformity to cause a functional and/or physiological deficit.	Yes
21181, 21182 21183, 21184	Reconstruction by contouring or following intra- and extracranial excision of a benign tumor of the cranial bones (e.g., fibrous dysplasia).	Reconstruction repair of a bony defect when performed incidental to or following surgery, trauma, infection, or other diseases of the involved part, or to correct a congenital disease or anomaly of a covered dependent child that has resulted in a functional impairment.	Yes
17106, 17107 17108	Treatment of cutaneous vascular lesions (e.g., hemangiomas, port wine stains) from which no significant improved physiologic function is achieved.	Pulse-dye laser for cutaneous vascular lesions when the lesion meets one of the following: • affecting a vital structure (e.g., nose, eyes, lips) • bleeding • painful • ulcerating	Yes
ICD-10: L91.0	Keloid or hypertrophic scar that is asymptomatic.	Steroid injection of symptomatic keloids or hypertrophic scars or excision when there is functional impairment and failure of steroid injections, if appropriate. **If intralesional steroid injections do	No No

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
		not improve symptoms after completion of 3-4 injections, 3-4 weeks apart, excision is considered medically necessary. If there has been no treatment for 1 year after the last intralesional injection(s), a new course of injections should be trialed before excision is performed. For adults only, who have excision of a keloid(s), radiation as an adjunctive therapy if initiated immediately following or within 72 hours following surgery. Up to a maximum of three fractionated doses are allowed. Radiation treatment as a stand-alone treatment without prior keloid excision may also be used for patients deemed not to be surgical candidates to improve subjective symptoms (e.g., pain, itching). Radiation therapy used for these indications as a monotherapy is only recommended for keloid scars and not hypertrophic scars.	
31570, 31571, 31574, L8607, C1878	Radiesse or Prolaryn™ used as a dermal filler (e.g., filling of vertical lip lines, corners of the mouth, and nasolabial folds; performed solely for purpose of enhancing appearance.	1. For the treatment for vocal cord insufficiency as follows: • Vocal fold paralysis resulting from: • Prior neck or chest surgery that damaged the vagus or recurrent laryngeal nerve • Complications from endotracheal intubation • Tumor invasion causing nerve damage • Blunt trauma to the neck or chest • Viral/inflammatory processes or • Degenerative neural disorders • Vocal cord paresis • Vocal cord scarring • Presblaryngitis (age related loosening of the vocal cords aka vocal cord atrophy) • Parkinson's disease 2. For management of Type 1 Laryngeal cleft when there has been a failed 3-month trial of conservative measures (i.e., thickening the	Yes

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
		consistency and viscosity of feed, feeding strategies and positioning).	
30400, 30410 30420, 30430 30435, 30450	Rhinoplasty for external nasal deformity not due to trauma or disease without functional impairment.	Rhinoplasty for external nasal deformity, in which there is a functional impairment, when incidental to or following surgery, trauma, infection, or disease, or congenital anomaly or disease of a covered dependent child. Medical documentation must include clinical to support all the following: • Relevant history of accidental or surgical trauma, congenital defect, or disease. • Prolonged obstructed nasal breathing. • Results of nasal endoscopy, CT, or other appropriate imaging that documents the degree of nasal obstruction. • Symptoms related to the nasal airway obstruction (e.g., chronic rhinosinusitis). • Obstructive symptoms that persist despite conservative treatment for 4 weeks or greater (e.g., nasal steroids, antihistamines, immunotherapy). • Photographs (frontal, lateral, and worms eye) that demonstrate an external nasal deformity. • Indication as to why septoplasty and turbinectomy alone will not resolve obstructive symptoms.	Yes
15824, 15825 15826, 15828 15829	Rhytidectomy (facelift) to diminish the aging process	Reconstructive rhytidectomy for burns.	Yes
36468, 36470, 36471	Sclerotherapy for telangiectasia (spider veins) as these are not associated with any physical symptoms and do not cause a functional deficit.	• Sclerotherapy as a medically necessary adjunctive treatment of symptomatic varicose and tributary veins, 3.0 mm or greater in diameter for individuals with a CEAP score of 2 or greater who are being treated or have previously been treated (ligation and stripping, radiofrequency ablation, endovenous laser ablation) for incompetence (i.e.,	Yes

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
		reflux) of the greater or small saphenous veins who meet the following criteria: • Perforator veins located under an open or healed venous ulceration, • **or** • Significant or recurrent bleeding from a ruptured varicosity or venulectasia, • **or** ○ • Meets either (a) or (b and c) below: • Severe and persistent pain resulting in a significant functional impairment (e.g., impaired mobility, inability to perform household chores, or interferes with essential job functions • **or** • Significant recurrent attacks of superficial phlebitis • **and** • These have been unresponsive to non-surgical medical management for at least three months (analgesics, elevation of legs, avoidance of prolonged immobility, and use of prescription gradient support compression stockings, unless contraindicated). For additional treatments, three months' time must elapse after prior treatment to document continued symptoms and/or functional impairment despite conservative treatments. **Exception**: For Medicare Advantage: The	

CPT Code	Non-covered Indication (cosmetic)	Covered Procedure (Indications to be supported by medical documentation)	Prior Authorization Requirement
		treatments of the varicose and tributary veins will be considered medically necessary if saphenous reflux is not present or already successfully eliminated, the veins are > than 4 mm in diameter and if the patient remains symptomatic after a six-week trial of conservative therapy. The patient is considered symptomatic if any of the following signs and symptoms of significantly diseased vessels of the lower extremities are documented in the medical record: • Stasis ulcer of the lower leg, • Significant pain and significant edema that interferes with activities of daily living, • Bleeding associated with the diseased vessels of the lower extremities, • Recurrent episodes of superficial phlebitis, • Stasis dermatitis, or • Refractory dependent edema.	
ICD-10: L82.1	Seborrheic keratosis that is asymptomatic.	Destruction of seborrheic keratosis only when repeatedly irritated, inflamed, or bleeding.	No
11200, 11201	Skin tags that are asymptomatic.	Skin tag removal only when repeatedly irritated or bleeding.	No
54660	Testicular prosthesis for purpose of enhancing appearance.	Testicular prosthesis for replacement of congenitally-absent testes or testes lost due to trauma, infection, or disease, or congenital anomaly with functional impairment.	Yes

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

Effective Date	Update
9/1/2026	Removed information on acne treatment with laser as this info is now housed in the Light and Laser Therapies for Dermatologic Conditions policy, 8.01.21. Removed information related to mastectomy as this is now in the Breast Reconstruction Surgery and Prophylactic Breast Cancer Risk-Reducing Mastectomy policy, 10.01.01. Removed termed code 15819
4/1/2026	Updated verbiage under acne treatment section.
1/1/2026	Under acne treatment, added comedone extractions as not medically necessary.
9/1/2025	Added additional criteria and coverage information for hypertrophic scars to keloids section.
5/1/2025 *No change to effective date for this policy	Added additional coverage criteria for Medicare Advantage for sclerotherapy.
5/1/2025* *No change to effective date for this policy	Updated requirements for submitting medical photographs.
5/1/2025	Clarified criteria for acne surgery.
9/1/2024	Added criteria for acne surgery (10040) and non-covered indications for acne treatment.
7/1/2024	Updated criteria for sclerotherapy.
3/1/2024	Added additional indication for Radiesse/Prolaryn. Added time frames for radiation treatment following keloid excision.
2/1/2024	Updated criteria for pulse dye laser (17106, 17107 17108) treatment. Removed codes 15830 and 15847 as these are addressed in policy 1370/20.000443.

POLICY NAME: COSMETIC AND RECONSTRUCTIVE SURGERY

1/1/2024 *No change to effective date of policy	Added "Attachment B" for breast reconstruction services and codes that will allow reconstruction without a PA. Updated keloid section to include radiation treatment.
1/1/2024	Added codes 31574, L8607 and the product Prolaryn to the Radiesse section.
11/1/2023 *No change to effective date of policy	For clarification, added the below statement to the Policy Considerations section: • Services in attachment "A" that have covered indications (not considered cosmetic) may not be inclusive of all indications for the specific service. Some indications could be considered not medically necessary or experimental/investigational and should be submitted for review prior to service being rendered to determine coverage status. Removed codes 21141, 21142 21143, 21145 21146, 21147, 21150, 21151 21154, 21155 21159, 21160, 21188, 21196, & 21248 from policy and PA requirement.
11/1/2023	Added criteria for benign lesion removal
12/1/22 *No change to effective date of policy	Added language to require original photographs when required
6/1/2022	No content changes. Removed Refractive Surgery/Keratoplasty, 1370/20.000257 under the related policies section. Added to refer to Gender Dysphoria Therapies policy regarding cosmetic procedures related to psychiatric and/or emotional distress.
3/1/22	Added criteria for rhinoplasty and updated verbiage to clarify that sclerotherapy for telangiectasia (spider veins) is considered cosmetic.
12/1/2021	Added the condition of Klinefelter Syndrome to the coverage allowance for gynecomastia surgery.
9/1/2021	Removed deleted CPT codes: 19324, 19366, 36469. Added replacement codes 15771 and 15772 for code 19324. Removed codes 30460 and 30462 from requiring a PA as these are related to congenital anomaly cleft palate repair, which is not

	cosmetic in nature. Removed from exclusions: Surgical procedures to correct refractive errors (65760, 65765, 65767, 65770, 65771, 65772, 65775, S0800, S0810)

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MEDICAL POLICY

Medical Policy Title	**Coverage for Ambulatory Surgery Unit (ASU)/Outpatient Facility and Anesthesia for Dental Services**
Policy Number	**7.03.01**
Current Effective Date	**January 1, 2027**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

This policy addresses medical coverage for ambulatory surgery unit (ASU)/outpatient facility and anesthesia for dental services. It does not address coverage for dental benefits.

POLICY STATEMENT(S)

I. Services at an outpatient facility or ambulatory surgery unit, including anesthesia by an anesthesiologist, for dental services are considered **medically appropriate** for members with **ANY** of the following indications:

   A. Age seven years or younger;

   B. Developmental disability, when treatment has been unsuccessful in the traditional dental setting;

   C. Concurrent hazardous medical condition(s) with medical documentation and justification, subject to review by a Health Plan Medical Director, that this service must be rendered in an ambulatory surgery unit (ASU) setting and not in the traditional setting;

   D. Behavioral management issues with documentation of an unsuccessful attempt to treat in the dental office, after the use of a sedation modality (e.g., oral sedation, nitrous oxide).

For situations described in Policy Statement I.B. and I.D listed above, if in the judgment of the Health Plan, it is inappropriate to treat the patient in the dental office due to the developmental disability, the severity of a behavioral issue, or the complexity of the treatment planned, an attempt to treat in the dental office may not be required.

RELATED POLICIES

Corporate Medical Policy

7.01.21 Dental and Oral Care under Medical Plans

POLICY GUIDELINE(S)

I. Anesthesia provided in an outpatient facility or ambulatory surgical unit is eligible for coverage only when rendered by an anesthesiologist.

II. When there has been an unsuccessful attempt to treat in the dental office, or it is inappropriate to treat in the dental office due to the severity of a behavioral issue, the severity of a hazardous medical condition, or the complexity of the treatment planned (Policy Statement I.B. and I.D. listed above), medical record documentation is required. Documentation should include the treatment plan, the patient's health history, date(s) treatment was attempted and the patient's response.

DESCRIPTION

Anesthesia is the administration of an anesthetic agent or anesthetic drug by injection, inhalation, or ingestion to achieve loss of sensation or loss of consciousness. Anesthesia is used in dentistry to numb the patient and prevent pain during dental procedures. There are several types of anesthesia available for dental work, including: local anesthesia, sedation dentistry or general anesthesia.

SUPPORTIVE LITERATURE

Not Applicable

PROFESSIONAL GUIDELINE(S)

The American Academy of Pediatric Dentistry (AAPD) best practice document on the management for pediatric dental patients addresses the following for behavior guidance:

- "General anesthesia is indicated for patients: who cannot cooperate due to a lack of psychological or emotional maturity and/or mental, physical, or medical disability; for whom local anesthesia is ineffective because of acute infection, anatomic variations, or allergy; who are extremely uncooperative, fearful, or anxious; who are a pre-communicative or non-communicative child or adolescent; requiring significant surgical procedures that can be combined with dental procedures to reduce the number of anesthetic exposures; for whom the use of general anesthesia may protect the developing psyche and/or reduce medical risk; and requiring immediate, comprehensive oral/dental care (e.g., due to dental trauma, severe infection/cellulitis, acute pain)". Conversely, the use of general anesthesia would be contraindicated for healthy, cooperative patients with minimal dental needs; a very young patient with minimal dental needs that can be addressed with deferred treatment or therapeutic interventions; convenience of the patient or practitioner; and/or predisposing medical conditions which would make general anesthesia inadvisable." (AAPD, 2023c, 2023d)

The AAPD best practice document on the management of dental patients with special health care needs also addresses behavior guidance:

- "Behavior guidance of the patient with SHCN [special health care needs] can be challenging. Communication may be limited due to anxiety, intellectual disability, or impaired hearing or vision. Because of dental anxiety, a lack of understanding of dental care, oral aversion, or fatigue from multiple medical visits and procedures, children with SHCN may exhibit resistant behaviors. These behaviors can interfere with the safe delivery of dental treatment. With the parent's/caregiver's assistance, most patients with physical and intellectual disabilities can

receive oral health care in the dental office. Protective stabilization can be helpful for some patients (e.g., those with aggressive, uncontrolled, or impulsive behaviors; when traditional behavior guidance techniques are not adequate) for safe delivery of care and with consent. When non-pharmacologic behavior guidance techniques are ineffective, the practitioner may recommend sedation or general anesthesia to allow completion of comprehensive treatment in a safe and efficient manner." (AAPD, 2023e, 2023f)

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) is responsible for ensuring the safety, efficacy, and quality of drugs sold in the United States. This includes both prescription and over-the-counter medications. Refer to the FDA Drug website. Available from: https://www.fda.gov/drugs [accessed 2026 Mar 19]

The FDA maintains information for consumers and health professionals on new drug warnings and other safety information, drug label changes, and shortages of medically necessary drug products. Available from: Drug Safety and Availability | FDA [accessed 2026 Mar 19]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
00170	Anesthesia for intraoral procedures, including biopsy; not otherwise specified
41899	Unlisted procedure, dentoalveolar structures

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HCPCS Codes

Code	Description
G0330	Facility services for dental rehabilitation procedure(s) performed on a patient who requires monitored anesthesia (e.g., general, intravenous sedation [monitored anesthesia care]) and use of an operating room

CDT Codes

Code	Description
D9224	Administration of general anesthesia with advanced airway - first 15-minute increment, or any portion thereof; With or without co-administration of nitrous oxide. Anesthesia time begins when the doctor administering the anesthetic agent initiates the appropriate anesthesia and non-invasive monitoring protocol and remains in continuous attendance of the patient. Anesthesia services are considered completed when the patient may be safely left under the observation of trained personnel and the doctor may safely leave the room. This procedure is determined by the provider's documentation of the presence of an advanced airway such as a supraglottic or subglottic airway device, which includes laryngeal tube, esophageal-tracheal tube (Combitube), laryngeal mask airway, or endotracheal tube.
D9225	Administration of general anesthesia with advanced airway - each subsequent 15-minute increment, or any portion thereof

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ICD10 Codes

Code	Description
E08.630	Diabetes mellitus due to underlying condition with periodontal disease
E09.630	Drug or chemical induced diabetes mellitus with periodontal disease
E10.630	Type 1 diabetes mellitus with periodontal disease
E11.630	Type 2 diabetes mellitus with periodontal disease
E13.630	Other specified diabetes mellitus with periodontal disease
K00.0-K01.1	Disorder of tooth development (code range)
K02.3-K02.9	Dental caries (code range)
K03.0-K03.9	Diseases of hard tissues of teeth (code range)
K04.0-K04.99	Diseases of pulp and periapical tissues (code range)
K05.0-K06.9	Disorders of gingiva and supporting structures (code range)
M26.30-M26.39	Anomalies of tooth position of fully erupted tooth or teeth (code range)

Code	Description
M26.79	Other specified alveolar anomalies
M27.61-M27.69	Endosseous dental implant failure (code range)
T18.0XXA	Foreign body in mouth, initial encounter
Z01.20-Z01.21	Encounter for dental examination and cleaning with or without abnormal findings (code range)

REFERENCES

American Academy of Pediatric Dentistry (AAPD). [Internet]. The Reference Manual of Pediatric Dentistry. Behavior guidance for the pediatric dental patient. [Latest revision 2024; accessed 2026 Mar 19]. Available from: https://www.aapd.org/globalassets/media/policies_guidelines/bp_behavguide.pdf

American Academy of Pediatric Dentistry (AAPD). [Internet]. The Reference Manual of Pediatric Dentistry. Hospitalization and operating room access for oral care of infants, children, adolescents, and persons with special health care needs. Original 2020 [Latest revision 2024; accessed 2026 Mar 19]. Available from: https://www.aapd.org/globalassets/media/policies_guidelines/p_hospitalization-infants.pdf

American Academy of Pediatric Dentistry (AAPD). [Internet]. The Reference Manual of Pediatric Dentistry. Oral Health Policies & Recommendations [accessed 2026 Mar 19]. Available from: Oral Health Policies and Recommendations

American Dental Association (ADA). [Internet]. Guidelines for the use of sedation and general anesthesia by dentists. Original 2007 [Last revision Oct 2016a; accessed 2026 Mar 19]. Available from: Anesthesia and Sedation | American Dental Association

Corrêa-Faria P, et al. Recommended procedures for the management of early childhood caries lesions – a scoping review by the Children Experiencing Dental Anxiety: Collaboration on Research and Education (CEDACORE). BMC Oral Health. 2020;20:75.

Lee HH, et al. Patterns in pediatric dental surgery under general anesthesia across 7 state Medicaid programs. JDR Clinical & Translational Research. 2020 Oct;5(4):358-365.

Mangione F, et al. Autistic patients: a retrospective study on their dental needs and the behavioral approach. Clinical Oral Investigations. 2020;24:1677-1685.

Mizutani, et al. Poor oral hygiene and dental caries predict high mortality rate in hemodialysis: a 3-year cohort study. Scientific Reports. 2020;10:21872.

Penna HM, et al. Comparison between oral midazolam versus oral ketamine plus midazolam as preanesthetic medication in autism spectrum disorder: double-blind randomized clinical trial. Braz Journal of Anesth. 2023;73(3):283-290.

World Health Organization 2019. [Internet]. Ending childhood dental caries: WHO implementation manual. [accessed 2026 Mar 19]. Available from: https://apps.who.int/iris/bitstream/handle/10665/330643/9789240000056-eng.pdf

Yilmaz NA, et al. Impact of dental treatments under general anesthesia on oral health-related quality of life in children: a comprehensive meta-analysis. BMC Oral Health. 2025;25:84.

SEARCH TERMS

Moderate sedation

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Coverage for Ambulatory Surgery Unit (ASU) and Anesthesia for Dental Surgery is not addressed in National or Regional Medicare coverage determinations or policies. Although there are several CMS communication documents regarding ambulatory surgery units and anesthesia, CMS does not specifically address coverage for ASU and Anesthesia for Dental Surgery.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

MEDICAL POLICY

Medical Policy Title	**Coverage for Dependents with Disabilities**
Policy Number	**10.01.08**
Current Effective Date	**November 1, 2026**
Next Review Date	**November 2027**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. For purposes of coverage for a dependent child (adult or minor) after the maximum age for dependent coverage has been reached, a Health Plan Medical Director will determine whether the member's condition constitutes a disability, based upon the certification of the dependent child's condition by the treating physician/therapist **AND** the medical criteria stated in the Disability Evaluation under Social Security (Blue Book), published by the Social Security Administration.

II. Certification by the dependent child's treating physician/therapist consists of submission of a completed disabled dependent application. In determining whether a child is a disabled dependent, the Health Plan Medical Director may review the dependent's medical records and/or discuss the member's condition with the requesting physician/therapist.

RELATED POLICIES

Not Applicable

POLICY GUIDELINE(S)

I. Refer to the member's subscriber contract for specific contract age limitations (Refer to the Regulatory Status section below for information regarding the Patient Protection and Affordable Care Act).

II. In order to be considered for ongoing coverage as a dependent with a disability, the disabling condition must have existed before the member reaches the age at which dependent coverage would otherwise terminate due to dependent age limitations.

III. In order to enroll for coverage as a dependent with a disability, the disabling condition must have existed prior to the date on which coverage for the dependent would otherwise have terminated under the subscriber contract due to attainment of the limiting age. If an individual who is past the maximum age of a qualified dependent requests enrollment as a dependent with a disability, enrollment will not be permitted if the disabling condition did not exist prior to reaching the maximum age for coverage as a dependent (age 26 or 29, depending on the policy).

IV. In order for a covered dependent to continue coverage beyond the date coverage would otherwise terminate due to age, the individual must have a disabling condition and be chiefly

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dependent upon the subscriber for support and maintenance. The subscriber must request continued coverage within 31 days from the date that dependent attains the termination age and submit an application and proof of the dependent's incapacity.

V. Requests for disabled dependent status based upon a physical, developmental, or intellectual disability will be reviewed by a Health Plan Medical Director, or his/her appointed designee. Denial of disabled dependent status based upon physical, developmental, or intellectual disability will be made by a Health Plan Medical Director.

VI. Requests for disabled dependent status based upon mental illness will be reviewed by a Health Plan Behavioral Health Medical Director, or his/her appointed designee. Denial of disabled dependent status based upon mental illness will be made by a Health Plan Behavioral Health Medical Director.

VII. The subscriber and the dependent's attending physician must complete a disabled dependent application and submit it to the Health Plan for review.

DESCRIPTION

Disabled dependent status is determined based upon the certification of the dependent's condition by the treating physician/therapist and the medical criteria stated in the Disability Evaluation under Social Security (Blue Book), published by the Social Security Administration. The Blue Book outlines the medical criteria used to determine whether an individual qualifies for social security disability insurance (SSDI) or supplemental security income (SSI) benefits. It serves as a guide for physicians, healthcare professionals, and disability adjudicators in evaluating disability claims. The book is divided into two parts: Part A (Adult Listings), which covers criteria for individuals aged 18 and older, and Part B (Childhood Listings), which addresses criteria for individuals under age 18. Each section is organized by body system such as neurological, cardiovascular, or musculoskeletal and lists specific impairments along with the severity required to be considered disabling. Additionally, the evidentiary requirements section outlines the types of medical documentation needed to support a claim, including clinical findings, laboratory results, imaging studies, and treatment history.

SUPPORTIVE LITERATURE

Not Applicable

PROFESSIONAL GUIDELINE(S)

According to the American Psychiatric Association (APA), the essential features of intellectual development disorder (intellectual disability) are deficits in general mental abilities (Criterion A), impairment in everyday adaptive functioning, in comparison to an individual's age, gender, and sociocultural matched peers (Criterion B), and onset during the developmental period (Criterion C).

Criterion A refer to deficits in general mental abilities, such as reasoning, problem-solving, planning, abstract thinking, judgment, academic learning, learning from experience, and practical understanding confirmed by clinical assessment and standardized testing of intellectual functions, standardized neuropsychological tests, and standardized tests of adaptive functioning.

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Criterion B refer to deficits how well a person meets community standards of personal independence and social responsibility, in comparison to others of similar age and sociocultural background. There are three domains of deficits in adaptive functioning:

- Conceptual (academic)- involving competence in memory, language, reading, writing, math reasoning, acquisition of practical knowledge, problem solving, and judgement in novel situations.
- Social- involving awareness of others' thoughts, feelings, and experiences; empathy; interpersonal communication skills; friendship abilities; and social judgement.
- Practical-involving learning and self-management across life settings, including personal care, job responsibilities, money management, recreation, self-management of behavior, school, and work task organization.

Criterion C, or onset during the developmental period, refer to recognition that intellectual and adaptive deficits are present during childhood or adolescence.

The American Association on Intellectual and Developmental Disabilities defines intellectual disability as a condition marked by significant limitations in both intellectual functioning such as reasoning, learning, and problem-solving and adaptive behavior, which includes everyday social and practical skills.

REGULATORY STATUS

Under the Patient Protection and Affordable Care Act (ACA), all health insurance plans regardless of product type (e.g., health maintenance organization (HMO), or Preferred provider organization (PPO) or funding arrangement (e.g., fully insured or self-funded) that offer dependent coverage are required to provide coverage for adult children until their 26th birthday. This provision became effective for plan years starting on or after September 23, 2010.

Under the New York insurance and public health laws, disabled dependent coverage will be made available to unmarried dependent children, regardless of age, who are incapable of self-sustaining employment by reason of physical handicap, mental illness, developmental disability, or intellectual disability as defined in the New York Mental Hygiene Law. This protection applies as long as the disabling condition began before the age at which dependent coverage would normally end, and the child remains dependent on the policyholder for support.

<u>Under the New York State Mental Hygiene Law</u>:

Mental illness is defined as an affliction with a mental disease or mental condition which is manifested by a disorder or disturbance in behavior, feeling, thinking, or judgment to such an extent that the person afflicted requires care, treatment, and rehabilitation.

Developmental disability is defined as a disability of a person which is attributable to:

- Intellectual disability, cerebral palsy, epilepsy, neurologic impairment, familial dysautonomia, Prader-Willi syndrome or autism;

- Any other condition of a person found to be closely related to intellectual disability because such condition results in similar impairment of general intellectual functioning or adaptive behavior to that of intellectually disabled persons or requires treatment and services similar to those required for such person; or
- Dyslexia resulting from disabilities described above;
- Originates before such person attains age twenty-two;
- Has continued or can be expected to continue indefinitely; and
- Constitutes a substantial handicap to such person's ability to function normally in society.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Multiple Codes	

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HCPCS Codes

Code	Description
Multiple Codes	

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

American Association on Intellectual and Developmental Disabilities [Internet]. Definition of intellectual disability. [accessed 2025 Oct 3]. Available from: http://aaidd.org/intellectual-disability/definition

American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR). Washington, DC, American Psychiatric Association, 2022.

New York Insurance Law [Internet]. Section § 3216 (c) (4) (A), § 4304 (d) (1), § 4305 (c). [Updated 2025 Sept 29; accessed 2025 Oct 3]. Available from: http://public.leginfo.state.ny.us/lawssrch.cgi?NVLWO

New York Mental Hygiene Law [Internet]. Laws of New York; Public Health PBH; Chapter 27, Title A, Article 1 Section § 1.03. [accessed 2025 Oct 3]. Available from: https://www.nysenate.gov/legislation/laws/MHY/1.03

Social Security Medical Professional/Relations [Internet]. Disability evaluation under social security: listing of impairments. [accessed 2025 Oct 3]. Available from: https://www.ssa.gov/disability/professionals/bluebook/AdultListings.htm

United States Department of Health and Human Services [Internet]. Young adult coverage. [Last reviewed 2022 Mar 17; accessed 2025 Oct 3]. Available from: https://www.hhs.gov/healthcare/about-the-aca/young-adult-coverage/index.html

SEARCH TERMS

Handicapped dependent, disabled dependent, dependent with a disability, disabilities determination, disability evaluation.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based on our review, coverage for dependents with disabilities is not addressed in National or Local Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 7/26

Revised:

Reviewed:	
Date	**Summary of Changes**
11/1/2026	• New

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: COVERAGE WITH EVIDENCE DEVELOPMENT FOR MEDICARE ADVANTAGE

POLICY EFFECTIVE DATE:	1/1/2026
Policy Control #:	1370/20.000517
Next Annual Review:	May, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

Allogeneic Hematopoietic Stem Cell Transplant for Multiple Myeloma (ICD 10: C90.00-C90.02): 38205, 38240
Allogeneic Hematopoietic Stem Cell Transplant for Myelofibrosis (ICD 10: C94.40, C94.41, C94.42, D47.4, D75.81): 38205, 38240
Allogeneic Hematopoietic Stem Cell Transplant for Sickle Cell Disease (ICD 10: D57.00 - D57.819): 38205, 38240
Autologous Platelet-rich Plasma: 0232T
Cardiac Contractility Modulation (CCM) for Heart Failure: 0408T, 0409T, 0410T, 0411T, 0915T, 0916T, 0917T, 0918T, 0919T, 0920T, 0921T, 0922T, 0923T, 0924T, 0925T, 0926T, 0927T, 0928T, 0929T, 0930T, 0931T, 0948T, 0949T
Extracorporeal Photopheresis for Bronchiolitis Obliterans Syndrome Following Lung Transplant: 36522
Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management: G0555
Leadless Pacemakers: C1605, 0795T-0797T, 0801T-0803T
Percutaneous Left Atrial Appendage Closure (LAAC): 33267, 33268, 33269, 33340
Pharmacogenomic Testing for Warfarin Response: G9143, 0030U
Renal Denervation for Uncontrolled Hypertension: 0338T, 0339T
Transcatheter Aortic Valve Replacement (TAVR): 33367, 33368, 33369
Transcatheter Edge-to-Edge Repair (TEER): 33419
Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER) 0569T, 0570T
Transcatheter Tricuspid Valve Replacement (TTVR): 0569T, 0570T, 0646T

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: COVERAGE WITH EVIDENCE DEVELOPMENT FOR MEDICARE ADVANTAGE

Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD): 61885, 61886, 61888, 64568, 64569, 64570, 64999, 95970, 95976, 95977, 0908T, 0909T, 0910T, 0911T, 0912T

DESCRIPTIONS

CMS may make a National Coverage Determination (NCD) and/or Decision Memo that requires participation in certain clinical trials, longitudinal studies, or registries for coverage of an investigational item/service and routine and related items/services.

CMS decides Coverage with Evidence Development (CED) after a formal review of the medical literature to cover an item or service only in the context of an approved clinical study or when additional clinical data are collected to assess the appropriateness of an item or service.

RELATED POLICIES/DOCUMENTS

Non-Covered Technologies, 1370/20.000444
Clinical Review Preauthorization List

Pharmacy Policies:
Pharmaceutical Treatment of Alzheimer's Disease, 1350/20.000416

POSITION STATEMENT

CDPHP will provide coverage of items and services in CMS approved CED studies when the member is part of an approved study for that specific NCD/Decision Memo. CDPHP covers the below services through CED:

- Allogeneic Hematopoietic Stem Cell Transplant for Multiple Myeloma
- Allogeneic Hematopoietic Stem Cell Transplant for Myelofibrosis
- Allogeneic Hematopoietic Stem Cell Transplant for Sickle Cell Disease
- Autologous Platelet-rich Plasma
- Cardiac Contractility Modulation (CCM) for Heart Failure
- Extracorporeal Photopheresis for Bronchiolitis Obliterans Syndrome Following Lung Transplant
- Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management
- Leadless Pacemakers
- Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (AD) (*reviewed by CDPHP Pharmacy program)
- Percutaneous Left Atrial Appendage Closure (LAAC)
- Pharmacogenomic Testing for Warfarin Response (*reviewed by HealthHelp)
- Renal Denervation for Uncontrolled Hypertension
- Transcatheter Aortic Valve Replacement (TAVR)

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POLICY NAME: COVERAGE WITH EVIDENCE DEVELOPMENT FOR MEDICARE ADVANTAGE

- Transcatheter Edge-to-Edge Repair (TEER)
- Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER)
- Transcatheter Tricuspid Valve Replacement (TTVR)
- Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD)

To access the CED's as well as the approved clinical trials for each CED, click on the below link. CED information that is not located in the below link will be identified in the applicable NCA/NCD.

CMS Coverage with Evidence

POLICY CONSIDERATIONS

For reimbursement of above CED services, claims must include the following information:

Professional Claims:

Paper claim: 8-digit NCT identifier number preceded by alpha characters 'CT' in Field 19 of Form CMS-1500 (e.g., CT12345678)

Electronic claim: 8-digit NCT identifier number on equivalent 837P in Loop 2300 REF02(REF01=P4) no 'CT' (e.g., 12345678)

Institutional claims

Paper: 8-digit NCT identifier number in the value amount value code 'D4' of FORM CMS UB-04 (Form Locators 39-41)

Electronic: 8–digit NCT identifier number on equivalent 837I in Loop 2300 REF02 (REF01=P4)

EXCLUSIONS

Investigational item/service when it is offered through a clinical trial that is not part of CED.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS: **Not Applicable.**

MEDICARE ADVANTAGE: Subject to all terms and conditions noted above in the policy.

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POLICY NAME: COVERAGE WITH EVIDENCE DEVELOPMENT FOR MEDICARE ADVANTAGE

SELECT PLAN/HARP: **Not Applicable.**

SOURCES

1. Medicare Managed Care Manual 100-16 | CMS
2. Mandatory Reporting of the 8-digit National Clinical Trial Identifier Number https://www.cms.gov/medicare/coverage/coverage-with-evidence-development/downloads/mandatory-clinical-trial-identifier-number.pdf
3. Mandatory Reporting of National Clinical Trial (NCT) Identifier Numbers on Medicare Claims – Qs & As https://www.cms.gov/medicare/coverage/coverage-with-evidence-development/downloads/mandatory-clinical-trial-identifier-number-qsas.pdf
4. Coverage with Evidence Development https://www.cms.gov/medicare/coverage/evidence
5. Other carrier policies

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POLICY APPROVAL DATES

New: 5/24

Revised: 9/24, 11/24, 3/25, 5/25, 9/25, 1/26, 3/26

Reviewed: 5/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
1/1/2026	Removed codes from policy as HealthHelp will be reviewing these codes: 33289 C2624 33274

	33275 33361 33362 33363 33364 33365 33366 0345T 33418 0275T
10/28/2025	Added Renal Denervation for Uncontrolled Hypertension and Cardiac Contractility Modulation (CCM) for Heart Failure to policy
9/1/2025	Added new Medicare CED to policy which was effective 7/2/2025: Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER)
3/19/2025	Added Transcatheter Tricuspid Valve Replacement (TTVR) to policy.
3/1/2025 *No change to effective date of policy	Added Vagus Nerve Stimulation to policy as there are now clinical trials for this CED.
3/1/2025	Added Implantable Pulmonary Artery Pressure Sensors for Heart Failure Management to policy which was effective 1/13/2025.
9/1/2024 *No change to effective date of policy	Added applicable CPT and ICD 10 codes.
9/1/2024 *No change to effective date of policy	Removed Allogeneic Hematopoietic Stem Cell Transplant for MDS from the list as there is now a NCD for coverage.
9/1/2024	New policy

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MEDICAL POLICY

Medical Policy Title	**Cranial and Auricular Neuromodulation**
Policy Number	**1.01.58**
Current Effective Date	**August 1, 2026**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

This policy does not address cranial electrotherapy stimulation for the treatment of behavioral health conditions, or implantable vagus nerve stimulation and vagus nerve blocking therapy.

POLICY STATEMENT(S)

I. The following neuromodulation types are **investigational**:

- A. Cranial Electrical Stimulation; (also known as transcranial electrical stimulation [tES] or cranial electrotherapy stimulation for pain (e.g., Alpha Stim-AID, Carvella, CES Ultra);
- B. External Trigeminal Nerve Stimulation (eTNS) (e.g., Monarch);
- C. Transcutaneous/Non-Implantable Vagus Nerve Stimulation (tVNS) (e.g., GammaCore Sapphire);
- D. Transcutaneous Supraorbital Neurostimulation (e.g., Cefaly);
- E. Auricular Electrostimulation, including Percutaneous Electrical Nerve Field Stimulation (PENFS) and Transcutaneous Nerve Field Stimulation (e.g., P-Stim, IB-Stim, NSS-2 Bridge device).

RELATED POLICIES

Corporate Medical Policies

1.01.59 Electromagnetic and Pulsed Field Stimulation

1.01.60 Implantable and Invasive Neuromodulation Systems

1.01.61 Non-Invasive Surface Electrical Stimulation for Pain and Rehabilitation

1.01.62 Specialized Neuromodulation for Specific Conditions

3.01.09 Transcranial Magnetic Stimulation and Cranial Electrotherapy Stimulation

7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

11.01.03 Experimental or Investigational Services

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POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

External Trigeminal Nerve Stimulation (eTNS)

The Monarch eTNS system, (NeuroSigma) is classified as a transcutaneous electrical nerve stimulator for attention deficit hyperactivity disorder device type. It is designed to generate and deliver electrical pulses to the trigeminal nerve, which directs signals to the parts of the brain that are believed to be associated with ADHD. The device is connected to a small patch that adheres to a patient's forehead. It is meant for at-home use during sleep and requires caregiver supervision.

Transcutaneous Supraorbital Neurostimulation

The Cefaly device (CEFALY Technology) received FDA approval for the prophylactic treatment of migraines in patients ages 18 years and older. Cefaly is a small, portable, battery-powered, prescription device that resembles a plastic headband worn across the forehead and atop the ears. The user positions the device in the center of the forehead, just above the eyes, using a self-adhesive electrode. The device applies an electric current to the skin and underlying body tissues to stimulate branches of the trigeminal nerve, which has been associated with migraine headaches. The user may feel a tingling or massaging sensation where the electrode is applied. The device should only be worn daily for 20 minutes.

Cranial Electrical Stimulation (CES)

CES is also known as cranial electrotherapy, transcranial electrical stimulation, or electrical stimulation therapy. The most common CES device in the United States, is the Alpha Stim products. Alpha Stim-AID, and Alpha-Stim M is a handheld prescription device that delivers an electronic microcurrent through electrodes placed further from the brain (i.e., earlobes, scalp, eyelids) and delivers a pulsed, low-intensity current to stimulate specific groups of nerve cells. Although the exact mechanism of action is unknown, CES has been approved by the FDA for the treatment of insomnia, depression, and anxiety. The user can select the level of stimulation and increase or reduce as needed, typically for 20- minute sessions. CES is being evaluated for a variety of other conditions including pain, and functional constipation.

Transcutaneous/Non-Implantable Vagus Nerve Stimulation (tVNS)

tVNS is a medical treatment that involves delivering electrical impulses to the auricular or cervical branch of the vagus nerve. It has been proposed as an adjunctive treatment for certain types of treatment-resistant depression, tinnitus, diabetes, endotoxemia, memory, myocardial infarction, headache, pain, intractable epilepsy, and stroke.

The gammaCore-S (electroCore LLC) is a noninvasive vagus nerve stimulation device for the acute treatment of adults with episodic cluster headaches. When the device is applied to the side of the neck by the patient, a mild electrical stimulation of the vagus nerve is carried to the central nervous system. Each stimulation using gammaCore-S lasts two minutes. The patient controls stimulation

strength. In 2021, the gamma-Core Sapphire received additional approval for indications for use including the preventative treatment of migraine headache in adolescent (age 12 and older) and adult patients, the acute treatment of pain associated with migraine headache in adolescent (age 12 and older) and adult patients, and for the adjunctive use for the preventative treatment of cluster headache in adults.

Auricular Electrostimulation

Electrical stimulation of auricular acupuncture points, or auricular electrostimulation, involves the stimulation of acupuncture points on the ear. Auricular electrostimulation has been proposed for the treatment of a variety of conditions, including pain, depression, and anxiety. Devices have been developed that provide electrical stimulation to auricular acupuncture sites over a period of several days.

The P-Stim (NeuroScience Therapy Corporation) is a single-use, miniature electrical stimulator for auricular acupuncture points that is worn behind the ear with a self-adhesive electrode patch. A selection stylus that measures electrical resistance is used to identify three auricular acupuncture points. The P-Stim device connects to three inserted acupuncture needles with caps and wires. The device is pre-programmed to be on for 180 minutes, then off for 180 minutes. The maximum battery life of this single-use device is 96 hours.

The E-pulse, or Electro Acupuncture device, is a microprocessor-controlled, battery-powered unit designed to administer auricular point nerve stimulation treatment for pain therapy over a 96-hour period.

Percutaneous Electrical Nerve Field Stimulation (PENFS)

Auricular PENFS is a variation of peripheral electrical nerve stimulation (PENS) in that it uses a low-frequency electrical current to stimulate the skin and underlying tissues in a general area of pain rather than targeting a specific nerve. PENFS devices are thought to work by sending electrical stimulation of peripheral cranial neurovascular bundles in the external ear to help modulate central pain pathways, however, the exact mechanism responsible for the analgesic effects remains unknown. PENFS involves a nonimplantable device that stimulates nerves remotely from the site of pain and has been studied for a variety of musculoskeletal and neuropathic pain conditions, and patients with opioid withdrawal.

The NSS-2 Bridge device (Innovative Health Solutions, Inc.) is a small electrical nerve stimulator placed behind the ear that emits electrical pulses to stimulate branches of certain cranial nerves, which may provide relief from opioid withdrawal symptoms. This device was approved for use in reducing the symptoms of opioid withdrawal.

The IB-Stim (Innovative Health Solutions, Inc.) is a disposable, battery-powered, percutaneous electrical nerve field stimulator (PENFS) system placed behind the ear. The device has four percutaneously placed electrodes (three frontal and one dorsal) applied to auricular areas innervated by branches of four cranial nerves (CN V, VII, IX, and X). It is intended for patients 11-18 years old with functional abdominal pain disorders (FAPD) associated with irritable bowel syndrome (IBS). The device is to be used 120 hours per week for three consecutive weeks.

SUPPORTIVE LITERATURE

External Trigeminal Nerve Stimulation (eTNS)

McGough et al (2019) assessed the efficacy and safety of eTENS in a double-blind, sham-controlled pilot study of pediatric patients with attention deficit hyperactivity disorder (ADHD). The study was a four -week trial followed by one blinded week without intervention. Clinical assessments included weekly clinician-administered ADHD-Rating and Clinical Global Impression (CGI) scales, and quantitative electroencephalography (EEG) at baseline as well as at week four. The primary outcome measure was the clinician completed ADHD-Rating Scale total score. Results revealed that ADHD-Rating Scale totals showed significant group-by-time interactions, demonstrating a differential treatment effect ($F=8.12$; $df=1/228$; $p=.005$). The CGI-Improvement scale also favored active treatment over sham ($p=.003$). Quantitative EEG readings were obtained in both groups but there were no participant specific correlations to other outcomes. No serious adverse events were observed in either group, and no patient withdrew from the study due to adverse events. Significant increases in weight and pulse were seen with active eTENS over the trial period; however, no differences between active and sham eTENS with regard to blood pressure were seen. Conclusions were that eTENS therapy is efficacious and well-tolerated in pediatric patients with ADHD. Limitations cited were the small sample size and relatively short duration of treatment and follow-up.

Transcutaneous Supraorbital Neurostimulation

Schoenen et al (2013) reported the results from the Prevention of Migraine (PREMICE) trial, a multi-center, randomized, sham controlled trial. They assessed the efficacy and safety of supraorbital transcutaneous neurostimulation (STNS) in migraine prophylaxis with the Cefaly device. The trial consisted of 67 patients randomized to receive the Cefaly device or sham treatment daily for 20 minutes for three months. After the first month of treatment both the treatment and sham groups showed a decrease in migraine days by an average of 20%. This decrease disappeared in the sham group by the second and third month but continued in the treatment group. The 50% responder rate was greater in the treatment group, and the therapeutic gain of effective stimulation over sham was 26%. The monthly attack frequency from the first to the third month was reduced by 18.8% in the treatment group and by only 3.5% in the sham group. Headache severity and the monthly intake of anti-migraine medications was also reduced in the treatment group. No adverse events or side effects were found for either the treatment or sham group. Compliance was moderately satisfactory in both groups. The responder rate for electrical stimulation was within the range of those reported for other migraine treatment modalities. However, the study size was small, and the individuals in the selected cohort were not severely disabled by their migraines.

Cranial Electrical Stimulation (CES)

CES has been investigated for individuals with headache, chronic pain, depression, and Parkinson disease. Trials that studied headaches found only marginal benefits. Trials studied for chronic pain did not show a benefit. The evidence for the use of CES for psychiatric, behavioral, or neurologic conditions include a systematic review and a number of small sham controlled randomized controlled trials (RCTs), only one of which (Barclay 2014) found a significant benefit for its use in depression,

but the sample size was small with strong potential placebo effects. Additionally, studies had significant heterogeneity in study populations and treatment protocols.

Ahn et al (2020) published a double-blind, randomized, sham-controlled pilot study of the feasibility and efficacy of remotely supervised CES via secure videoconferencing in 30 older adults with chronic pain due to knee osteoarthritis. Mean age was 59.43 years. CES was delivered via the Alpha-Stim M Stimulator, which was preset at 0.1 mA at a frequency of 0.5 Hz and applied for one hour daily on weekdays for two weeks. The sham electrodes were identical in appearance and placement, but the stimulator did not deliver electrical current. The study was conducted in a single center in Houston. All 30 participants completed the study and were included in the outcome analyses. For the primary outcome of clinical pain at two weeks as assessed by a Numeric Rating Scale, a significantly greater reduction occurred in the active CES group (-17.00 vs. +5.73; $p<.01$). No patients reported any adverse effects. Important relevancy limitations include lack of assessment of important health outcomes or long-term efficacy. An important conduct and design limitation is that it is unclear how convincing the sham procedure was as it did not involve any feature designed to simulate a tingling sensation and give the patient the feeling of being treated (i.e., subtherapeutic amplitude, initial current slowly turned to zero). Therefore, findings may be subject to the placebo effect. This trial was also limited by the small number of participants. These limitations preclude drawing conclusions based on these findings.

Wu et al (2020) published a double-blind, randomized, sham-controlled trial of the efficacy and safety of CES as an add on treatment for tic disorders in 62 children and adolescents who lacked a clinical response to prior treatment of four weeks of pharmacotherapy. Cranial electrotherapy stimulation was delivered via the CES Ultra stimulator (American Neuro Fitness LLC) at 500 µA-mA and applied for 30 minutes daily on weekdays for 40 days. The sham CES was delivered at lower than 100 µA. The study was conducted at a single academic medical center in China. A total of nine participants (14.5%) discontinued the intervention early and were excluded from the analyses. There was no significant difference between the active CES and sham groups in the change in Yale Global Tic Severity Scale (YGTSS) score (-31.66% vs. 23.96%; $p=.13$).

Transcutaneous Vagus Nerve Stimulation (tVNS)

The evidence for tVNS stimulation in individuals who have epilepsy, depression, schizophrenia, headache, or impaired glucose tolerance includes at least one randomized controlled trial and case series for some of the conditions. The RCTs are small and have various methodologic problems. Definitive efficacy of tVNS in improving outcomes among patients has not been demonstrated. The evidence is insufficient to determine the effects of the technology on health outcomes.

Percutaneous Electrical Nerve Field Stimulation (PENFS)

Kovacic et al (2017) conducted an RCT comparing the Neuro-Stim PENFS device with a sham device in adolescent patients with abdominal pain-related functional gastrointestinal disorders including IBS. Patients 11 to 18 years of age with abdominal pain (pain score ≥ 3 on an 11-point scale) occurring at least twice weekly for at least two (2) months were included. The devices were worn for five (5) days each week for four (4) weeks. Baseline medications were continued except for antispasmodics which were not allowed during the study period. Enrolled patients were primarily female (91%) and White

(90%). Pain, as measured on the Pain Frequency-Severity-Duration (PFSD), was the primary outcome. The PFSD scale incorporates several aspects of the pain experience and is generally calculated over 14 days but was modified as a weekly score in this trial with a high composite score of 70. Both "worst pain" and median PFSD composite scores were better with PENFS than placebo. The Symptom Response Scale (-7 to +7 [with negative scores as worse and positive scores as better]) was used to assess the overall symptoms. Although the authors reported statistically significantly improved scores with the Neuro-Stim device at 3 weeks, numerical differences between groups were small. Longer-term pain scores obtained at a median of 9.2 weeks after treatment remained improved from baseline in the active treatment group with a decrease of composite PFSD scores of -8.4 compared with 0.0 in the sham group. Adverse events including ear discomfort and adhesive allergy were similar between groups. The study is limited by the small sample size, the heterogeneous population of gastrointestinal disorders, the lack of bowel habit measurement, and the short duration of follow-up. Krasaelap et al (2020) evaluated a subgroup of 50 patients with IBS from the Kovacic et al (2017) RCT. At three (3) weeks there were more responders with the active treatment (response defined as ≥ 30% reduction in worst abdominal pain) than with the sham device. At the extended follow-up (8-12 weeks), the percentage of responders was similar between groups (32% vs. 18%; p=.33).

PROFESSIONAL GUIDELINE(S)

In 2024, the European Society for Pediatric Gastroenterology, Hepatology and Nutrition/North American Society for Pediatric Gastroenterology, Hepatology and Nutrition Guideline Development Group (ESPGHAN/NASPGHAN GDG) published recommendations for the treatment of abdominal pain-related disorders of gut-brain interaction such as irritable bowel syndrome and functional abdominal pain-not otherwise specified in children, based upon a systematic review and comprehensive synthesis of the available literature. After evaluation of the benefits and harms of PENFS, the GDG made a conditional recommendation with a moderate certainty of evidence for its use in the reduction of pain intensity. The GDG acknowledged that the recommendation came from a single-institution study, and that the treatment comes at a relatively high initial cost, requiring weekly new device placement for the entirety of the treatment course.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates electrical stimulation devices as medical devices. All electrical stimulation devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Mar 26]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Mar 26]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0783T (E/I)	Transcutaneous auricular neurostimulation, set-up, calibration, and patient education on use of equipment
64567 (E/I)	Percutaneous electrical nerve field stimulation, cranial nerves, without implantation (e.g., IB-Stim) (Effective 1/1/26)

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HCPCS Codes

Code	Description
A4541	Monthly supplies for use of device coded at E0733
A4543 (E/I)	Supplies for transcutaneous electrical nerve stimulator, for nerves in the auricular region, per month
A4596 (E/I)	Cranial electrotherapy stimulation (CES) system supplies and accessories, per month
E0720 (*E/I)	TENS, two lead, localized stimulation (*E/I when used for Cefaly device)
E0721 (E/I)	Transcutaneous electrical nerve stimulator for nerves in the auricular region (e.g., Sparrow Ascent)
E0732 (E/I)	Cranial electrotherapy stimulation (CES) system, any type
E0733 (E/I)	Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve (e.g., Monarch, Cefaly)
E0735 (E/I)	Noninvasive Vagus Nerve Stimulator

ICD10 Codes

Code	Description
F10.10-F10.99	Alcohol related disorders (code range)
F11.10-F11.99	Opioid related disorders (code range)
F12.10-F12.99	Cannabis related disorders (code range)

Code	Description
F13.10-F13.99	Sedative, hypnotic, or anxiolytic related disorders (code range)
F14.10-F14.99	Cocaine related disorders (code range)
F15.10-F15.99	Other stimulant related disorders (code range)
F16.10-F16.99	Hallucinogen related disorders (code range)
F17.200-F17.299	Nicotine dependence (code range)
F18.10-F18.99	Inhalant related disorders (code range)
F19.10-F19.99	Other psychoactive substance related disorders (code range)
G43.001-G43.019	Migraine without aura (code range)
G43.101-G43.419	Migraine with aura (code range)
G43.701-G43.719	Chronic migraine without aura (code range)
G43.B0-G43.B1	Ophthalmoplegic migraine (code range)
G43.801-G43.919	Other types of migraines (code range)
G44.1	Vascular headache, not elsewhere classified
G44.201-G44.209	Tension-type headache, unspecified (code range)
G44.211-G44.219	Episodic tension-type headache (code range)
G44.221-G44.229	Chronic tension-type headache (code range)
G44.301-G44.309	Post-traumatic headache, unspecified (code range)
G44.321-G44.329	Chronic post-traumatic headache (code range)
G46.0-G46.8	Vascular syndromes of brain in cerebrovascular diseases (code range)
G50.0-G50.9	Disorders of trigeminal nerve (code range)
G51.2-G51.9	Facial nerve disorders (code range)
G56.00-G56.03	Carpal tunnel syndrome (code range)
H92.01-H92.09	Otalgia (code range)
I67.2	Cerebral atherosclerosis
I67.81-I67.82	Other specified cerebrovascular diseases (code range)
I67.89	Other cerebrovascular disease
I67.9	Cerebrovascular disease, unspecified
I68.0	Cerebral amyloid angiopathy
I68.8	Other cerebrovascular disorders in diseases classified elsewhere
J30.1-J30.9	Allergic rhinitis (code range)
K58.0-K58.9	Irritable bowel syndrome (code range)
K91.0	Vomiting following gastrointestinal surgery
M15.0-M15.9	Polyosteoarthritis (code range)

Code	Description
M16.0-M16.9	Osteoarthritis of hip (code range)
M17.0-M17.9	Osteoarthritis of knee (code range)
M18.0-M18.9	Osteoarthritis of first carpometacarpal joint (code range)
M19.011-M19.079	Primary osteoarthritis (code range)
M19.111-M19.179	Post-traumatic osteoarthritis (code range)
M19.211-M19.279	Secondary osteoarthritis (code range)
M19.90-M19.93	Osteoarthritis, unspecified site (code range)
M25.50-M25.579	Pain in joint (code range)
M26.621-M26.629	Arthralgia of temporomandibular joint (code range)
M43.26-M43.28	Fusion of spine (code range)
M43.8x6-M43.8x9	Other specified deforming dorsopathies (code range)
M51.16-M51.17	Intervertebral disc disorders with radiculopathy (code range)
M53.1	Cervicobrachial syndrome
M53.2x7	Spinal instabilities, lumbosacral region
M53.2x8	Spinal instabilities, sacral and sacrococcygeal region
M53.3	Sacrococcygeal disorders, not elsewhere classified
M53.86-M53.88	Other specified dorsopathies (code range)
M53.9	Dorsopathy, unspecified
M54.06-M54.09	Panniculitis affecting regions of neck and back (code range)
M54.16-M54.18	Radiculopathy (code range)
M54.30-M54.32	Sciatica (code range)
M54.40-M54.42	Lumbago with sciatica (code range)
M54.5	Low back pain
M60.80-M60.9	Other myositis (code range)
M62.830	Muscle spasm of back
M77.10-M77.12	Lateral epicondylitis (code range)
M79.0	Rheumatism, unspecified
M79.10-M79.18	Myalgia (code range)
M79.2	Neuralgia and neuritis, unspecified
M79.601-M79.676	Pain in limb, hand, foot, fingers and toes (code range)
M79.7	Fibromyalgia
N64.4	Mastodynia
N94.4-N94.6	Dysmenorrhea (code range)

Code	Description
O21.0-O21.9	Excessive vomiting in pregnancy (code range)
R51	Headache
T45.1x5A-T45.1x5S	Adverse effect of antineoplastic and immunosuppressive drugs (code range)

REFERENCES

Gil-Lopez, et al. External trigeminal nerve stimulation for drug resistant epilepsy: A randomized controlled trial. Brain Stimulation. 2020 Jun;(13):1245-1253.

Groen J, et al. ESPGHAN/NASPGHAN guidelines for treatment of irritable bowel syndrome and functional abdominal pain-not otherwise specified in children aged 4–18 years. J Pediatr Gastroenterol Nutr. 2025;81:442-471.

Irwin SL, et al. Transcranial magnetic stimulation for migraine prevention in adolescents: a pilot open-label study. Headache. 2018 May;58(5):724-731.

Kim et al. Effects of cranial electrotherapy stimulation with novel in-ear electrodes on anxiety and resting-state brain activity: A randomized double-blind placebo-controlled trial. J Affect Disord. 2021 Dec 01;295:856-864.

Kovacic K, et al. Neurostimulation for abdominal pain-related functional gastrointestinal disorders in adolescents: a randomised, double-blind, sham-controlled trial. Lancet Gastroenterol Hepatol. 2017 Oct;2(10):727-737.

Magis D, et al. Safety and patients' satisfaction of transcutaneous supraorbital neurostimulation (tSNS) with the Cefaly(R) device in headache treatment: a survey of 2,313 headache sufferers in the general population. J Headache Pain. 2013;14:95.

McGough JJ, et al. Double-Blind, Sham-Controlled, Pilot Study of Trigeminal Nerve Stimulation for Attention-Deficit/Hyperactivity Disorder. J Am Acad Child Adolesc Psychiatry. 2019;58(4):403–411.

Mori N, et al. Analgesic effects of repetitive transcranial magnetic stimulation at different stimulus parameters for neuropathic pain: a randomized study. Neuromodulation. 2022 Jun;25(4):520-527.

Schoenen J, et al. Migraine prevention with a supraorbital transcutaneous stimulator: a randomized controlled trial. Neurology. 2013;80(8):697-704.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Cranial and Auricular Neuromodulation are not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 7/26

Revised:

Reviewed:

Date	Summary of Changes
8/1/2026	• New policy in conjunction with other new policies 1.01.59, 1.01.60, 1.01.61, & 1.01.62, which will replace Neuromuscular/Functional Electrical Stimulation policy 1370/20.000073 which is being made obsolete.

MEDICAL POLICY

Medical Policy Title	**Cryotherapy (Cold Therapy) Devices**
Policy Number	**1.01.21**
Current Effective Date	**January 1, 2027**
Next Review Date	**June 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.

(Link to Product Disclaimer)

This policy does not address whole body cooling devices or the use of compression devices for venous thromboembolism prophylaxis. Refer to CMP #1.01.51 Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis.

POLICY STATEMENT(S)

I. The use of active or passive cryotherapy (cold therapy) devices is considered **not medically necessary** for any indication.

RELATED POLICIES

Corporate Medical Policy

1.01.51 Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis

1.01.00 Durable Medical Equipment (DME) and Devices: Standard and Non-Standard

8.01.24 Therapies (Speech, Physical, & Occupational)

Administrative Policy

AP-53 Chemotherapy Treatment

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Cryotherapy or "cold therapy" refers to the local or general application of therapeutic cold, whether that be through passive durable medical items such as icepacks, cold packs, compresses, and garments (e.g., vests, cuffs, or gel caps) that may or may not use gravity or a hand pump to circulate cold water, or via active cold therapy, which uses separate pumps for circulation in order to maintain temperature. These active devices may or may not include compression or vibration in addition to cooling.

Cold therapy is considered a standard part of treating pain and inflammation following injuries involving musculoskeletal tissue, trauma, or orthopedic surgery. Recent applications aim to reduce or

prevent chemotherapy-related side effects such as alopecia, mucositis, and peripheral neuropathy.

SUPPORTIVE LITERATURE

Studies supporting the use of various cooling devices for pain and inflammation have not demonstrated health outcome improvements beyond increased convenience for the user, that exceed what is achieved with standard cryotherapy and compression using ice and wraps.

Cold Therapy Following Surgery

Quesnot and colleagues (2024) conducted a single center randomized controlled trial (NCT06037824) of compressive cryotherapy versus standard cryotherapy after total knee arthroplasty (TKA) and compared knee range of position after 21 days of rehabilitation following surgery. A total of 40 patients were randomized into two groups, patients whose treatment included compressive cryotherapy (n=20) versus those that included cryotherapy alone (n=20). Authors additionally compared other skin, pain and functional outcomes including knee circumference, fluctuation tests, pain at rest and during activity, six-minute walking tests and Knee Injury and Osteoarthritis Score (KOOS) questionnaires. Reported baseline characteristics of the two groups were minimal, aside from the median age. Study participants in the cryotherapy and compression group used the Game Ready Device (Coolsystems, Inc.) which consisted of a control unit, connector hose, and knee wrap. A block of ice was placed inside the Game Ready reservoir, the wrap was placed around the patient's knee, and parameters for the controller were set. Sessions were 30 minutes long. Alternatively, patients in the standard cryotherapy group received standard ice wraps placed in sleeves to protect the skin for 30 minutes, three times per day. On day 21, there were no differences between the groups in passive or active range of motion. Authors reported significant improvements in joint effusion, pain during activity, the 6-minute walk test, and the Knee Injury and Osteoarthritis Score (KOOS) in the cryotherapy and compression group, but numerically, the differences were small, given the limitation of small sample size.

Liang and Colleagues (2024) conducted a systematic review and meta-analysis to investigate whether cryotherapy is able to improve the rehabilitation of patients undergoing TKA and to also determine which device type offered superior results, either continuous cold flow or cold packs. A literature search was conducted in May 2024 for randomized controlled trials comparing cryotherapy with no cryotherapy or continuous cold flow devices with cold packs after TKA. The primary outcome was the visual analogue scale (VAS) for pain. Secondary outcomes included adverse events, range of motion, swelling, blood loss and length of stay. A total of 31 trials were included in the metanalysis (18 cryotherapy versus no cryotherapy, and 13 comparing continuous cold flow device versus cold packs). Results indicated lower VAS scores for the cryotherapy group compared to the no cryotherapy group on post-operative days 1, 2, and 3. Additionally, cryotherapy reduced opioid consumption, improved range of motion, as well as reduced blood loss and drainage. Results of the continuous cold flow device group were comparable to all outcomes in the cold pack group. Authors concluded that the findings support the use of cryotherapy in TKA patients, but that traditional cold packs are still recommended over continuous cold flow devices.

Khan and colleagues (2024) investigated the outcomes for 200 patients post unilateral shoulder surgery in an open- label randomized controlled trial. The patients were randomized to either the

Game Ready GRPro 2.1 cooling device or standard care, which consisted of one of the following treatments: CryoCuff, ice packs or no cryotherapy. There was no difference in pain between groups at baseline, week 2, week 6, or week 12. Opioid consumption was lower in the Game Ready group versus the standard of care group, but the interquartile range was 66.1 mg -99.4mg, which is large. In addition to the open label design, the study is limited by the heterogeneity in the standard of care treatments. Further studies with improved methodologies are warranted.

A Cochrane Review by Aggarwal and colleagues (2023) investigated cryotherapy after surgery compared with other or no treatments following TKR for osteoarthritis. A total of 22 trials (20 randomized trials, two controlled trials) representing 1,839 patients were included. The authors cite several limitations of the studies which included poor design, lack of true randomization, dropouts, small number of participants, and homogeneity. The plain language summary states, "We have little confidence in the evidence showing that cold therapy may slightly improve blood loss, pain and range of motion after surgery. We are uncertain if it lowers the risk of blood transfusion, improves knee function, increases the risk of adverse events or contributed to withdrawals due to adverse events."

Oral Cryotherapy

A 2016 Cochrane Review by Riley and colleagues defined oral cryotherapy as "the cooling of the mouth using ice, ice-cold water, ice cream, or ice lollies/popsicles." An independent search was conducted by two authors and resulted in 14 randomized controlled trials (n=1,280) included in the review. The authors determined that based upon the results from the studies, oral cryotherapy reduces oral mucositis across all severities in adults receiving fluorouracil-based chemotherapy for solid cancers. Further, that it is a low cost, natural treatment without serious side effects.

In 2024, Bragues and colleagues set out to identify therapies for the prevention and treatment of oral mucositis in pediatric patients through a systematic review of the literature. The review included observational and experimental studies of children up to age 18 who had completed or were undergoing oncologic treatment. Studies were required to present outcomes for an oral mucositis therapeutic intervention. A total of 59 articles were included. The treatment that was deemed most effective for oral mucositis was chlorhexidine. The use of oral cryotherapy (i.e., ice chips), although demonstrating a reduction in incidence and severity of mucositis in adults, only showed a reduction when administered with propantheline and demonstrated no effect when administered alone in children. The authors identify that the number of studies in the pediatric population are small, and that scientific evidence for cryotherapy is lacking in this age group.

In 2022, Walladbegi and colleagues conducted a vendor-sponsored randomized, blinded, parallel group, multi-center, phase 3 trial (NCT03203733) comparing the use of conventional ice therapy with an intraoral cooling device for the prevention of chemotherapy induced oral mucositis in 172 patients diagnosed with multiple myeloma (n=146) or lymphoma (n=26), scheduled to receive high-dose chemotherapy prior to autologous hematopoietic stem cell transplantation. The primary outcome was the highest oral mucositis score during the study period. Secondary outcomes included the degree of tolerability and patient-reported oral pain. Tertiary outcomes evaluated were the quality of life upon admission and discharge, number of days with total parenteral nutrition, number of hospital days, total dose of analgesics, weight loss, number of days from transplant to bone marrow engraftment, and maximum temperature increase. Outcomes inclusive of the entire study cohort determined there

was no statistically significant difference between the use of ice and the intraoral device in the prevention of chemotherapy induced oral mucositis. A significant difference was noted in the lymphoma group, however the number of lymphoma patients included was small, with the majority enrolled from a single site which uses BEAC (carmustine, cytarabine, etoposide, cyclophosphamide) regimens as a conditioning for lymphoma, which is already known to cause less severe mucositis when compared with BEAM (carmustine, cytarabine, etoposide and melphalan). For secondary outcomes, discomfort experienced was less for the device group compared to the group randomized to ice (5% vs. 16.1%) which was statistically significant at 4.4% vs. 15.8% in the multiple myeloma group compared with 8.3% vs. 18.2% in the lymphoma group. There were no statistically significant differences identified for the tertiary outcomes. Authors concluded that the use of the device enhances the efficacy of the ice in the prevention of mucositis in lymphoma, as well as improves tolerability, although not statistically significant. Authors suggest that the use of the device would eliminate the risk of contaminated water and subsequent infection in immunodeficient patients, however, this was not included as part of the study.

There is a paucity of literature available regarding the effectiveness of the Cooral device, and therefore, conclusions regarding comparison to standard, less costly treatments with ice cannot be made.

PROFESSIONAL GUIDELINE(S)

In 2016, the American Academy of Orthopaedic Surgeons (AAOS) published guidelines on the surgical management of osteoarthritis of the knee, stating "Moderate evidence supports that the use of cryotherapy devices after knee arthroscopy do not improve outcomes". The guidelines were updated in 2022 and no longer make any reference to the use of cryotherapy as a recommendation.

In 2021, The American Academy of Orthopaedic Surgeons (AAOS) published clinical practice guidelines for pharmacologic, physical, and cognitive pain alleviation for musculoskeletal extremity and pelvic surgeries. The authors downgraded the strength of the 2015 guideline recommendation of cryotherapy two levels to "limited" and state the following, "limited evidence suggests no significant difference in patient pain, function and opioid use between cryo-compression and control/ice/circulating water."

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates [device] as medical devices. All [device] including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Apr 02]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 April 02]

A large number of circulating and noncirculating cooling devices have been cleared for marketing by the FDA since 1976. The following list may not be all inclusive.

Device	Manufacturer	Clearance Date	Indication
Xrecovery	Shenzhen Xinrun Electric Appliances Co, LTD	11/14/2024	To treat post-surgical and acute injuries to reduce swelling and pain
Cold Compression	JKH Health Co., Ltd	05/01/2024	To treat post-surgical and acute injuries to reduce swelling and pain
Cold/Hot Compression	JKH Health Co., Ltd	10/27/2023	To treat post-surgical and acute injuries to reduce swelling and pain
Cryo-Thermo Compression Device	Suzhou MicroPort RehabTech (Group) Co., Ltd.	03/08/2023	To treat post-surgical and acute injuries to reduce swelling and pain
Armory Motion	Pain Management Technologies, Inc.	06/10/2022	To treat post-surgical and acute injuries to reduce swelling and pain
Ice Compression First, Duo, & Moove Systems	MksParis	1/11/2021	To treat post-surgical and acute injuries to reduce swelling and pain
Game Ready GRPro 2.1 System	Cool Systems, Inc (Dba Game Ready)	10/29/2019	To treat post-surgical and acute injuries to reduce swelling and pain
Polar Care Wave	Breg Inc	03/01/2019	To treat post-surgical and acute injuries to reduce swelling and pain
Therm-X, Therm-X At, Therm-X Pro Ath	Zenith Technical Innovations	5/10/2019	To treat post-surgical and acute injuries to reduce swelling and pain
Med4 Elite	Cool Systems, Inc (DBA Game Ready)	09/29/2017	To treat post-surgical and acute injuries to reduce swelling and pain
Nice1	Nice Recovery Systems, LLC	12/23/2014	To treat post-surgical and acute injuries to reduce swelling and pain
Dynatron Peltier Thermostim	Dynatronics Corp.	08/20/2012	To treat post-surgical and acute injuries to reduce swelling and pain

Probe			
VibraCool	MMJ Labs, LLC	05/15/2023	Temporary relief of minor injuries (muscle or tendon aches) and the treatment of myofascial pain post-surgery. Also, for use prior to or during physical therapy to treat myofascial pain caused by trigger points, restricted motion, and muscle tension.

In 2020, the FDA published a consumer update regarding the risk of injury related to devices that circulate water to provide hot or cold therapy, when not used properly, with an emphasis on cold-induced injuries- particularly numbness to frostbite.

In 2022, the U.S. Food and Drug Administration (FDA) awarded breakthrough device designation to the Cooral intraoral cooling system (for oral mucositis prevention). The system consists of closed conduits that continuously circulates sterile, cold water via a portable thermostat unit to a mouthpiece that is fitted to the patient. The duration of treatment is dependent on chemotherapy type, with treatment typically beginning 30 minutes prior to the start of an infusion and continuing until 30 minutes after the infusion is stopped. Treatment can be administered as often as required.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0881T (NMN)	Cryotherapy of the oral cavity using temperature regulated fluid cooling system, including placement of an oral device, monitoring of patient tolerance to treatment, and removal of the oral device

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HCPCS Codes

Code	Description
A9273 (NMN)	Cold or hot fluid bottle, ice cap or collar, heat and/or cold wrap, any type

Code	Description
C9817 (NMN)	Electronic cryo-pneumatic compression, pain management system (e.g., Game Ready GRPro 2.1 system), including control unit, anatomically correct wrap(s), and other system component(s), non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023) (Effective 01/01/26)
E0218 (NMN)	Fluid circulating cold pad with pump, any type
E0236 (NMN)	Pump for water circulating pad
E1399 (*NMN)	Durable medical equipment, miscellaneous. (*NMN when specified as an active cooling device with heating, compression, or vibration for pain therapy)

ICD10 Codes

Code	Description
C00-C96.9	Malignant neoplasm (code range)
G62.0	Drug-induced polyneuropathy
K12.31	Oral mucositis (ulcerative) due to antineoplastic therapy
M17.0-M17.9	Osteoarthritis of knee (code range)
M23.50	Chronic instability of knee, unspecified knee
Z51.11	Encounter for antineoplastic chemotherapy

REFERENCES

Aggarwal A, et al. Cryotherapy following total knee replacement. Cochrane Database of Systematic Reviews 2023 Sep 14;9(9):CD007911.

American Academy of Orthopaedic Surgeons. [Internet]. Clinical practice guideline for pharmacologic, physical, and cognitive pain alleviation for musculoskeletal extremity/pelvis surgery. 2021 Jul 19 [accessed 2026 April 02]. Available from: https://www.aaos.org/painalleviationcpg

American Academy of Orthopaedic Surgeons [AAOS] [Internet]. Surgical management of osteoarthritis of the knee. 2022 Dec 02 [accessed2026 Apr 02]. Available from: https://www.aaos.org/quality/quality-programs/surgical-management-of-osteoarthritis-of-the-knee/

Bragues R, et al. Oral mucositis management in children under cancer treatment: a systematic review. Cancers. 2024 Apr 18;16(1548):1-16.

Khan M, et al. Cryo-pneumatic compression results in a significant decrease in opioid consumption after shoulder surgery: a multicenter randomized controlled trial. Am J Sports Med. 2024

Sep;52(11):2860-2865.

Liang Z, et al. Cryotherapy for rehabilitation after total knee arthroplasty: a comprehensive systematic review and meta-analysis. Orthop Surg. 2024 Dec; 16(12):2897-2915.

Riley P, et al. Interventions for preventing oral mucositis in patients with cancer receiving treatment: oral cryotherapy. Cochrane Database of Systematic Reviews [Internet]. 2015 [accessed 2026 Apr 02 12. Art No.:CD0111552. Available from: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD011552.pub2/full?highlightAbstract=prevent%7Cmucositis%7Cinterventions%7Cpreventing%7Cfour%7Cfor%7Cmucos%7Coral%7Cintervent

Quesnot A, et al. Randomized controlled trial of compressive cryotherapy versus standard cryotherapy after total knee arthroplasty: pain, swelling, range of motion and functional recovery. BMC Musculoskelet Disord. 2024 Feb 28;25(1):182.

U.S. Food & Drug Administration [FDA] [Internet]. Consumer Updates: cold facts to help avoid injury from water-circulating hot/cold devices. 2020 Sep 09 [accessed 2026 Apr 02]. Available from: https://www.fda.gov/consumers/consumer-updates/cold-facts-help-avoid-injury-water-circulating-hotcold-therapy-devices

Walladbegi J, et al. Efficacy of a novel device for cryoprevention of oral mucositis: a randomized, blinded, multicenter, parallel group, phase 3 trial. BMT. 2022.57:191-197.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

LCD - Cold Therapy (L33735) [accessed 2026 March 31]

LCA - Cold Therapy (A52460) [accessed 2026 March 31]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: CUSTODIAL CARE

POLICY EFFECTIVE DATE:	8/1/2024
Policy Control #:	1370/20.000490
Next Annual Review:	July 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

REVENUE CODES

0120, 0121, 0124, 0160, 0169

DESCRIPTION

Care is considered custodial when it is primarily for the purpose of helping an individual with functional limitations and chronic illnesses who needs assistance with activities of daily living or meeting personal needs and can be provided safely and reasonably by persons without professional skills or training. Custodial care may occur in settings other than the home. The following activities are considered custodial care:

- Help walking and getting in or out of bed;
- Assistance bathing, dressing, feeding, and using the toilet;
- Periodic turning and positioning in bed;
- Routine care of the incontinent individual, including use of diapers and protective sheets;
- Routine services to maintain satisfactory functioning of indwelling bladder catheters;
- Preparation of special diets; and
- Supervision over medication that usually can be self-administered.

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: CUSTODIAL CARE

RELATED POLICIES/DOCUMENTS

Resource Coordination Policy:

Home Care Services: Home Health Care/Tele-Home Care/Personal Care/ Personal Emergency Response System, 1370/20.000048.

POSITION STATEMENT

CDPHP does not provide coverage for custodial care except for Select Plan as outlined below.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	In addition to services in a skilled nursing facility and rehabilitation facility, custodial care or rest cures and services are excluded from coverage.
MEDICARE ADVANTAGE:	Custodial care, except in the case of hospice care, is excluded from coverage.
HARP:	Long term care in a residential health care facility (RHCF) or a skilled nursing facility (SNF) is excluded from coverage.
SELECT PLAN:	Coverage for long term care in a residential health care facility (RHCF) or a skilled nursing facility (SNF) for Medicaid managed care members is available in accordance with the Medicaid Managed Care/HIV SNP Model Contract. Approval for coverage for long-term placement into a RHCF or SNF will be based upon the member's individual needs and their financial eligibility, as determined by the local Department of Social Services (DSS). Long term care services are provided in the most integrated, least restrictive setting available to meet the member's needs. Admittance to an RHCF or SNF for long-term custodial care must be authorized and is considered medically necessary for enrollees, age 21 years and older, meeting all of the following criteria: • The member meets the Nursing Facility Level of Care (NFLOC) as determined by the Uniform Assessment System for New York (UAS-NY) or other appropriate assessment; **and**

- After reviewing the appropriate documentation, CDPHP agrees with the RHCF and SNF that community-based long-term care services (e.g., home care, personal care services, consumer-directed personal assistance, adult day health care) are not sufficient to meet the needs of the member or are not available in the amount, duration, or scope necessary to meet the needs of the member; **and**
- The member is unable to self-direct their care and does not have a representative willing and able to direct their care.

For long-term care in an RHCF or SNF to be covered, after reviewing the information provided to CDPHP, CDPHP must agree with the RHCF or SNF that the member should be placed long-term in the facility. In addition, the member must have been determined financially eligible for institutional long-term care by the local DSS. Payment to the RHCF or SNF is available for services provided to members meeting the criteria above while eligibility is being assessed by the local DSS subject to the final eligibility determination. Eligibility must be determined by the local DSS within ninety (90) days that the member has been determined eligible for long-term care and authorized by CDPHP.

The following documentation will be reviewed for determination of coverage for long-term placement in an RHCF or SNF:

A. For CDPHP to review a request for long-term care placement in an RHCF or SNF, the following documents may be requested for review:
   - Care Assessment Areas (CAAS);
   - Minimum Data Set (MDS);
   - Pre-admission Screening and Resident Review (PASRR);
   - Patient Review Instrument (PRI);
   - Plan of Care
   - Clinical/Medical Records
   - LDSS3559 Form

B. For members living in the community, CDPHP will review

the most recently completed UAS-NY, the plan of care, and clinical/medical records of community-based providers.

If a member is approved for long-term placement in an RHCF or SNF, and has been determined eligible for long-term care, CDPHP will reassess the need for long-term care every six months from the initial date of the determination.

If CDPHP does not agree that the member should be placed long-term in the RHCF or SNF, CDPHP may recoup the funds paid to the provider. CDPHP will continue efforts to coordinate a safe discharge of the member.

Payment for long-term care in an RHCF or SNF can only be applied retroactively for ninety (90) days from the date the person is deemed financially eligible by the local DSS for long-term placement. If the member is deemed eligible beyond this 90-day time frame, CDPHP may recoup any days beyond 90 days. If the member is deemed ineligible, CDPHP may recoup the funds paid to the provider. CDPHP will continue efforts to coordinate a safe discharge for the member.

Members who are determined to be medically and financially eligible for long term care in an RHCF or SNF that is located outside the CDPHP Medicaid service area, or in another state, must disenroll from CDPHP Medicaid plans due to the change of residency. CDPHP will advise the RHCF or SNF of the disenrollment so that the member may pick another available plan.

SOURCES

1. New York State Department of Health, Uniform Assessment System for New York: Nursing Facility Level of Care, https://commerce.health.state.ny.us/uasny/moodle/pluginfile.php/1156/mod_resource/content/1/UAS-NY%20NFLOC%2007_final.pdf

2. Uniform Assessment System for New York, https://www.health.ny.gov/health_care/medicaid/redesign/uniform_assessment_system/
3. Medicaid Managed Care/HIV Special Needs Plan Model Contract: Requirements for Long-Term Services and Supports, Appendix S, S2-S7, 2024.
4. Office of Health Insurance Programs: Transition of Nursing Home Benefit and Population Into Managed Care, February 2015 Implementation.
5. CDPHP Participating Facility Agreement.

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POLICY APPROVAL DATES

New: 07/16

Revised: 07/17, 07/21, 7/23, 7/24

Reviewed: 07/18, 07/19, 07/20, 7/22, 7/25, 7/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
8/1/2024	Added LDSS3559 Form to the list of documents required for long-term placement in an RHFC or SNF. Updated Sources section.
7/1/2021* *No change to effective date for this update	Changed references throughout policy from "his or her" to "their." Updated link in Sources for UAS-NY Nursing Facility Level of Care.

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: CUSTODIAL CARE

7/1/2021	Under Product Variations: added long-term care in a residential health care facility (RHCF) or a skilled nursing facility (SNF) is excluded from coverage for HARP. This benefit is for Select Plan only.

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Policy/Procedure Name: Cytomegalovirus (CMV) Policy **Control Number: 1350/20.000589**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Cytomegalovirus (CMV) is a common herpes virus that infects 1 in 3 children in the US and over half of adults by age 40 years. Infected individuals with a competent immune system typically do not require treatment but certain groups are at high risk for CMV infection: infants infected in utero (congenital CMV), very low birth weight and premature infants, and immunocompromised individuals (such as transplant patients and people infected with HIV). While infection of healthy individuals may be asymptomatic or present mild symptoms such as fatigue and sore throat, infection of patients with compromised immune systems may lead to severe clinical manifestations such as retinitis, colitis, esophagitis, pneumonia, and neurologic defects like dementia and central nervous system vasculitis.

Diagnosis of CMV in individuals at least 12 months of age is primarily done via serologic tests to detect CMV antibodies (IgM and IgG). Newborns may be tested through PCR testing of their saliva and a confirmatory urine test to verify the presence of CMV-specific IgM and or four-fold rise in CMV-specific IgG.

Initial management of CMV involves antiviral therapy with intravenous (IV) ganciclovir or oral valganciclovir as the preferred agents for both treatment and prophylaxis. For patients with resistant or refractory disease, IV foscarnet, IV cidofovir, and oral maribavir are alternative agents that may be used.

Livtencity (maribavir) is a CMV pUL97 kinase inhibitor that impedes protein phosphorylation to stop viral DNA replication and nuclear egress. It is indicated for treatment of post-transplant CMV infection or disease that is refractory to treatment, regardless of genotypic resistance, with ganciclovir, valganciclovir, cidofovir, or foscarnet in adults and pediatric patients 12 years of age and older weighing at least 35 kg.

Specific populations may be indicated for CMV prophylaxis or preemptive therapy due to their risk of developing CMV-disease related complications (e.g. hematopoietic stem cell transplantation [HSCT] recipients). Prophylactic therapy is administration of a drug to prevent infection in patients at increased risk whereas preemptive therapy is defined as administration of antiviral therapy to asymptomatic patients with laboratory markers of viremia to avoid disease progression, in which case valganciclovir, ganciclovir, or foscarnet are recommended. Medications for CMV prophylaxis include ganciclovir, foscarnet, acyclovir, valacyclovir, valganciclovir, and letermovir. Of note, foscarnet, acyclovir, and valacyclovir are not FDA-approved for this indication.

Prevymis (letermovir) is a non-nucleoside CMV inhibitor that targets the CMV DNA terminase complex which is required for viral DNA processing and packaging. It is indicated for prevention of CMV infection and disease in adults and pediatric patients 6 months of age and older weighing at least 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant, as well as the prophylaxis of CMV disease in adults and pediatric patients 12 years of age and older who are kidney transplant recipients at high risk (donor CMV seropositive/recipient seronegative [D+/R-]). The NCCN guidelines for the Prevention and Treatment of Cancer-Related Infections include consideration of letermovir for primary prophylaxis in allogeneic HCT recipients who are CMV seropositive.

Summary

Effective Date of Policy:	2/12/2026
Availability	Livtencity: 200 mg tablet Prevymis: 240 or 480 mg tablets, 20 mg or 120 mg oral pellet packets, 240 mg/12 mL or 480 mg/24 mL IV solution in single dose vials
HCPCS Code	Prevymis: J3490 (no specific HCPCS Code)
Duration	Product dependent

Required Criteria for Initial Approval		
All of the following conditions for the requested indication must be met in order to approve therapy		
Specific Drug	**Inclusion Criteria**	**Dosing Regimen**
Livtencity (maribavir) Rx benefit	1. Must be 12 years of age or older and weigh at least 35 kg AND 2. Must be prescribed by, or in consultation with, a hematologist, infectious disease specialist, oncologist, or a physician affiliated with a transplant center AND 3. Must have a diagnosis of cytomegalovirus (CMV) infection/disease following a hematopoietic stem cell transplant (HSCT) or a solid organ transplant (SOT) AND 4. Must have post-transplant CMV infection/disease that is refractory to treatment (with or without genotypic resistance) to at least one of the following therapies: a. Ganciclovir b. Valganciclovir c. Cidofovir d. Foscarnet 5. Refractory infection/disease is defined below (a or b): a. Definition of Refractory CMV infection: CMV viremia (DNAemia or antigenemia) that increases (> 1 log10) or persists (< 1 log10 increase or decrease) after at least 2 weeks of antiviral therapy b. Definition of Refractory CMV end-organ disease: Worsening in signs and symptoms or progression into end- organ disease (for a patient not previously diagnosed with CMV end-organ disease) OR lack of improvement in signs and symptoms after at least two weeks of appropriately dosed antiviral therapy 6. Must not have CMV disease involving the central nervous system, including the retina AND 7. Livtencity will not be authorized for use in combination with ganciclovir or valganciclovir AND 8. Livtencity will not be approved for non-FDA approved diagnoses (such as for the prevention of CMV infection/disease). 9. Approval will be provided for a total of 8 weeks. a. As therapy with Livtencity has not been studied for longer than 8 weeks, recertification will not be authorized. 10. Quantity Limit: 120 tablets per 30-day supply. a. An increase in the quantity limit in accordance with the prescribing information may be provided with documentation Livtencity is being co-administered with certain anticonvulsants	Refer to the Livtencity prescribing information for approved dosing.
Prevymis (letermovir) Rx benefit or medical benefit	1. Member must meet ONE of the following criteria (a or b): a. Member is a recipient of an allogenic hematopoietic stem cell transplant (HSCT) AND i. Member must be 6 months of age or older and weigh least 6 kg AND ii. Member is CMV-seropositive (R+) AND iii. Prevymis is being requested for CMV prophylaxis AND iv. Member will initiate therapy with Prevymis between Day 0 and Day 28 post transplantation (documentation of date of transplant is required) OR b. Member is a recipient of a kidney transplant AND i. Member must be 12 years of age or older and weigh at least 40 kg AND ii. Member is CMV-seronegative AND iii. Member must have received a primary or secondary allograft kidney from a seropositive [D+] donor AND iv. Prevymis is being requested for CMV prophylaxis AND v. Member will initiate Prevymis between Day 0 and Day 7 post transplantation (documentation of date of transplant is required).	Refer to the Prevymis prescribing information for approved dosing.

	2. Prescriber attests member is not concurrently using medications that are contraindicated with Prevymis (i.e., pimozide, ergot alkaloids, pitavastatin and simvastatin when co-administered with cyclosporine) AND 3. All requests for Prevymis IV will require clinical justification why the oral formulation cannot be used. 4. For kidney transplant recipients, authorization will be provided for 7 months to allow for 200 days of treatment post-transplant. Reauthorization will not be permitted. 5. For allogenic HSCT recipients, initial authorization will be provided for 4 months to allow for 100 days post-transplant 6. Quantity Limits: a. Prevymis 240 mg or 480 mg tablets: 30 per 30 days b. Prevymis 20 mg or 120 mg oral pellet packets: 120 per 30 days	

Continuation Criteria

Prevymis:

- Reauthorization for kidney transplant recipients past 200 days of treatment post-transplant will not be permitted.
- For allogenic HSCT recipients recertification for an additional 4 months to allow an additional 100 days of therapy (maximum 200 days of treatment post-transplant) may be authorized with documentation of the following:
  - Member is high-risk for late CMV infection and disease with one or more of the following risk factors:
    - HLA-related (sibling) donor with at least one mismatch at one of the following three HLA-gene loci: HLA-A, -B or –DR; or
    - Unrelated donor with at least one mismatch at one of the following four HLA-gene loci: HLA-A, -B, -C and -DRB1; or
    - Haploidentical donor; or
    - Use of umbilical cord blood as stem cell source; or
    - Use of ex vivo T-cell-depleted grafts; or
    - Receipt of anti-thymocyte globulin; or
    - Receipt of alemtuzumab; or
    - Use of systemic prednisone (or equivalent) at a dose of ≥1 mg/kg of body weight per day.

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.

References

		Updated	Accessed
1	Prevymis [package insert]. Whitehouse Station, NJ. Merck & Co., Inc		1/2026
2	Livtencity [package insert]. Lexington, MA: Takeda Pharmaceuticals America, Inc	11/2025	1/2026
3	Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents With HIV. Hiv.gov. July 14, 2025. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/cytomegalovirus	1/2026	1/2026
4	Razonable RR, Humar A. Cytomegalovirus in solid organ transplant recipients—Guidelines of the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019; 33:e13512. https://doi-org.gate.lib.buffalo.edu/10.1111/ctr.13512		1/2026
5	National Comprehensive Cancer Network®. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) prevention and treatment of cancer-related infections V.1.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. To view the most recent and complete version of the guideline, go online to NCCN.org.		1/2026
6	Hakki M, Aitken SL, Danziger-Isakov L, et al. American Society for Transplantation and Cellular Therapy series: #3—prevention of cytomegalovirus infection and disease after hematopoietic cell transplantation. Transplant Cell Ther. 2021;27(9):707-719. https://doi.org/10.1016/j.jtct.2021.05.001		1/2026
7	Yong MK, Shigle TL, Kim Y, et-al. American Society for Transplantation and Cellular Therapy Series: #4 - Cytomegalovirus treatment and management of resistant or refractory infections after hematopoietic cell transplantation. Transplant Cell Ther. 2021;27(12):957-967. https://doi.org/10.1016/j.jtct.2021.09.010.		1/2026

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Prevymis IV: Subject to the terms and conditions noted in above policy for those medications listed as a medical benefit when administered and provided by physician office, coverage will be provided as a medical benefit.

All other medications for Medicare Advantage with Part D members listed are subject to coverage under the current Part D benefit and Medicare Advantage Part D formulary..

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application if administered under the medical benefit.

Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program.

CDPHP Pharmacy Services 2/12/2026

New: 2/2026

Revised	Reviewed

Revision Date	Changes Made

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MEDICAL POLICY

Medical Policy Title	**Deep Brain Stimulation**
Policy Number	**7.01.23**
Current Effective Date	**September 1, 2026**
Next Review Date	**April 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

This medical policy does not address occipital nerve stimulation for chronic migraines or occipital neuralgia.

POLICY STATEMENT(S)

I. Unilateral or bilateral deep brain stimulation of the ventral intermediate nucleus (VIM) thalamus is a **medically appropriate** treatment option in the management of disabling, medically unresponsive essential tremor or tremor due to Parkinson's disease when **BOTH** of the following criteria are met (Disabling, medically unresponsive tremor is defined as both of the following):

   A. Tremor causing significant limitation in daily activities; **and**

   B. Inadequate control with maximal dosage of medication for at least three (3) months before implant.

II. Conventional bilateral deep brain stimulation of the subthalamic nucleus (STN) or globus pallidus interna (GPi) is a **medically appropriate** treatment option for Parkinson's disease when **ALL** of the following criteria are met:

   A. The patient has a good response to levodopa;

   B. Motor complications are not controlled by pharmacologic therapy; **and**

   C. **ONE** of the following:

      1. a minimum score of 30 points on the motor portion of the Unified Parkinson Disease Rating Scale (UPDRS) when the individual has been without medication for approximately 12 hours; **or**

      2. Parkinson's disease for at least four (4) years.

III. Conventional unilateral or bilateral deep brain stimulation of the STN or GPi is **medically appropriate** when **BOTH** of the following criteria are met:

   A. Individual is seven (7) years of age or older;

   B. Individual has chronic, intractable primary dystonia, including **any** of following indications:

      1. generalized or segmental dystonia,

2. hemidystonia; **or**
3. cervical dystonia (torticollis).

IV. Unilateral or bilateral deep brain stimulation of the anterior nucleus of the thalamus (ANT) is **medically appropriate** when **ALL** of the following criteria are met:

A. A confirmed diagnosis of epilepsy;

B. 18 years of age or older;

C. Focal partial onset seizures with or without generalized seizure;

D. Refractory to medical therapy defined as failure to adequately control seizures after two (2) (or more) appropriate and adequately dosed anti-seizure medications or intolerance to anti-seizure medications;

E. Currently having an average of three (3) or more disabling seizures (e.g., motor partial seizures, complex partial seizures, or secondary generalized seizures) per month over the most recent three (3) months; **and**

F. Absence of progressive neurological conditions such as neurodegenerative disease.

V. Deep brain stimulation is contraindicated and therefore, **not medically necessary** for **ANY** individuals in the following situations:

A. Not a good surgical candidate due to unstable medical conditions;

B. Presence of a cardiac pacemaker;

C. A medical condition that requires repeated magnetic resonance imaging (MRI);

D. Presence of dementia that may interfere with the ability to cooperate; **or**

E. Recent treatment with botulinum toxin injections within the last six (6) months.

<u>Device Repair</u>

VI. Repair of a medically necessary DBS System or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** of the following:

1. date of device implantation/initiation;
2. manufacturer warranty information, if applicable;
3. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device;

B. The device is no longer functioning adequately; and **BOTH** of the following criteria are met:

1. inadequate function interferes with activities of daily living; **and**
2. repair is expected to make the equipment fully functional (as defined by manufacturer).

C. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

Device Replacement

VII. Replacement of a medically necessary DBS System or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

A. The device is no longer functioning adequately and has been determined to be non-repairable or the cost of the repair is in excess of the replacement cost; **or**

B. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

VIII. The replacement of a properly functioning DBS System, its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing.

IX. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

X. Accessories or components for DBS System that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

XI. Directional deep brain stimulation (e.g., St. Jude Medical Infinity DBS System and Vercise DBS System) is **investigational** for all indications.

XII. Conventional deep brain stimulation is **investigational** for all conditions not specifically identified in Policy Statements I through IV, including, but not limited to, the following conditions:

A. Multiple sclerosis tremor;

B. Post-traumatic dyskinesia;

C. All other movement disorders;

D. Chronic pain syndromes, including cluster headache;

E. Tardive dyskinesia;

F. Tourette syndrome;

G. Dementias, including Alzheimer's disease;

H. Eating disorders, including anorexia nervosa;

I. Alcohol addiction;

J. Treatment-resistant depression;

K. Treatment-resistant obsessive-compulsive disorder.

RELATED POLICIES

Corporate Medical Policy

07.01.103 Responsive Neurostimulation for the Treatment of Refractory Focal Epilepsy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Bilateral stimulators may be implanted simultaneously or in staged procedures.

DESCRIPTION

Deep brain stimulation (DBS) has been investigated as an alternative to permanent neuro-ablative procedures, such as thalamotomy and pallidotomy. The procedure involves the stereotactic placement of an electrode into a targeted region of the brain. The electrode is then attached, via a cable/wire, to a programmable stimulator implanted subcutaneously. DBS is designed to turn off overactive brain regions without destroying them. The immediate advantage of DBS over conventional destructive surgery is that the lesions are titratable and, hence, reversible. After implantation, noninvasive programming of the neurostimulator can be adjusted to the individual's symptoms.

The effect of DBS depends on where the electrodes are placed. The three common target sites are the VIM thalamus, STN and GPi. Whereas unilateral/bilateral DBS of the thalamus is utilized to treat essential tremor or tremors of advanced Parkinson's disease, DBS of the STN or of the GPi is used for treatment of the entire constellation of Parkinsonian symptoms (e.g., tremor, rigidity, and bradykinesia). DBS is performed at specialty centers.

DBS has also been investigated for the treatment of primary dystonia, defined as a neurological movement disorder characterized by involuntary and painful muscle contractions and contortions. Dystonia can be classified according to cause and the bodily distribution of symptoms. Primary or idiopathic dystonia is not associated with any other pathology, whereas secondary dystonia is caused by a known insult (e.g., trauma, infarct, stroke) to the basal ganglia. Generalized dystonia affects a wide range of body areas, while focal dystonia affects specific body parts (e.g., spasmodic torticollis/cervical dystonia, blepharospasm). Dystonia is the third most common movement disorder, behind Parkinson's disease and essential tremor. Unless contraindicated, DBS of either the STN or GPi requires a bilateral procedure.

In addition to essential tremors, Parkinson's disease, and primary dystonia, DBS is also being investigated for disorders such as major depression, cluster headaches, chronic pain syndromes, Tourette syndrome, epilepsy, and obsessive-compulsive disorder.

Unified Parkinson's Disease Rating Scale (UPDRS)

The Unified Parkinson's Disease Rating Scale (UPDRS) is the most widely applied rating instrument

for the evaluation of a person with Parkinson's Disease to determine disease severity. The total UPDRS score includes 31 items contributing to three (3) subscales: (I) Mentation, Behavior and Mood; (II) Activities of Daily Living; and (III) Motor Examination. The UPDRS does not assess general cardiovascular fitness and provides only limited information on functional performance relative to daily activities.

Conventional DBS

Conventional DBS systems use ring-shaped electrodes, which generate an approximately spherical electrical field. In these systems, programming of polarity and stimulation pulse parameters allows only limited control of the shape of the volume of tissue activated. While physicians try to target a very specific area of the brain with conventional DBS, there is a risk of stimulating neighboring regions as they cannot steer the stimulation precisely.

Directional DBS

Directional DBS systems use novel lead designs with segmented, multi-contact electrodes that allow for the activation of individual electrode contacts which also allow the physician to specify the exact amount of current needed for every contact of the electrode. By activating specific electrode contacts and defining the amount of stimulation for each contact, stimulation precision is significantly increased. More precise stimulation is thought to reduce side effects of DBS, such as muscle contractions, dysarthria, and cognitive or behavioral disturbances sometimes seen in conventional DBS.

SUPPORTIVE LITERATURE

Unilateral Stimulation of the Thalamus

Schuurman et al (2008) reported on 5-year follow-up of 68 patients comparing thalamic stimulation with thalamotomy for the treatment of tremor due to Parkinson's disease (n=45 patients), essential tremor (n=13 patients), and multiple sclerosis (MS; n=10 patients). Forty-eight (71%) patients were assessed at five years: 32 with Parkinson's disease, 10 with essential tremor, and 6 with MS. The Frenchay Activities Index, the primary study outcome measure, was used to assess change in functional status. Secondary measures included tremor severity, complication frequency, and patient-assessed outcomes. The mean difference between interventions, as measured on the Frenchay Activities Index, favored thalamic stimulation at all time points: 4.4 (95% confidence interval [CI], 1.1 to 7.7) at 6 months, 3.3 (95% CI, -0.03 to 6.6) at 2 years, and 4.0 (95% CI, 0.3 to 7.7) at 5 years. The procedures had similar efficacy for suppressing tremors. The effect of thalamic stimulation diminished in half of the patients with essential tremor and MS. Neurologic adverse effects were higher after thalamotomy. Subjective assessments favored stimulation.

Hariz et al (2008) evaluated outcomes of thalamic deep brain stimulation in patients with tremor-predominant Parkinson's disease who participated in a multicenter European study. The authors reported that at 6 years post-surgery, tremor was still effectively controlled and appendicular rigidity and akinesia remained stable compared with baseline.

Bilateral Stimulation

Jost et al (2023) conducted an observational study of the long-term effect of bilateral DBS on the subthalamus nucleus and its effects on quality of life, motor functions, and medication requirements for patients with advanced Parkinson's. The final analysis included 108 patients with 62 receiving DBS and 46 receiving medications matched to a sub cohort of 25 patients per group. At the five years follow up, the Parkinson's Disease Questionnaire 8 (PDQ-8) and ADL scores worsened only in the medication group, while remaining stable in the DBS group. The group that received DBS also experienced favorable effects on motor complications.

Epilepsy

Results of Medtronic's Stimulation of the Anterior Nuclei of Thalamus for Epilepsy (SANTÉ) trial (Fisher 2010) showed promising outcomes on the adjunct use of DBS of the ANT over placebo stimulation for patients suffering from severe, refractory, partial-onset seizures. All subjects underwent DBS implantation followed by three months of randomized and blinded active stimulation (n=54) or no stimulation (n=55), then followed by nine months of active stimulation for all subjects. Two years after implantation of the device, seizures were reduced by a median 56% compared with baseline, and 14 patients (12.7%) became seizure-free for at least six months. Longer-term studies were needed to better define its safety and efficacy, as well as the subset of patients who would benefit most from this treatment.

Salanova and others published a long-term follow-up study of the SANTÉ trial in 2015. Beginning 13 months following device implantation, 105 subjects receiving active stimulation were followed for an additional four years. The authors reported that for subjects with at least 70 diary entries recorded at one (1) year (n=99), median change for seizure frequency from baseline decreased by 41% ($p < 0.001$), and by 69% at five (5) years (n=59; $p < 0.001$). For the same population, reduction in the most severe type of seizure was 39% at one year ($p < 0.001$) and 75% at five years ($p < 0.001$). During the 5-year study, 17 of 109 subjects (16%) reported a 6-month seizure-free interval. A 2-year seizure-free interval was reported for 6 of 109 subjects (5.5%). Mean improvement in the Liverpool Seizure Severity Score (LSSS) was 13.4 at one year and 18.3 at five years ($p < 0.001$ for both). Similarly, results from the Quality of Life in Epilepsy-31 (QOLIE-31) tool improved from baseline by 5.0 points at one (1) year and 6.1 points at (5) five years ($p < 0.001$ for both). A change of 5 points on this measure is considered clinically significant and was experienced by 46% and 48% of subjects at one and five years. Device-related adverse events included site infection, leads not within the target area, depression and memory impairment. This study demonstrated significant long-term benefit from DBS for individuals with epilepsy, although the study was relatively small and unblinded.

On April 27, 2018, the FDA approved the Medtronic DBS System for Epilepsy for bilateral stimulation of the anterior nucleus of the thalamus (ANT) based on the SANTÉ trials as an adjunctive therapy for reducing the frequency of seizures in individuals 18 years of age or older who are diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are refractory to three or more antiepileptic medications. The FDA indicated that the Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness for patients who average six (6) or more seizures per month over the three (3) most recent months prior to implantation of the DBS system (with no more than 30 days between seizures). The Medtronic DBS System for Epilepsy has not been evaluated in patients with less-frequent seizures.

The effect of deep brain stimulation of the anterior nuclei of the thalamus (ANT-DBS) after implantation has been reported as approximately 50% seizure frequency reduction in approximately 60% of patients (Herrman 2019) and the seizure frequency reduction increased over the following ten years (Salanova 2018 and Salanova 2021). Multiple literature reviews of randomized and blinded clinical trials and case series with high-quality data support the use of DBS for the treatment of medically refractory epilepsy.

Other Indications

Published clinical trials have not provided evidence to support the efficacy and safety of DBS for other conditions, including, but not limited to multiple sclerosis, post-traumatic dyskinesia, treatment-resistant depression, Alzheimer's disease, and Tourette syndrome; or for bilateral DBS of the VIM thalamus. Studies of DBS for the treatment of chronic pain have not provided evidence that DBS is an effective treatment method over already-established treatment methods.

PROFESSIONAL GUIDELINE(S)

In 2003, the National Institute for Health and Care Excellence (NICE) published guidance on DBS for Parkinson's Disease stating that the evidence on the safety and efficacy of deep brain stimulation for treatment of Parkinson's disease "appears adequate to support the use of the procedure." The guidance noted that deep brain stimulation should only be offered when Parkinson's disease is refractory to best medical treatment.

The American Academy of Neurology (AAN) 2011 updated its guidelines on the treatment of essential tremor, which were reaffirmed in 2022. The guidelines stated that bilateral DBS of the thalamic nucleus may be used to treat medically refractory limb tremors in both upper limbs (level C, possibly effective) but that there were insufficient data on the risk/benefit ratio of bilateral versus unilateral deep brain stimulation in the treatment of limb tremor. There was insufficient evidence to make recommendations on the use of thalamic deep brain stimulation for head or voice tremors (level U, treatment is unproven).

In December of 2021, the American Society of Stereotactic and Functional Neurosurgery (ASSFN) published the following position statement: "Deep brain stimulation (DBS) of the bilateral anterior nucleus of the thalamus (ANT) is a Food and Drug Administration (FDA)-approved, safe, and efficacious treatment option for patients with refractory focal epilepsy" who meet specific criteria.

REGULATORY STATUS

The FDA first approved Medtronic's Activa Tremor Control System for DBS in 1997 for the unilateral treatment of tremors. This approval was expanded in 2002 to include bilateral implantation for individuals with advanced Parkinson's disease whose symptoms were inadequately managed with medication. In 2016, the FDA further broadened the indication to include patients who had been diagnosed with Parkinson's disease for at least four years and who had developed motor complications not sufficiently controlled by drug therapy. This expanded indication was supported by findings from the EARLYSTIM trial (Schuepbach WM et al., 2013), which demonstrated a 26 percent improvement in quality of life for patients treated with DBS in combination with best medical therapy,

compared with a 20 percent improvement among those receiving medical therapy alone.

In April 2003, the FDA gave Humanitarian Device Exemption (HDE) approval to the Activa Therapy System for the unilateral or bilateral stimulation of the internal STN or GPi, to aid in the management of chronic, intractable (drug-resistant) primary dystonia, including generalized and/or segmental dystonia, hemidystonia, and cervical dystonia in individuals seven years of age or older. In 2016, the FDA identified that the HDE for the Activa Therapy System remained appropriately approved for pediatric use. In 2018, the Activa deep brain stimulation system received FDA approval with an expanded indication as an adjunctive therapy for epilepsy.

The Brio Neuromodulation System (St. Jude Medical) received FDA approval in June 2015 for use in deep brain stimulation therapy. The system is indicated for bilateral stimulation of the subthalamic nucleus (STN) to reduce symptoms of advanced, levodopa-responsive Parkinson's disease that are insufficiently controlled with medication, as well as for unilateral or bilateral stimulation of the VIM of the thalamus to manage disabling upper extremity tremor in adults with essential tremor. A key distinction from Medtronic's Activa system is that the Brio device delivers stimulation using constant current rather than constant voltage. FDA approval was supported by two clinical trials involving patients with Parkinson's disease and essential tremor whose symptoms were not adequately managed with medication. "Both groups showed statistically significant improvement on their primary effectiveness endpoints when the device was turned on compared to when it was turned off," the statement notes.

Clinical studies support that deep brain stimulation (DBS) is a safe and effective treatment for several movement disorders. Unilateral DBS targeting the ventral intermediate nucleus (VIM) of the thalamus is highly effective for essential tremor and tremor associated with Parkinson's disease, producing complete or clinically meaningful tremor reduction in approximately 82–91% of patients, with sustained benefits and minimal adverse effects. When tremors recur, symptoms can often be effectively managed through adjustments to stimulation settings. Although long-term outcome data remain limited, bilateral DBS of the STN or GPi has been shown to significantly improve neurological function in individuals with advanced Parkinson's disease. Evidence from studies evaluating DBS for dystonia indicates substantial improvements in motor function and activities of daily living among patients with primary dystonia, whereas patients with secondary dystonia experience limited benefit.

Directional DBS

The St. Jude Medical Infinity DBS System was the first FDA-approved deep brain stimulation system to use directional leads, allowing more precise targeting of brain areas to reduce stimulation-related side effects. It received FDA approval on September 19, 2016, as a design and component update to the previously approved Brio Neurostimulation System. The Infinity system is indicated for bilateral stimulation of the STN to treat advanced, levodopa-responsive Parkinson's disease not adequately controlled by medication, and for unilateral or bilateral stimulation of the VIM of the thalamus to suppress disabling upper extremity tremor in adults with essential tremor. Although the system's 8-channel directional leads were recalled in 2018 due to manufacturing issues, the recall was terminated in September 2020.

In January 2020, Abbott received FDA approval to expand indications for the Infinity DBS system to

include targeting the internal GPi for treating Parkinson's disease symptoms not adequately controlled by medication. The Infinity system uses directional leads to optimize stimulation and reduce side effects.

Boston Scientific's Vercise DBS systems were FDA approved between 2019 and 2021, including the Vercise PC, Vercise Gevia, and Vercise Genus systems. These systems are indicated for bilateral stimulation of the STN or GPi for moderate to advanced levodopa-responsive Parkinson's disease, and unilateral stimulation of the VIM of the thalamus to control disabling tremor in essential tremor or parkinsonian tremor. The Vercise systems feature current steering across eight contacts per lead to enable precise and customizable stimulation.

Obsessive Compulsive Disorder (OCD)

In February 2009, the FDA granted a Humanitarian Device Exemption (HDE) to Medtronic's ReClaim Deep Brain Stimulator, making it the first DBS device approved to treat obsessive-compulsive disorder (OCD). The device is indicated for bilateral stimulation of the anterior limb of the internal capsule (AIC) as an adjunct to medication and an alternative to anterior capsulotomy for adults with chronic, severe, treatment-resistant OCD who have failed at least three SSRIs. Approval was based on a small study of 26 patients, which showed an average 40% reduction in symptoms after 12 months. However, study limitations included lack of full blinding, raising concerns about placebo effects. As of 2021, the World Society for Stereotactic and Functional Neurosurgery considered DBS for OCD to be an emerging but unproven treatment, noting that larger, well-designed studies are needed to establish long-term safety and effectiveness.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
61863	Twist drill, burr hole, craniotomy or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
61864	each additional array
61867	Twist drill, burr hole, craniotomy or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), with use of

Code	Description
	intraoperative microelectrode recording; first array
61868	each additional array
61880	Revision or removal of intracranial neurostimulator electrodes
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
61886	with connection to two or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact groups[s], interleaving, amplitude, pulse width, frequency [HZ], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional
95984	each additional 15 minutes face-to-face time with physician or other qualified health care professional (list separately in addition to code for primary procedure)

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HCPCS Codes

Code	Description
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1787	Patient programmer; neurostimulator
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging

Code	Description
	system
C1822	Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system
L8679	Implantable neurostimulator pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non- rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

ICD10 Codes

Code	Description
G20.A1-G20.C	Parkinson's disease (code range)
G21.11-G21.9	Secondary Parkinsonism (code range)
G24.1-G24.3	Dystonia (code range)
G24.8	Other dystonia
G24.9	Dystonia, unspecified
G25.0	Essential tremor

Code	Description
G40.0-G40.919	Epilepsy and recurrent seizures (intractable) (code range)
Investigational Codes:	
All other ICD10 diagnosis codes are considered investigational.	

REFERENCES

American Academy of Neurology [Internet]. Update: treatment of essential tremors practice guidelines. Oct 2011. [updated 2022 Jul 16; accessed 2026 Mar 16]. Available from: https://www.aan.com/Guidelines/home/GuidelineDetail/492

Cruz S, et al. Deep brain stimulation in obsessive-compulsive disorder: results from meta-analysis. Psychiatry Research. 2022;317:114869.

Fisher R, et al. Electrical stimulation of the anterior nucleus of the thalamus for treatment of refractory epilepsy. Epilepsia. 2010 May 5;51(5):899-908.

Hariz MI, et al. Multicentre European study of thalamic stimulation for Parkinsonian tremor: a 6 year follow-up. J Neurol Neurosurg Psychiatry. 2008 Jun;79(6):694-9.

Herrman H, et al. Anterior thalamic deep brain stimulation in refractory epilepsy: A randomized, double-blinded study. Acta Neurol Scand. 2019 Mar;139(3):294-304.

Jost ST, et al. International Parkinson and Movement Disorders Society Non-Motor Parkinson's Disease Study Group and EUROPAR. neurostimulation for advanced Parkinson disease and quality of life at 5 Years: A nonrandomized controlled trial. JAMA Netw Open. 2024 Jan 2;7(1):e2352177.

Krauss JK, et al. Technology of deep brain stimulation: current status and future directions. Nat Rev Neurol. 2021 Feb;17(2):75-87.

National Institute for Health and Clinical Excellence [Internet]. Deep brain stimulation for intractable trigeminal automatic cephalalgias. IPG381. 2011 Mar. [accessed 2026 Mar 16]. Available from: https://www.nice.org.uk/guidance/ipg381

National Institute for Health and Clinical Excellence [Internet]. Deep brain stimulation for Parkinson's disease. IPG19. 2003 Nov. [accessed 2026 Mar 16]. Available from: https://www.nice.org.uk/guidance/ipg19

National Institute for Health and Clinical Excellence [Internet]. Deep brain stimulation for refractory chronic pain syndromes. IPG382. 2011 Mar. [accessed 2026 Mar 16]. Available from: https://www.nice.org.uk/guidance/ipg382

National Institute for Health and Clinical Excellence [Internet]. Deep brain stimulation for refractory

epilepsy in adults. IPG678. 2020 Aug 12. [accessed 2026 Mar 16]. Available from: https://www.nice.org.uk/guidance/ipg678

National Institute for Health and Clinical Excellence [Internet]. Deep brain stimulation for tremor and dystonia (excluding Parkinson's disease). IPG188. 2006 Aug. [accessed 2026 Mar 16]. Available from: https://www.nice.org.uk/guidance/ipg188

Rodrigues FB, et al. Deep brain stimulation for dystonia. Cochrane Database Syst Rev. 2019 Jan 10;1:CD012405.

Rodrigues JP, et al. Globus pallidus stimulation in advanced Parkinson's disease. J Clin Neurosci. 2007 Mar;14(3):208-15.

Rodriquez-Oroz MC, et al. Bilateral deep brain stimulation in Parkinson's disease: a multicentre study with 4 years follow-up. Brain. 2005 Oct;128(pt 10):2240-9.

Rodriguez-Oroz MC, et al. Efficacy of deep brain stimulation of the subthalamic nucleus in Parkinson's disease 4 years after surgery: double blind and open label evaluation. J Neurol Neurosurg Psych. 2004 Oct;75(10):1382-5.

Salanova V, et al. The SANTÉ study at 10 years of follow-up: effectiveness, safety, and sudden unexpected death in epilepsy. Epilepsia. 2021;62(6):1306-17.

Schnitzler A, et al. Directional deep brain stimulation for Parkinson's Disease: results of an international crossover study with randomized, double-blind primary endpoint. Neuromodulation. 2022;25:817-828.

Schupbach WM, et al. Neurosurgery at an earlier stage of Parkinson disease: a randomized, controlled trial. Neurol. 2007 Jan 23;68(4):267-71.

Schuurman PR, et al. A comparison of continuous thalamic stimulation and thalamotomy for suppression of severe tremor. NEJM. 2000 Feb 17;342(7):505-8.

Staudt MD, et al. Congress of Neurological Surgeons systematic review and evidence-based guidelines for deep brain stimulation for obsessive-compulsive disorder: update of the 2014 guidelines. Neurosurgery. 2021; 88(4):710-712**.**

Tir M, et al. Exhaustive, one-year follow-up of subthalamic nucleus deep brain stimulation in a large, single-center cohort of Parkinsonian patients. Neurosurg. 2007 Aug;61(2):297-304.

U. S. Food and Drug Administration [Internet]. Brio neuromodulation system. Summary of safety and effectiveness data. [updated 2015 Jun 12; accessed 2026 Mar 16]. Available from: http://www.accessdata.fda.gov/cdrh_docs/pdf14/P140009b.pdf

U. S. Food and Drug Administration [Internet]. Medtronic DBS System for Epilepsy. Summary of safety and effectiveness data. [updated 2010 Mar 12; accessed 2026 Mar 16]. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf/P960009S219B.pdf

U. S. Food and Drug Administration [Internet]. Vercise Deep Brain Stimulation System. Summary of safety and effectiveness data. [updated 2017 Dec 08; accessed 2026 Mar 16]. Available from:

https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150031B.pdf

Visser-Vanderwalle V, et al. Long-term effects of bilateral subthalmic nucleus stimulation in advanced Parkinson disease: a four-year follow-up study. Parkinsonism Relat Disord. 2005 May;113(3):157-65.

Volkmann J, et al. Pallidal deep brain stimulation in patients with primary generalized or segmental dystonia: a 5-year follow-up of a randomized trial. Lancet Neurol. 2012 Dec;11(12):1029-38.

Zong H, et al. Clinical study of the effects of deep brain stimulation on urinary dysfunctions in patients with Parkinson's disease. Clin Interv Aging. 2019 Jun 25;14:1159-1166.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Deep Brain Stimulation (NCD 160.24) [accessed 2026 Mar 19]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 5/26

Revised:

Reviewed:

Date	Summary of Changes
9/1/2026	• New

MEDICAL POLICY

Medical Policy Title	**Dental and Oral Care under Medical Plans**
Policy Number	**7.01.21**
Current Effective Date	**January 1, 2027**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Oral surgical procedures are ineligible for coverage under the medical portion of a member's subscriber contract, unless otherwise stated. Oral surgical procedures may include, but are not limited to dental extractions, periodontal treatment, or biopsies for dental related cysts or tissue of dental origin (e.g., amalgam tattoo, fibroma, or hyperkeratoses).

I. Developmental Cysts

A. Developmental cysts of epithelial remnants (e.g., globulomaxillary cysts, median alveolar cysts, median palatine cysts, nasopalatine cysts) are not tooth related. Removal of these cysts is considered **medically appropriate** under medical/surgical contracts, subject to the terms of the member's subscriber contract.

B. Removal of tooth-related cysts (e.g., follicular-dentigerous, primordial, or multilocular-cysts, cysts of mallassez, radicular cysts, residual cysts, and odontomas) is considered **medically appropriate** under dental contracts; dental benefits are contract-specific.

C. The removal of tooth-related cysts is **ineligible for coverage** as a medical/surgical benefit.

II. Oral Biopsies

A. A biopsy of the buccal mucosa, tongue, palate or floor of the mouth is considered **medically appropriate** under medical/surgical contracts; benefits are contract specific.

B. A biopsy of the gingiva or supporting structures of the teeth is a medical procedure and is considered **medically appropriate** under medical/surgical contracts, unless tissue was obtained as part of a routine tooth extraction or a routine periodontal procedure.

C. If the biopsy reveals only a dental condition, then subsequent care or treatment of that condition is **ineligible for coverage** under medical/ surgical contracts, unless otherwise stated.

III. Accidental Injury to Sound, Natural Teeth

An accidental injury is defined as a "blow to the face" and does not include biting injuries. Services for the treatment of an accidental injury to sound, natural teeth, when rendered within 12 months from the date of injury, are **eligible for coverage** in accordance with the benefits

set forth in the member's medical/surgical contract, provided that the tooth is sound and natural, with no restorative treatment and no disease prior to the injury. A sound tooth is one sufficiently supported by its natural structure (bone and gum tissue) that was formed by the human body and is not decayed or weakened by previous dental work at the injury site (for example, a tooth with no crown, root canal, periodontal condition, or fracture that is not in need of treatment for any reason other than the accidental injury).

Coverage under the medical/surgical contract will only be provided for services that include **ALL** of the following criteria:

A. Fall within a category of services for which there is a benefit provided under the member's subscriber contract;

B. Deemed medically necessary according to the criteria set forth in Corporate Medical Policy #11.01.15, which addresses Medically Necessary Services; **and**

C. Rendered within 12 months* of an accidental injury.

(*Please note that exceptions to the 12-month time frame are not granted for the staging of procedures.)

IV. Congenital Anomaly or Disease

Services for the treatment of a congenital anomaly or disease are **eligible for coverage** under the member's medical/surgical contract in accordance with the benefits set forth in the contract when:

A. The services are for the treatment or correction of functional impairment of an underlying congenital anomaly or disease that was present at birth, and medical documentation of the anomaly is provided (e.g., genetic testing records, birth defects). Congenital anomaly or disease is defined as an abnormality of structure or function that was present at birth (e.g., cleft palate, ectodermal dysplasia, ankyloglossia).

   1. Coverage under the medical/surgical contract will only be provided for frenectomy (CPT code 41115), frenotomy (CPT code 41010) or frenoplasty (CPT code 41520) of the lingual frenum related to congenital ankyloglossia, when the ankyloglossia restricts the movement of the tongue leading to problems with newborn feeding, and speech articulation in children.

   2. Frenectomy (CPT code 41115), frenotomy (CPT code 41010), and frenoplasty (CPT code 41520) of the lingual frenum are considered **not medically necessary** when performed prophylactically to promote speech development/articulation in children or adults, because the effectiveness of this approach has not been established.

B. Coverage under the medical/surgical contract will only be provided for services that fall within a category of services for which there is a benefit provided under the member's subscriber contract which are considered medically necessary in accordance with the criteria set forth in Corporate Medical Policy #11.01.15 Medically Necessary Services.

RELATED POLICIES

Corporate Medical Policy

7.03.01 Coverage for Ambulatory Surgery Unit (ASU)/ Outpatient Facility and Anesthesia for Dental Services

11.01.15 Medically Necessary Services

POLICY GUIDELINE(S)

I. X-rays, including cone beam imaging for implant placement (Computed Tomography (CT) scans), are **ineligible for coverage** under the medical benefit of a member's subscriber contract, unless otherwise stated.

II. All other dental services rendered by a dental provider (e.g., Doctor of Medical Dentistry, Doctor of Dental Surgery) not listed in the above Policy Statements are **ineligible for coverage** under the member's medical/surgical contract, unless otherwise stated.

DESCRIPTION

Oral surgery involves the correction of conditions of or damage to the mouth, teeth, and jaw. Oral surgery is commonly performed to remove wisdom teeth, prepare the mouth for dentures, repair jaw conditions, and perform more advanced procedures, as required after trauma or severe disease damage to the structure of the mouth.

There are two categories of dentoalveolar bone cysts which include cysts arising from epithelial remnants (developmental) and cysts arising from dental tissue. Developmental cysts of epithelial remnants (e.g., globulomaxillary cysts, median alveolar cysts, median palatine cysts, nasopalatine cysts) are not tooth-related. Examples of cysts arising from dental tissue (tooth-related) include follicular-dentigerous, primordial, or multilocular-cysts, cysts of mallassez, radicular cysts, residual cysts, and odontomas.

Routine dental procedures, which are not covered under medical/surgical contracts, include, but are not limited to:

I. Correction of impactions;

II. Endodontic therapy;

III. Extraction of teeth:

   A. Implant placement;

   B. Oral biopsies with a dental diagnosis;

   C. Periodontal treatment;

   D. Placement of fillings;

   E. Preventive care;

   F. Prosthetics;

G. Sedation; and

H. X-rays.

Accidental Injury to Teeth

Trauma involving the dento-alveolar region is a frequent occurrence which can result in the fracture and displacement of teeth, crushing, and/or fracturing of bone, and soft tissue injuries including contusions, abrasions, and lacerations. Traumatic dental injuries (TDIs) of permanent teeth occur most frequently in children, young adults and elderly persons. Crown fractures and luxations of these teeth are the most commonly occurring of all dental injuries. Proper diagnosis, treatment planning, and follow up are important for achieving a favorable outcome.

Congenital Anomalies

Congenital anomalies are defined by the World Health Organization as birth defects, congenital disorders or congenital malformations. Congenital anomalies can be defined as structural or functional anomalies (for example, metabolic disorders) that occur during intrauterine life and can be identified prenatally, at birth, or sometimes may only be detected later in infancy, such as hearing defects. In simple terms, congenital refers to the existence at or before birth. A clinical condition that develops after birth but is based on inherited factors (e.g., diabetes) is not considered congenital.

Ankyloglossia

Ankyloglossia, also known as tongue tie, identifies conditions ranging in severity from a malposition of the frenulum on the underside of the tongue (lingual frenum) to partial or total fusion of the tongue to the floor of the mouth. Normally the frenulum does not impede the movement of the tip of the tongue but when the frenulum is too short or attaches close to the tip of the tongue, it restricts the movement of the tongue and may cause difficulty with feeding in infants and speech development in children.

Various grading tools exist to assist practitioners with diagnosing ankyloglossia. The Coryllos classification tool is useful to determine the type of frenulum, but it does not include the evaluation of function nor a criterion for ankyloglossia. The Hazelbaker Assessment Tool for Lingual Frenulum Function (HATLFF) assesses both frenulum anatomy and function and scores ankyloglossia. Regardless of the evaluation tool used, it is essential to demonstrate restricted tongue movement and ascertain that the lingual frenulum exclusively causes this limitation.

Frenectomy for Congenital Ankyloglossia

Frenectomy for congenital ankyloglossia is a surgical procedure that removes the lingual frenum of the tongue. This differs from frenotomy for congenital ankyloglossia, where the frenum is simply incised and not removed. Frenoplasty for congenital ankyloglossia, is the surgical revision of lingual frenum with Z-plasty. All three procedures are performed under local anesthesia and result in greater range of motion of the tongue.

SUPPORTIVE LITERATURE

The published literature on ankyloglossia and its treatment is large and diverse and provides conflicting evidence due to many studies lacking appropriate control groups, and lacking systematic measurement of outcomes. There is clinical evidence to suggest that frenotomy, frenectomy or frenoplasty is associated with improvements in breastfeeding in infants or in promoting subsequent speech development in infants and children.

Bruney and colleagues (2022) performed a systematic review and meta-analysis of a total of six (6) studies (four randomized and two non-randomized) involving breastfeeding interventions for full-term infants to examine the effectiveness of ankyloglossia treatment on breastfeeding difficulties. The study sample sizes ranged from 25 to 107 mother–infant dyads, which totaled 329. The meta-analysis of standardized mean differences in breastfeeding difficulty scores in four studies showed statistically significant differences in favor of frenotomy (Pooled SMD +2.12, CI:(0.17–4.08) p = 0.03). Similarly, a statistically significant difference in favor of frenotomy was observed for pain (Pooled SMD −1.68, 95% CI: (−2.87 to−0.48). The authors concluded that infant frenotomy is effective for improving standardized scores on breastfeeding difficulty and maternal pain scales. However, future trials should also include longer-term follow-up, to determine whether observed improvements immediately following frenotomy increase the likelihood of achieving the WHO recommendations of at least six (6) months of exclusive breastfeeding.

PROFESSIONAL GUIDELINE(S)

There is no uniformity of an accepted diagnostic criteria for ankyloglossia by professional societies. There is also a lack of consensus for treatment of ankyloglossia, leading to wide practice variation in the United States and internationally.

REGULATORY STATUS

New York Insurance Law § 3217: The law provides allowable exclusions in such policies and contracts as set forth in N.Y. Comp. Codes R. & Regs. Tit, 11, § 52.16(c) (2002): (9) dental care or treatment, except for such care or treatment due to accidental injury to sound natural teeth within 12 months of the accident and except for dental care or treatment necessary due to congenital disease or anomaly.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
41010	Incision of lingual frenum (frenotomy); (Please refer to Policy Statement IV)
41115	Excision of lingual frenum (frenectomy); (Please refer to Policy Statement IV)

Code	Description
41520	Frenoplasty (surgical revision of frenum, e.g., with Z-plasty); (Please refer to Policy Statement IV)

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HCPCS Codes

Code	Description
Multiple Codes	

ICD10 Codes

Code	Description
P92.2	Slow feeding of newborn
P92.3	Underfeeding of newborn
P92.4	Overfeeding of newborn
P92.5	Neonatal difficulty in feeding at breast
P92.6	Failure to thrive in newborn
P92.8	Other feeding problems of newborn
P92.9	Feeding problem of newborn, unspecified
Q35.1	Cleft hard palate
Q35.3	Cleft soft palate
Q35.5	Cleft hard palate with cleft soft palate
Q35.7	Cleft uvula
Q35.9	Cleft palate, unspecified
Q37.0	Cleft hard palate with bilateral cleft lip
Q37.1	Cleft hard palate with unilateral cleft lip
Q37.2	Cleft soft palate with bilateral cleft lip
Q37.3	Cleft soft palate with unilateral cleft lip
Q37.4	Cleft hard and soft palate with bilateral cleft lip

Code	Description
Q37.5	Cleft hard and soft palate with unilateral cleft lip
Q37.8	Unspecified cleft palate with bilateral cleft lip
Q37.9	Unspecified cleft palate with unilateral cleft lip
Q38.1	Ankyloglossia
Q38.5	Congenital malformations of palate, not elsewhere classified
Q82.4	Ectodermal dysplasia (anhidrotic)
Multiple Other Codes	

REFERENCES

Baxter R, et al. Functional improvements of speech, feeding, and sleep after lingual frenectomy tongue-tie release: A prospective cohort study. Clinical Pediatrics. 2020;59(9-10):885-892.

Bourguignon C, et al. International Association of Dental Traumatology guidelines for the management of traumatic dental injuries: fractures and luxations. Dent Traumatol. 2020;36(4):314-330.

Bruney TL, et al. Systematic review of the evidence for resolution of common breastfeeding problems-ankyloglossia (tongue tie). Acta Paediatrica. 2022;111:940–947.

Chowdhry R, et al. Alternative therapies for ankyloglossia-associated breastfeeding challenges: a systematic review. Breastfeed Med. 2024 Apr 9. doi:10.1089/bfm.2024.0072. Online ahead of print.

Cordray H, et al. Quantitative impact of frenotomy on breastfeeding: A systematic review and meta-analysis. Pediatr Res. 2024 Jan;95(1):34-42.

Garrido MDPG, et al. Effectiveness of myofunctional therapy in ankyloglossia: A systematic review. Int J Environ Res Public Health. 2022;19(19):12347.

Thomas J, et al. Identification and management of ankyloglossia and its effect on breastfeeding in infants: clinical report. Pediatrics. 2024 Aug;154(2):e2024067605.

Wang J, et al. The effect of ankyloglossia and tongue-tie division on speech articulation: A systematic review. Int J Paediatr Dent. 2022;32(2):144-156.

SEARCH TERMS

Odontogenic cysts

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Oral Surgery is not addressed in National or Regional Medicare coverage determinations or policies. Please refer to the Medicare Dental Coverage Guidance [Last updated 2025 Jan 3; accessed 2026 Apr 21] Available from: Medicare Dental Coverage

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: DENTAL SERVICES COVERED UNDER THE MEDICAL BENEFIT

POLICY EFFECTIVE DATE:	5/1/2025
Policy Control #:	1370/20.000417
Next Annual Review:	May, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

DESCRIPTION

Dental services may be covered under the medical benefit when needed as a result of accidental injury to sound and natural teeth (accidental dental benefit), or congenital disease or anomaly (congenital dental benefit).

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

Clinical Review Preauthorization List
Temporomandibular Joint Disorder, 1370/20.000062

Payment Policies:

Preventive Services Guidelines, 1550/20.000211

POSITION STATEMENT

CDPHP administers benefits for dental services required as a result of an accidental injury or congenital disease or anomaly under the medical benefit when all of the following criteria are met:

POLICY NAME: DENTAL SERVICES COVERED UNDER THE MEDICAL BENEFIT

- Determination as to whether there exists an accidental injury or congenital disease or anomaly as defined below.
- Determination as to whether the dental care and treatment is needed as a result of an accidental injury or congenital disease or anomaly.
- Determination that a congenital disease or anomaly has resulted in a functional impairment.
- Determination as to whether the enrollee's medical contract provides coverage for the treatment necessary for the accidental dental injury or congenital disease or anomaly.

Accidental Dental Benefit

Dental care services required due to trauma to a sound natural tooth caused by something other than a natural function. A natural function includes, but is not limited to, activities such as chewing, biting, and grinding of teeth (bruxism). A sound natural tooth is defined as a tooth that has not had prior restoration or has been restored to full function prior to the injury; examples of teeth that are not sound and natural would be, but are not limited to, dental implants, crowns, bridges or pontics, capped teeth, teeth in the presence of moderate or severe periodontal disease or teeth that have a cavity or injury that has not been restored to full function or that have had previous endodontic treatment (such as a root canal) or placement of posts.

In the event of an accidental injury to a sound natural tooth, CDPHP administers benefits under the medical contract within the first 12 months after such injury for medically necessary treatment associated with the injury.

- The 12-month limitation may be extended in cases where future growth of the member prohibits necessary treatment from being performed within 12 months of the accidental injury. Requests for extensions of the 12-month limitation will be reviewed on an individual case basis and should be approved during the initial treatment.
- Coverage ends if the member leaves CDPHP, even if 12 months have not elapsed.

CDPHP administers benefits for emergency care following an accidental injury. Emergency care is defined as care performed within 24 hours of the accidental injury, which serves to stabilize and/or prevent additional injury. Care may be rendered in an emergency room, urgent care center, a private dental office, or an oral surgeon's office.

- All services required beyond emergency care as defined above must be provided by a dentist or oral surgeon. The provider rendering services is required to submit a plan of care as well as appropriate radiographs to demonstrate the medical necessity. Whenever possible, proof that tooth/teeth in question was sound and natural, is also required.
- Coverage is provided for dental prostheses, including dental implants, made necessary due to accidental injury to sound, natural teeth and provided within 12 months of the accident, and when medically necessary in treatment of a congenital anomaly or as part

of reconstructive surgery.
- Orthodontic services will only be provided when the enrollee has a comprehensive dental and orthodontics benefit rider. This applies to bridges and other dental appliances prescribed for the sole purpose of maintaining alignment.

Congenital Dental Benefits

A congenital anomaly is defined as a malformation that occurs before birth and is present at birth. Coverage may be available under the medical benefit for dental services directly related to and an integral part of the medical and surgical correction of a functional impairment resulting from a congenital disease (such as ameliogenesis imperfecta) or anomaly (such as cleft palate). Congenital diseases or anomalies that result in a functional impairment will not be considered cosmetic.

Medical management of children with congenital cleft palate may involve what might otherwise be considered dental in nature, including orthodontics.

- CDPHP considers orthodontic treatment medically necessary for coverage under the medical benefit when it is provided in conjunction with bone graft surgery of the alveolar cleft, referred to as pre- and post-surgical orthodontics. Orthodontic appliances are used pre-surgically to align the segments of the maxillary arch prior to bone graft surgery and for stabilization following surgery to hold the maxillary alveolar segments in position until the bone grafts have stabilized.

Orthodontic services, other than those stated above for congenital cleft palate repair, will be provided only when the enrollee has a comprehensive dental and orthodontics benefit rider. This applies to bridges and other dental appliances prescribed for the sole purpose of maintaining alignment.

Routine dental services, such as cleaning or management of dental caries, will not be covered under the congenital dental benefit.

Dental Services Integral to Medical Procedures

A dental service that would otherwise be excluded from coverage under CDPHP medical plans may be a covered medical expense if the dental service is medically necessary and is incident to and an integral part of a service covered under the medical plan.

CDPHP considers the following dental services to be an integral part to a medical procedure:

- Extraction of teeth to prepare the jaw for radiation treatments of neoplastic disease (Dental reconstruction for the replacement of extracted teeth is not covered by the medical plan).

POLICY NAME: DENTAL SERVICES COVERED UNDER THE MEDICAL BENEFIT

- Reconstruction of a dental ridge performed as a result of, and at the same time as, the surgical removal of a tumor (for other than dental purposes).
- Removal of broken teeth when performed in connection with the reduction of a jaw fracture.

Dental Services Not Integral to Medical Services:

Dental services and dental-in-nature oral and maxillofacial surgery services do not become eligible for medical coverage merely by virtue of their being performed prior to a covered medical service for the treatment of systemic disease, even if the medical service makes the dental service medically necessary. Removal of teeth at risk of infection, periodontal therapies, and subsequent oral rehabilitation reconstruction (i.e., the replacement of teeth) are not covered under medical plans even where these services are medically necessary prior to major surgical procedures such as open-heart surgery, organ transplantation, joint reconstructive surgery, or other types of surgery.

POLICY CONSIDERATIONS

Reimbursement for services will be based upon CDPHP dental fee schedule at the time of the visit.

Coverage is provided for fluoride varnish treatments every 3-6 months based on caries risk (D1206, D1208, 99188) for children from birth through age five when applied by a dentist, physician or nurse practitioner.

EXCLUSIONS

Dental services are not covered under the medical benefit when:

- The procedure is not intended primarily to improve/restore bodily function or to correct significant deformity that resulted from an accidental injury; or
- The procedure is not for the correction of functional impairment related to congenital defects and anomalies.

In addition, the following exclusions will apply:

- Dental services which are not medically necessary for the diagnosis and treatment of an accidental injury or functional deficit resulting from a congenital anomaly (i.e., routine dental services to include cleaning, fillings, crowns, etc.)
- Dental services that are cosmetic in nature.

Coverage for accidental dental/congenital dental benefits end when the enrollee leaves CDPHP.

CDPHP PRODUCT VARIATIONS

POLICY NAME: DENTAL SERVICES COVERED UNDER THE MEDICAL BENEFIT

CHILD HEALTH PLUS:

Subject to all terms and conditions noted above in application with the following exceptions:

- Coverage of dental implants for congenitally missing teeth or defective teeth is excluded from the benefit plan.
- All requests for orthodontia, including those related to accidental/congenital dental, are to be submitted to Delta Dental.
- Fluoride varnish is reimbursable to physicians and nurse practitioners once per three (3) month intervals under CPT code 99188 (application of topical fluoride varnish by a physician or other qualified health care professional) for members 0-6 years of age.
- For dentists and dental hygienists, the benefit is limited to gel, foam, and varnish up to every 3 months through age 19 under CDT codes D1206 and/or D1208.

MEDICARE ADVANTAGE:

Subject to all terms and conditions noted above in the policy.

SELECT PLAN/HARP:

CDPHP utilizes the New York State Medicaid Management Information System (MMIS) Dental Policy and Procedure Code Manual for guidance with dental services covered under the medical benefit (e.g., dental implants) as described within this policy:

https://www.emedny.org/ProviderManuals/Dental/PDFS/Dental_Policy_and_Procedure_Manual.pdf

Topical fluoride treatment is reimbursable when professionally administered in accordance with appropriate standards. Benefit is limited to gel, foam, and varnish. There must be a minimum interval of three (3) months between all fluoride treatments (D1206/99188 and/or D1208).

D1206
Topical application of fluoride varnish
Reimbursable once per three (3) month period for members between six months and 20 years of age (inclusive). For individuals 21 years of age and older D1206 is only approvable for those individuals identified with a recipient exception code of RE 81 ("TBI Eligible") or RE 95 ("OPWDD/Managed Care Exemption"), or, in cases where salivary gland function has been compromised through surgery, radiation, or disease. Topical application of Fluoride Varnish is permitted by registered dental assistants, provided that such function is performed under the direct personal supervision of a licensed dentist in the course of the performance of dental services and should be billed by the supervising dentist.

Reimbursable to physicians and nurse practitioners under CPT code 99188. Fluoride varnish can be applied by licensed practical nurses, registered nurses, and physician assistants to optimize treatment and should be billed by the supervising physician.

POLICY NAME: DENTAL SERVICES COVERED UNDER THE MEDICAL BENEFIT

D1208
Reimbursable once per six (6) month period for members between 6 and 20 years of age (inclusive). Fluoride must be applied separately from prophylaxis paste. For individuals 21 years of age and older D1208 is only approvable for those individuals identified with a Restriction Exception code of RE 81 ("TBI Eligible") or RE 95 ("OPWDD/Managed Care Exemption"), or, in cases where salivary gland function has been compromised through surgery, radiation, or disease.

Fluoride treatments that are not reimbursable:

- Treatment that incorporates fluoride with prophylaxis paste;
- Topical application of fluoride to the prepared portion of a tooth prior to restoration;
- Fluoride rinse or "swish"; and,
- Treatment for desensitization.

All requests for orthodontia are to be submitted to Delta Dental.

SOURCES

1. Other Payers.
2. Member Contract Language
3. New York State Departments of Health and Insurance
4. New York State Insurance Regulation, 11 NYCRR §52.16(c)(9)
5. Medicare Explained 2005; Dental Services, sections 218, 340 & 634
6. NYS Medicaid Program Dental Policy and Procedure Code Manual: https://www.emedny.org/ProviderManuals/Dental/PDFS/Dental_Policy_and_Procedure_Manual.pdf
7. USPSTF Final Recommendation Statement: Dental Caries in Children Birth Through Age 5: Screening http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/dental-caries-in-children-from-birth-through-age-5-years-screening
8. American Academy of Pediatrics, Fluoride Use in Caries Prevention in the Primary Care Setting: https://pediatrics.aappublications.org/content/146/6/e2020034637

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POLICY APPROVAL DATES

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: DENTAL SERVICES COVERED UNDER THE MEDICAL BENEFIT

New: 07/04

Revised: 06/05, 07/05, 09/06, 03/09, 05/09, 05/10, 05/11, 09/11, 11/11, 11/12, 05/13, 05/15, 05/16, 09/16, 07/18, 03/19 (regulatory), 11/20 (regulatory), 5/21, 1/23, 5/23, 5/25, 9/25

Reviewed: 06/07, 05/08, 05/14, 05/17, 05/18, 05/19, 5/20, 5/22, 5/24, 5/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
5/1/2025 *No change to effective date of policy	Effective 4/1/2025, added additional professional types who can administer fluoride varnish under Medicaid section as per NYS Medicaid Update April 2025.
5/1/2025	Updated verbiage for fluoride varnish in main policy as well as under Child Health Plus and Select Plan/HARP sections.
1/1/2023 *No change to effective date of policy	Under the Medicaid section, updated Fluoride allowance.
1/1/2023	Under Child Health Plus section, updated fluoride allowance as per CHP expansion benefits. Under Medicaid section, removed all allowances/criteria for orthodontics as these are all reviewed by Delta Dental.
9/1/2021	Under Medicaid- Removed statement: CDPHP is responsible for managing orthodontia services in conjunction with an approved surgery.
10/1/20	Statement regarding fluoride varnish was updated to include additional provider types in the Child Health Plus and Select Plan/HARP sections.

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: DENTAL SERVICES COVERED UNDER THE MEDICAL BENEFIT

This Resource Coordination Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI) and Capital District Physicians' Healthcare Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: DENTAL SERVICES: CRITERIA FOR USE OF HOSPITAL INPATIENT OR OUTPATIENT AMBULATORY FACILITY SERVICES

POLICY EFFECTIVE DATE:	7/1/2018
Policy Control #:	1370/20.000181
Next Annual Review:	July 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

DESCRIPTION

Dental services and/or oral surgery can generally be provided in an office setting. However, an acute care inpatient facility or ambulatory surgery center may be indicated for the provision of dental services due to an individual's underlying medical condition, severity of the dental procedure, or when anesthesia is indicated for patient management.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policy:

Dental Services Covered Under the Medical Benefit, 1370/20.000417

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: DENTAL SERVICES: CRITERIA FOR USE OF HOSPITAL INPATIENT OR OUTPATIENT AMBULATORY FACILITY SERVICES

POSITION STATEMENT

CDPHP administers benefits for general anesthesia services and related inpatient hospital or ambulatory surgery center facility services under the medical benefit when performed in conjunction with a dental procedure and when medically necessary for the following conditions:

- A documented concurrent medical or mental health condition that would make the inpatient hospital or outpatient ambulatory surgery setting medically necessary to safeguard the health of the patient.
- When facility-based anesthesia services are required for safe and effective administration of dental procedures for young children (age eight and under).
- Persons exhibiting severe behavioral problems, or who are unable to cooperate for dental procedures, such as persons with developmental disabilities.
- Complex oral surgery procedure with a high probability of complications due to the nature of the surgery.

POLICY CONSIDERATIONS

This policy addresses hospital inpatient facility services and ambulatory surgery center facility services, not the provision of dental care or oral surgery. Professional dental services provided by a dentist or oral surgeon are covered only to the extent that the enrollee has dental benefits or is associated with an accidental injury or congenital dental anomaly, or a medical-oral surgical procedure covered under the medical benefit. Refer to the following policy: *Dental Services Covered Under the Medical Benefit.*

Facility services, to include anesthesia, provided by a hospital or outpatient ambulatory surgery facility in conjunction with dental treatment are covered under the medical benefit only when the conditions listed above are met.

EXCLUSIONS

Services performed inpatient or in an outpatient ambulatory surgery setting for the dentist or enrollee's convenience.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy with the following exceptions: • A dental rider is not required. • Professional services rendered by a dentist in an inpatient or ambulatory surgery setting must be performed by a Healthplex Dental network provider.

Capital District Physicians' Health Plan, Inc.
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Capital District Physicians' Healthcare Network, Inc.

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POLICY NAME: DENTAL SERVICES: CRITERIA FOR USE OF HOSPITAL INPATIENT OR OUTPATIENT AMBULATORY FACILITY SERVICES

MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy for services performed in an ambulatory surgery setting. An oral or dental examination performed on an inpatient basis as part of a comprehensive workup prior to renal transplant surgery is a covered service. Inpatient hospitalization for a dental procedure not otherwise covered by original Medicare, is covered on a case-by-case basis (including charges of dentist or oral surgeon) only if inpatient care is necessary due to the severity of the disease, complexity of the procedure, or to ensure proper medical management of a non-dental impairment.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy. • Dental surgical services, for which it is medically necessary the procedure be performed in a hospital or in an ambulatory surgery setting, are covered. • Professional services rendered by a dentist in an inpatient or ambulatory surgery setting must be performed by a Healthplex network provider.

SOURCES

1. The CDPHP Technology Assessment Team
2. Other Payers
3. Member Contract Language
4. American Academy of Pediatrics, "Pediatrics in Review," Volume 20, No. 3, March 1999.
5. American Society of Anesthesiologists, Inc., "Anesthesiology," Volume 90, No. 3, March1999.
6. W-B Saunders Company, "Pediatric Clinics of North America," Volume 46, No. 6, December 1999.
7. Medicare Coverage Issues Manual, "Dental Examinations prior to Kidney Transplantations," Section 50-26.

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: DENTAL SERVICES: CRITERIA FOR USE OF HOSPITAL INPATIENT OR OUTPATIENT AMBULATORY FACILITY SERVICES

POLICY APPROVAL DATES

New:	06/98
Revised:	05/99, 10/99, 11/00, 11/02, 09/03, 03/05, 02/06, 09/07, 07/08, 07/11, 07/12, 07/13, 07/18, 7/24
Reviewed:	01/01, 06/04, 01/07, 07/09, 07/10, 07/14, 07/15, 07/16, 07/17, 07/19, 07/20, 7/21, 7/22, 7/23, 7/25, 7/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
7/1/2024	No change to criteria. Removed references to Oral Surgery, 1550/20.000185 policy that is obsolete.

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: DESIGNATED SPECIALTY CARE NETWORK: TRANSPLANT SERVICES

POLICY EFFECTIVE DATE:	7/1/2026
Policy Control #:	1370/20.000435
Next Annual Review:	September, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care for enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

DESCRIPTION

CDPHP may designate specific facilities to serve as the exclusive network for selected services. These designated specialty care facilities are the CDPHP participating network for transplants and transplant related services. Such facilities will have exhibited successful clinical outcomes, met quality of care standards, and have contractually agreed to participate with CDPHP for these services. The CDPHP designated specialty care network will provide for transplantation of any organ or tissue, including bone marrow and stem cell transplantation.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

- Allogeneic Hematopoietic (STEM) Cell Transplantation (HSCT), 7.02.02
- Autologous Hematopoietic (Stem) Cell Transplantation (HSCT), 7.02.03
- Chimeric Antigen Receptor T-Cell (CAR-T) Therapy for Candidate Selection, 7.02.11
- Experimental or Investigational Services, 11.01.03
- Heart and Heart-Lung Transplant, 7.02.06
- Kidney Transplantation, 07.02.04
- Liver Transplantation, 7.02.07
- Lung and Lobar Lung Transplant, 7.02.10

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: DESIGNATED SPECIALTY CARE NETWORK: TRANSPLANT SERVICES

- Out-of-Network Services, 11.01.14
- Pancreas Transplant (Pancreas Transplant Alone, Pancreas Transplant after Kidney Transplant, Simultaneous Pancreas Kidney Transplant) Islet Cell Transplant, 07.02.01
- Small Bowel and Multivisceral Transplants in Adults and Children, 07.02.05

Payment Policy:

- Organ Transplant-Donor, 1550/20.000207

Credentialing Policy:

- Designated Specialty Care Network: Transplant Services Credentialing & Recredentialing, 1315/20.000135.

POSITION STATEMENT

CDPHP administers benefits for transplant services only when such services are performed at participating approved transplant facilities or within the designated networks. The following identifies the designated network/facilities:

- OptumHealth Transplant Centers of Excellence Network: https://www.myoptumhealthcomplexmedical.com/gateway/public/transplants/transplants.jsp

POLICY CONSIDERATIONS

CDPHP requires prior authorization for transplants, including transplants at an OptumHealth designated transplant center of excellence.

CDPHP will consider coverage for medically necessary transplantation at centers that are not in the OptumHealth designated transplant centers of excellence network based on all the following criteria:

1. The facility is contracted with CDPHP and participates in the network for the relevant benefit plan.
2. Adequate written transplant program description including patient selection criteria.
3. Adequate patient management plans and protocols that include therapeutic and evaluative procedures for the waiting period, in-hospital period, and post-transplant phases of treatment.
4. Sufficient commitment of resources and planning to demonstrate the importance of the program at all levels, to include a multidisciplinary team that includes representatives with expertise in the appropriate organ specialty.
5. Experience and success with clinical organ transplants as follows:
    a. The facility staff must annually perform a number of transplants sufficient to demonstrate proficiency.

   b. Outcomes, to include patient and graft survival at 1, 3, and 5 years, must be comparable to outcomes attained by OptumHealth designated transplant centers.
6. Be an active member of the United Network for Organ Sharing (UNOS).
7. Facility must be Medicare approved for the requested transplant.
8. Facility meets requirements for participation in the CDPHP designated specialty care network in accordance with CDPHP Network Services policy: *Designated Specialty Care Network: Transplant Services Credentialing & Recredentialing, 1315/20.000135.*

CDPHP resource coordination department reviews all requests for transplant services.

- A registered nurse care manager will be assigned to an identified transplant patient to assist with treatment coordination, from evaluation through post-transplant recovery, and identification of potential resources available to the patient.

CDPHP allows an enrollee to be listed at more than one CDPHP designated specialty care transplant center.

- *Coverage for additional listings applies to the consultation only.* It is understood that eligibility criteria for a specific transplant may differ among transplant centers. However, CDPHP expects results of the initial evaluation, including all laboratory work and testing, be obtained from the primary facility. Requests for additional testing or treatment, beyond what was performed at the primary facility, is subject to benefit limitations stated in the enrollee's contract and will require prior authorization.

Enrollees must use CDPHP designated specialty care network to be considered in-network for coverage of transplants. Failure to use a CDPHP designated facility may result in the following:

- Non-coverage for all transplant related charges; or
- Coverage at the out-of-network level of benefits, if applicable.

Coverage of transplant services is subject to all the terms and conditions listed in the enrollee's contract.

EXCLUSIONS

Coverage for transplants of artificial or animal organs, or for procedures and/or services considered experimental and investigational.

Travel, food, and lodging expenses for transplant recipient and/or family members or companion, unless coverage for such expenses is specifically provided in the enrollee's benefit plan.

CDPHP PRODUCT VARIATIONS

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: DESIGNATED SPECIALTY CARE NETWORK: TRANSPLANT SERVICES

CHILD HEALTH PLUS:	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted above in the policy to include: • Covered transplants are to be performed in a facility approved by the Centers for Medicare & Medicaid for the specified organ transplant that is part of the CDPHP designated specialty care network.
SELECT PLAN/HARP:	Subject to all terms and conditions noted above in the policy to include: • Covered transplants are to be performed in a facility that is part of the CDPHP designated specialty care network in New York State when available.

SOURCES

1. The CDPHP Designated Specialty Care Network Workgroup
2. CDPHP contract language
3. Other payers
4. OptumHealth, www.myoptumhealthcomplexmedical.com
5. United Resource Network, www.urnweb.com
6. United Network for Organ Sharing, www.unos.org
7. Centers for Medicare & Medicaid Services: Decision Memo for Transplant Centers: Re-evaluation of Criteria for Medicare Approval, http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=75

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POLICY APPROVAL DATES

New: 11/06

Revised: 09/10, 09/11, 09/14, 11/14, 09/17, 9/20, 9/21, 9/23, 9/24, 5/26

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: DESIGNATED SPECIALTY CARE NETWORK: TRANSPLANT SERVICES

Reviewed: 10/07, 09/08, 09/09, 09/12, 09/13, 09/15, 09/16, 09/18, 09/19, 9/22, 9/25, 9/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
7/1/2026	Added 9 new transplant policies to the Related Policies section and updated language to state that prior authorization is required for transplants.
10/1/2024	No criteria change: Updated policy to remove Find-A-Doc and Member Services as sources to transplant centers.
10/1/2022 *No change to effective date of policy	Under Policy Considerations, clarified care management services.
10/1/2022	No content change. Updated new title from "case manager" to "care manager"
1/1/2021	Changed reference of Organ Transplant Donor policy from Resource Coordination to payment policy. Updated OptumHealth web link. Removed outdated web link from Medicare Advantage section.

This Resource Coordination Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI) and Capital District Physicians' Healthcare Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

POLICY EFFECTIVE DATE:	9/1/2026
Policy Control #:	1370/20.000047
Next Annual Review:	December, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

Multiple

DESCRIPTION

CDPHP administers benefits for medically necessary diabetic services to include equipment, supplies, pharmaceuticals, eye exams, therapeutic shoes, and educational counseling, used in the management and treatment of diabetes.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

- Durable Medical Equipment, Prosthetics/Orthotics, & Medical Supplies, 1370/20.000509
- Foot Care, 1370/20.000106

Pharmacy Policies:

- Medical Exception/Preauthorization Review Process, 1350/20.000021

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

POSITION STATEMENT

CDPHP administers benefits for medically necessary equipment, supplies, oral agents, and insulin, for the monitoring and treatment of diabetes, to include the following:

- Diabetic supplies, equipment, insulin, and oral agents must be prescribed by a physician or other licensed health care professional legally authorized to prescribe under Title 8 of the New York Education Law and obtained through a durable medical equipment vendor or pharmacy.
  Note: Blood glucose monitors and test strips must be obtained at a participating pharmacy.
- Supplies, insulin, or oral agents may be purchased up to the maximum allowable amount per enrollee's contract, which in general, is up to a 30-day supply retail or 90-day supply at the CDPHP mail-order pharmacy.
- Diabetic test strips are subject to a maximum quantity limit of 100 test strips every 30 days for non-insulin users and 300 test strips every 30 days for insulin users. Please refer to the pharmacy policy, Medical Exception/Preauthorization Review Process, 1350/20.000021 if a member has a need to exceed this quantity.
- Diabetic supplies, insulin, oral agents, and equipment are subject to the applicable cost-share as specified in the enrollee's contract.

The following *supplies* are considered eligible for coverage:

- Alcohol swabs
- Cartridges for the visually impaired
- Control solutions used in blood glucose monitors
- Insulin pump supplies, including reservoirs, infusion sets, and batteries
- Insulin syringes
- Lancets and automatic lancing devices
- Semi-permeable transparent dressing required for the purpose of securing placement of an insulin infusion catheter
- Tests strips for glucose monitors and visual reading
- Urine testing products for glucose and ketones

The following *pharmaceuticals* are considered eligible for coverage under the medical portion of the enrollee's contract:

- All insulin preparations
- Disposable insulin cartridges and pen cartridges
- Glucagon for injection to increase blood glucose concentration
- Oral agents for treating hypoglycemia, such as glucose tablets and gels
- Oral anti-diabetic agents used to reduce blood sugar levels

The following *durable medical equipment (DME)* is considered eligible for coverage:

- Insulin aids, including insulin drawing devices for the visually impaired
- Standard blood glucose monitors (E0607)
- Specialized blood glucose monitors, including but not limited to non-invasive or subcutaneous
- Blood glucose monitors for the visually impaired
- Diabetes data-management systems for management of blood glucose
- Insulin infusion devices
- Insulin pumps (E0784)

Continuous Glucose Monitoring

Professional glucose monitoring (95249, 95250, 95251)

Professional continuous glucose monitoring may be used as an adjunct to standard care for diabetic patients meeting the following criteria:

- Recurrent unexplained or unpredictable hypoglycemia or hyperglycemia despite multiple daily finger-stick monitoring
- There is discordant data from finger-stick and HgbA1c testing

Professional continuous glucose monitoring is performed under physician supervision. The sensor is typically inserted, and data collection begins while the patient is in the office. After a minimum of 72 hours of wear, the patient returns to the office, at which time the sensor is removed, data is downloaded, and a printout is obtained for review. It is expected that the results derived from such monitoring will be used to direct changes in diabetic management, resulting in improved treatment regimens and glycohemoglobin measurements.

Professional glucose monitoring is conducted after a minimum of 72-hours of wear. It may be repeated at a subsequent time depending on the patient's level of diabetic control.

Services for professional glucose monitoring should be billed using the above-listed codes with reporting no more than once per month per code. Associated technical services including, but not limited to, monitor applications, sensors, patient training, removal of monitor, and data, downloading are included in the reimbursement for ambulatory subcutaneous continuous blood glucose monitoring (95249, 95250).

The interpretation and reporting (95251) of data from a patient-owned continuous glucose monitor may be reported once every 30 days.

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

Diabetic Education (G0108, G0109, S9465)

CDPHP administers benefits for diabetes self-management and training program rendered in an outpatient or office-based setting to include education regarding the following:

- Monitoring of blood glucose
- Nutrition
- Exercise
- Insulin treatment plan developed specifically for the patient who is insulin-dependent

The enrollee may self-refer for diabetes education counseling.

CDPHP administers benefits for diabetic educational counseling when all of the following criteria are met:

- The services are provided by a physician or hospital, registered dietitian (ADA), certified nutritionist, or certified diabetes educator (National Certification Board for Diabetes Educators).
- The services are medically necessary for the medical management of diabetes.
- Diabetic nutrition assessment/session must include nutritional counseling plus the evaluation of the diabetic condition, including history and examination as indicated, review of medical management, evaluation of appropriate diagnostic tests and procedures, and recommendations for the adjustment of therapeutic management. It must also include the calculation of selected nutrients/energy intake, such as carbohydrates, protein, fat, and kilocalories.
- CDPHP expects the registered dietitian, certified nutritionist, or certified diabetes educator will submit a consult report of education services to the physician managing the member's care.
- Diabetic education sessions are subject to applicable office visit cost-share as stated in the enrollee's contract.

Claims for diabetic education should be submitted using HCPCS codes S9465, G0108, or G0109. Codes G0108 and G0109 are to be billed in increments of 30 minutes per unit.

CDPHP will not separately reimburse for evaluation and management codes (99202-99239, 99281-99359) in conjunction with diabetes education (G0108, G0109, S9465) when billed by the same provider for the same date of service.

Diabetes Prevention Program (0403T, 0488T)

CDPHP administers benefits for members with pre-diabetes to participate in a recognized

diabetes prevention lifestyle change program to help prevent or delay the onset of type 2 diabetes. The diabetes prevention program is a yearlong program to assist individuals in making real lifestyle changes such as eating healthier, incorporating physical activity into their daily lives, and improving problem solving and coping skills.

- *Refer to specific member contracts for availability of benefits relating to this program.*

Eye Exams for Diabetics

CDPHP administers benefits for vision care for enrollees with a diagnosis of diabetes to include:

- A self-referral for up to one routine diabetic eye examination once every 12 months.

Therapeutic Shoes for Diabetics A5500, A5501, A5503-A5507, Therapeutic Shoe Inserts: A5512, A5513, A5514

CDPHP administers benefits for therapeutic shoes, inserts, and/or modifications to therapeutic shoes that aid in the healing process and prevent further diabetic foot disease when all of the following criteria are met:

1. Patient is a diabetic; and

Description	ICD-10 codes effective 10/1/2015
Diabetes	E08.00-E13.9, O24.011-O24.93

2. Patient is being treated under a comprehensive plan of care for diabetes; and

3. Patient has one or more of the following conditions in one or both feet:
   - Partial or complete foot amputation
   - History of previous foot ulceration
   - History of pre-ulcerative calluses
   - Peripheral neuropathy with evidence of callus formation
   - Foot deformity
   - Poor circulation

For patients meeting above criteria, coverage is limited to one of the following within one calendar year:

- One pair of depth-inlay shoes (A5500) and three pairs of inserts (A5512, A5513,

A5514) (not including the non-customized removable inserts provided with such shoes); **or**

- One pair of custom-molded shoes (A5501) (which includes inserts provided with these shoes) and two additional pairs of inserts (A5512, A5513, A5514).

A custom-molded shoe is indicated when the patient has a foot deformity that cannot be accommodated by a depth shoe.

A modification of a custom-molded or depth shoe may be covered as a substitute for an insert. Examples of the most common shoe modifications are rigid rocker bottoms (A5503), roller bottoms (A5503), wedges (A5504), metatarsal bars (A5505), or offset heels (A5506). Other modifications to diabetic shoes (A5507) include flared heels. Payment for the modification(s) may not exceed the limit set for the inserts for which the individual is entitled.

A deluxe feature of a diabetic shoe (A5508) does not contribute to the therapeutic function of the shoe, and therefore is not covered.

Compression molding inserts (A5510) are considered non-covered, as they do not require total contact with the patient's foot at the time of fitting, but rather are molded to the patient's foot over time through the heat and pressure generated by wearing a shoe with the insert present.

Foot Orthotics

- CDPHP will provide coverage for custom foot orthotics (L3000-L3030) in lieu of therapeutic shoe inserts (A5512, A5513, A5514) for enrollees who meet all the criteria (1-3) outlined in the section above, *Therapeutic Shoes for Diabetics.*
- Benefits are limited to one pair of custom foot orthotics or three pairs of therapeutic shoe inserts within one calendar year.

Over-the-counter shoe inserts are not considered to be custom foot orthotics, and therefore, are not eligible for reimbursement.

Claims submitted for custom foot orthotics (L3000-L3030) will be processed as diabetic durable medical equipment when the enrollee has a diagnosis of diabetes and all of the required criteria (1-3) outlined in the section above are met.

Foot orthotics and shoe inserts (L3000-L3030, A5512-A5514) must be billed with modifier KX to ensure that coverage criteria are met, and that documentation exists to support the medical necessity.

EXCLUSIONS

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

Equipment repair or replacement due to misuse, neglect, and/or loss.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy with the following exception: The Diabetic Prevention Program (DPP) is not a covered benefit.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy with the following exceptions: <u>Medicare Diabetes Prevention Program</u> Benefits are provided for the Medicare diabetes prevention program (MDPP) as outlined below. The MDPP is a structured intervention with the goal of preventing type 2 diabetes in individuals with an indication of prediabetes. The program consists of a minimum of 16 intensive "core" sessions of a Centers for Disease Control and Prevention (CDC) approved curriculum furnished over six months in a group-based, classroom-style setting that provides practical training in long-term dietary change, increased physical activity, and behavior change strategies for weight control. After completion of the core sessions, less intensive follow-up meetings are furnished monthly to help ensure participants maintain healthy behaviors. The primary goal of the program is at least 5-percent weight loss by participants. <u>Codes:</u> **Code** — **Descriptor** G9886 — Behavioral counseling for diabetes prevention, in-person, group, 60 minutes G9887 — Behavioral counseling for diabetes prevention, distance learning, 60 minutes G9880 — 5 percent WL Achieved from baseline weight G9881 — 9 percent WL Achieved from baseline weight

	G9888 Maintenance 5 percent WL from baseline in months 7-12 Core Sessions: • Beneficiaries may attend up to 16 weekly sessions during months 1-6 of the MDPP Core Services period. • The MDPP Core Services period starts with the first claim for G9886 or G9887. Beneficiaries must attend one core session to initiate MDPP services. • A supplier is paid based on the beneficiary's attendance, regardless of the beneficiary's weight loss. • A supplier is paid performance payments if the beneficiary achieves weight-loss goals. Core Maintenance Sessions: • Beneficiaries may attend up to 6 monthly sessions during months 7-12 of the MDPP Core Services period. • A supplier is paid based on the beneficiary's attendance, regardless of the beneficiary's weight loss. • A supplier is paid performance payments if the beneficiary achieves weight-loss goals and/or continues to meet the 5% weight-loss goal at each session Key Points to Remember: • Three G-codes can be used when submitting claims for beneficiary achievement of performance milestones: 1) 5% weight loss (G9880), 2) 9% weight loss (G9881), and 3) maintenance of 5% weight loss in a core maintenance session (G9888). • Note that codes G9880 and G9888 cannot be used with the same date of service (DOS), and the DOS for code G9880 must occur prior to any DOS submitted for G9888. Claims for G9888 will be rejected if 1) there is no claim for G9880 with a DOS prior to claim for G9888 and 2) DOS for G9888 is within the first 6 months of the MDPP services period. • Suppliers may bill for a maximum of 22 sessions, including

	up to 16 weekly sessions in months 1-6, and up to 6 monthly sessions in months 7-12. • Suppliers must use one of two G-codes (G9886 or G9887) when filing claims for attendance payments after every core and core maintenance session furnished to an MDPP beneficiary. Once 22 sessions have been paid for a beneficiary, any additional claims with DOS after the 22nd paid claim will be rejected, including out-of-sequence claims. • Each HCPCS G-code should be listed with the corresponding session DOS, MDPP organizational NPI, and rendering provider NPI. Note that the coach is the rendering provider on the claim Medicare Advantage members are eligible for MDPP services when all the following criteria are met: • Enrolled in Medicare Part B • Body mass index (BMI) of at least 25 (23 if self-identified as Asian) on the date of the first core session • Meet 1 of 3 blood test requirements within the 12 months prior to attending the first core session: o A hemoglobin A1c test with a value between 5.7% and 6.4%, or o A fasting plasma glucose of 110-125 mg/dL, or o A 2-hour plasma glucose of 140-199 mg/dL (oral glucose tolerance test) • No previous diagnosis of diabetes prior to the date of the first core session (with exception of gestational diabetes) • Do not have end-stage renal disease (ESRD) • Have not previously received MDPP services (program is once-per-lifetime limit) Members may self-refer to a MDPP as a physician referral is not required. <u>Diabetes Self-Management Training</u> Benefits are provided for diabetes self-management training rendered by a participating provider (refer to section on *Diabetic*

	Education) for newly diagnosed diabetics up to 10 hours during a continuous 12-month period and up to two hours follow-up training in subsequent years. Diabetes self-management training is not subject to an office visit cost-share, as stated in the enrollee's contract. Benefits for Medicare Part D prescription drugs are available only to enrollees who have elected the CDPHP Medicare Advantage product with the Part D option. The CDPHP Medicare Advantage product does not cover any prescription drugs not covered by Medicare. In addition, for those individuals enrolled in the CDPHP Medicare Advantage product who have not elected the Part D option, CDPHP covers only those prescription drugs covered by Medicare Parts A and B, not those covered by Part D.
SELECT PLAN/HARP:	Subject to all terms and conditions noted above in the policy with the following exceptions: CDPHP utilizes the New York State Medicaid Management Information System Provider Manual (MMIS) to determine a medical or surgical supply versus durable medical equipment, orthotic, or prosthetic. Durable medical equipment is not subject to a deductible or copayment. Benefits are provided for medically necessary medical supplies, including insulin and diabetic supplies. Medically necessary prescription footwear and shoe modifications and additions are a covered benefit. Prescription footwear applies to all "L" codes listed in the prescription footwear section of the MMIS provider manual (4.6), as well as codes for diabetic shoes. Enrollees diagnosed with diabetes may self-refer to any participating provider of vision services (optometrist or ophthalmologist) for a dilated eye (retinal) examination once in any 12-month period. <u>Diabetic Self-Management Training (DSMT)</u>

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

	Benefits are provided for DSMT when rendered in a hospital outpatient department or free-standing diagnostic and treatment center and by one of the following NYS licensed, registered, or certified professionals affiliated with a DSMT program: • Registered Nurse • Registered Nurse Practitioner • Registered Dietician • Physician (MD or DO) • Pharmacist • Physician Assistant • Physical Therapist • Clinical Psychologist • Optometrist • Occupational Therapist • Podiatrist DSMT services are also allowed in an office-based setting when provided by one of the above licensed, registered, or certified health care professionals who is also certified as a Certified Diabetes Education (CDE) by the Certified Diabetes Care and Education Specialist (CBDCE). DSMT is covered for enrollees that are newly diagnosed with diabetes, have stable diabetes, or have diabetes with a medically complex condition such as poor diabetes control or another complicating factor. No more than 10 hours for newly diagnosed enrollees or enrollees with a medically complex condition will be allowed during a continuous six-month period. Enrollees with diabetes who are medically stable may receive up to one hour of DSMT in a continuous six-month period. DSMT services may be provided in individual sessions, or in group sessions of no more than eight patients. National Diabetes Prevention Program (NDPP) Services (0403T, G9880) This is an educational and support program designed to assist at-risk people from developing Type 2 diabetes. The program

	consists of group training sessions that focus on the long-term, positive effects of healthy eating and exercise. The goals for these lifestyle changes include modest weight loss and increased physical activity. NDPP sessions are taught using a trained lifestyle coach. • *Refer to specific member contracts for availability of benefits relating to this program.*

SOURCES

1. CDPHP Technology Assessment Team
2. NYS Diabetic Mandate
3. Other Payors
4. Contract Clarification
5. New York State Medicaid Redesign Team: Medicaid Managed Care Benefit Changes, 2011-2012, www.health.ny.gov
6. Medicare Diabetes Prevention program (MDPP) Expanded Model, https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/Bode B, Gross T, Thornton K, Mastrototaro J; Continuous Glucose Monitoring Used to Adjust Diabetes Therapy Improves Glycosylated Hemoglobin: A Pilot Study. Diabetes Research and Clinical Practice. 46 (1999) 183-190. Review.
7. Mastrototaro J, Levy R, Georges L-P, White M, Mestman J; Clinical Results from a Continuous Glucose Sensor Multi-Center Study. Journal of the American Diabetes Association. Diabetes Abstract Book, 59th Scientific Sessions June 1998. Abstract #0238.
8. Department of Health Division of Managed Care Response to Coverage Question for the Omnipod
   Diabetes Management System, Reference number: MA-00562, 7/22/10.
9. Wooldridge, J; Bergeron, J; Thorton, C: Preventing Diabetic Foot Disease: Lessons from the Medicare Therapeutic Shoe Demonstration. American Journal of Public Health, July 1996, 86(7), pp.
   Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity and Adults - The Evidence Report. The National Heart, Lung and Blood Institute (NHLBI) – National Institutes of Health. June 1998.
10. American Diabetes Association: Clinical Practice Recommendations 2000, www.diabetes.org.
11. Medicare Explained Part B Benefits section 370
12. New York State Department of Health: www.health.state.ny.us
13. DMERC Region A Medical Review Policy: Therapeutic Shoes for Patients with Diabetes,

http://www.umd.nycpic.com/leavingRegionA_lmrp.html
14. Medicare Modernization Act, 2003.
15. GlucoWatch G2 Biographer Glucose Monitoring System Important Product News, http://www.glucowatch.com/
16. Division of Managed Care Response to Coverage Question. Reference number: MA-00552, response 2/9/10.
17. Provider (MMIS) Manual to the New York Medicaid, DME Manual, https://www.emedny.org/ProviderManuals/DME/index.aspx
18. NYS Department of Health Update, Policy and Billing Guidance: NYS Medicaid Expands Coverage to include Real Time Continuous Glucose Monitors for Individuals with Type I Diabetes, October 2017, https://www.health.ny.gov/health_care/medicaid/program/update/2017/oct17_mu.pdf
19. CMS Medicare Learning Network (MLN) Matters (MM)10436: New "K" Code for Therapeutic Shoe Inserts, https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10436.pdf
20. CMS Guidance Letter: Medical Supplies Associated with the Injection of Insulin, 1/5/18.
21. NYS Department of Health Update: Reimbursement of Continuous Glucose Monitoring for Individuals with Type I Diabetes, https://www.emedny.org/ProviderManuals/communications/CGM_Update_-_5-16-18.pdf
22. NYS DOH update https://www.health.ny.gov/health_care/medicaid/program/update/2021/no05_2021-04.htm#monitors
23. NYS DOH Update January 2022 Volume 38 https://health.ny.gov/health_care/medicaid/program/update/2022/no01_2022-01.htm#glucose

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POLICY APPROVAL DATES

New:	04/90
Revised:	10/92, 07/93, 12/94, 09/96, 03/98, 06/99, 07/99, 10/99, 06/00, 12/00, 01/01, 09/01, 01/02, 09/02, 04/03, 01/04, 06/05, 09/05, 11/05, 12/05, 09/07, 01/08, 01/09, 03/09, 09/09, 11/09, 01/10, 07/10, 01/11, 03/11, 09/11, 01/12, 01/13, 05/13, 01/14, 03/14, 05/14, 07/14, 09/14, 01/15, 07/15, 01/16, 07/17, 11/17, 01/18, 03/18, 05/18, 07/18, 11/18, 01/19, 01/20, 3/20, 7/20, 01/21, 03/21, 5/21, 7/21, 9/21, 11/21, 1/22, 3/22, 5/22, 7/22, 9/22, 11/22, 1/23, 3/23, 5/23, 11/23, 1/24, 5/24, 7/24, 1/25, 7/25, 9/25, 3/26, 5/26

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

Reviewed: 10/95, 12/06, 01/17, 1/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
9/1/2026	Removed all information for continuous glucose monitors as CGM information is now in policy Continuous Glucose Monitoring Systems/External Insulin Pump Therapy for Diabetes, 1.01.30
4/1/2026	Removed insulin requirement for CGM's and exclusion of CGM's for diagnosis of gestational diabetes.
10/1/2025	Updated CGM verbiage to indicate "insulin dependent" only. Removed Bridge payment code from Medicare Advantage section under Medicare Diabetes Prevention Program (MDPP). This payment was removed by CMS effective 1/1/2025. Under Medicare section, added LCA information for CGM's.
2/1/2025* *No change to effective date for this update	Clarified in the Child Health Plus section that the Diabetic Prevention Program is not a covered benefit.
2/1/2025	Removed information for foot orthotics for vascular disease as this is now in the foot care policy. Updated CGM criteria. Added coverage for implantable CGM's and updated Medicare implantable CGM criteria per updated LCD.
1/1/2024* *No change to effective date for this update	Under the Foot Orthotics section added information that was in the Foot Care policy regarding coverage indications. Added information regarding billing KX modifier with codes L3000-L3030 and A5512-A5514.
1/1/2024*	Updated the coding requirements for the Medicare Diabetes Prevention Program (MDPP) in the Medicare Advantage section.

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

*No change to effective date for this update	
1/1/2024	Removed termed code G0308 and G0309.
11/1/2023	Under Medicaid section- since CGM's are billed to Medicaid FFS (part of Medicaid carve out eff 4-1-23) removed criteria and provided link for the MMIS that outlines the criteria.
10/1/2023	Under Medicaid section updated CGM requirements per DOH mandate.
4/16/2023	Under the Position Statement for Diabetes Prevention Program, added the codes to bill for these services. Under Medicaid added info for National Diabetes Prevention Program. Under Medicare, updated CGM criteria which is effective 4/16/23.
1/1/2023 *No change to effective date of policy	Under Medicaid section 1. added updated CGM codes and guidance for A9276, A9277, and A9278.
1/1/2023	Added new CPT codes E2103 and A4239 and removed deleted codes K0553 and K0554
8/1/2022* No change to effective date	Under Medicare section for the Diabetes Prevention Program, added codes G9890, G9891 which are allowable under the program.
8/1/2022* No change to effective date	Added information to the Medicare CGM's section regarding coverage as a stand-alone device.
8/1/2022	For custom foot orthotics, expanded code range to include codes between L3000-L3030. Under the Medicare section, added coverage for Implantable Continuous Glucose Monitors.
04/01/2022* No change to effective date	CMS coverage update: Effective 2/28/2022, CMS will allow for coverage of a non-therapeutic (adjunctive) continuous glucose monitor (CGM) when it is being used with an integrated insulin pump system. New HCPCS codes (E2102 and A4238) effective 4/1/2022 for

	adjunctive CGM added to policy.
04/01/2022	Revised Select Plan/HARP section to expand CGM coverage to now include members who have type 2 diabetes and gestational diabetes.
02/01/2022	Added additional verbiage to policy regarding providers who can prescribe equipment, supplies, oral agents, and insulin: -"or other licensed Health Care Professional legally authorized to prescribe under Title 8 of the New York Education Law" Removed verbiage in the body of the policy that implantable monitors/implantable CGM devices are considered covered DME as these are listed under the exclusions section. Relocated CGM's for gestational diabetes to the exclusions section and removed the following exclusion: -Personal subcutaneous continuous blood glucose monitoring for children with diabetes
12/1/2021	Added quantity limits for diabetic test strips.
7/18/2021	Updated CGM criteria in the Medicare Advantage section in accordance with Medicare LCD update.
7/1/2021	Updated Select Plan/HARP section: effective 7/1/21, as per DOH updated guidance April 2021, CGM criteria changed to allow an enrolled Medicaid provider with experience in diabetes treatment to order the device and changed criteria of performing at least "four" finger stick glucose tests daily to "multiple". In addition, effective 4/1/2021, expanded the list of practitioners able to provide Diabetes Self-Management Training and clarified enrollees that are eligible for such training under Select Plan/HARP.
5/1/2021 (Effective date on policy remains the same)	In the Position Statement added verbiage in regards to code 95251 that was previously housed in the External Ambulatory Insulin Infusion Pump policy.
5/1/2021	Removed information under Medicaid in regards to National Diabetes Prevention Program (NDPP) as this language is now in the 2021 Member Handbook. Removed verbiage under Medicaid and Medicare in regards to

	Omnipod insulin pumps and V-Go insulin delivery systems as this information is housed in the External Ambulatory Insulin Infusion Pump policy.
4/1/2021	Updated verbiage in section on continued glucose monitoring to indicate a minimum of 72 hours.
7/15/20	Updated policy to include coverage of CGM for Type II diabetics when criteria in policy is met.
2/1/20 (Effective date on policy remains the same)	Added statement to Select Plan section to address coverage of Omnipod/Omnipod Dash as an acceptable alternative to an external ambulatory insulin infusion pump.
2/1/2020	Removed termed code K0903 and added code A5514 for shoe inserts. Removed requirement of finger sticks for individuals prescribed a therapeutic continuous glucose monitor. Made the following changes to the Select Plan section: • Added coverage for National Diabetes Prevention Program (NDPP) • Removed exclusion statement for non-coverage of Omnipod. Added Omnipod Dash to the Medicare Section to the list of insulin delivery devices covered under Part D.

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

POLICY EFFECTIVE DATE:	4/1/2026
Policy Control #:	1370/20.000047
Next Annual Review:	December, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

Multiple

DESCRIPTION

CDPHP administers benefits for medically necessary diabetic services to include equipment, supplies, pharmaceuticals, eye exams, therapeutic shoes, and educational counseling, used in the management and treatment of diabetes.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

- Durable Medical Equipment, Prosthetics/Orthotics, & Medical Supplies, 1370/20.000509
- External Ambulatory Insulin Infusion Pump, 1370/20.000457
- Foot Care, 1370/20.000106
- Medical Nutritional Counseling, 1370/20.000472
- Vision Services by Eye Care Specialists, 1370/20.000005

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

Pharmacy Policies:

- Medical Exception/Preauthorization Review Process, 1350/20.000021

POSITION STATEMENT

CDPHP administers benefits for medically necessary equipment, supplies, oral agents, and insulin, for the monitoring and treatment of diabetes, to include the following:

- Diabetic supplies, equipment, insulin, and oral agents must be prescribed by a physician or other licensed health care professional legally authorized to prescribe under Title 8 of the New York Education Law and obtained through a durable medical equipment vendor or pharmacy.
  Note: Blood glucose monitors and test strips must be obtained at a participating pharmacy.
- Supplies, insulin, or oral agents may be purchased up to the maximum allowable amount per enrollee's contract, which in general, is up to a 30-day supply retail or 90-day supply at the CDPHP mail-order pharmacy.
- Diabetic test strips are subject to a maximum quantity limit of 100 test strips every 30 days for non-insulin users and 300 test strips every 30 days for insulin users. Please refer to the pharmacy policy, Medical Exception/Preauthorization Review Process, 1350/20.000021 if a member has a need to exceed this quantity.
- Diabetic supplies, insulin, oral agents, and equipment are subject to the applicable cost-share as specified in the enrollee's contract.

The following *supplies* are considered eligible for coverage:

- Alcohol swabs
- Cartridges for the visually impaired
- Control solutions used in blood glucose monitors
- Insulin pump supplies, including reservoirs, infusion sets, and batteries
- Insulin syringes
- Lancets and automatic lancing devices
- Semi-permeable transparent dressing required for the purpose of securing placement of an insulin infusion catheter
- Tests strips for glucose monitors and visual reading
- Urine testing products for glucose and ketones

The following *pharmaceuticals* are considered eligible for coverage under the medical portion of the enrollee's contract:

- All insulin preparations

- Disposable insulin cartridges and pen cartridges
- Glucagon for injection to increase blood glucose concentration
- Oral agents for treating hypoglycemia, such as glucose tablets and gels
- Oral anti-diabetic agents used to reduce blood sugar levels

The following *durable medical equipment (DME)* is considered eligible for coverage:

- Insulin aids, including insulin drawing devices for the visually impaired
- Standard blood glucose monitors (E0607)
- Specialized blood glucose monitors, including but not limited to non-invasive or subcutaneous
- Blood glucose monitors for the visually impaired
- Diabetes data-management systems for management of blood glucose
- Insulin infusion devices
- Insulin pumps (E0784)

Continuous Glucose Monitoring

Professional glucose monitoring (95249, 95250, 95251)

Professional continuous glucose monitoring may be used as an adjunct to standard care for diabetic patients meeting the following criteria:

- Recurrent unexplained or unpredictable hypoglycemia or hyperglycemia despite multiple daily finger-stick monitoring
- There is discordant data from finger-stick and HgbA1c testing

Professional continuous glucose monitoring is performed under physician supervision. The sensor is typically inserted, and data collection begins while the patient is in the office. After a minimum of 72 hours of wear, the patient returns to the office, at which time the sensor is removed, data is downloaded, and a printout is obtained for review. It is expected that the results derived from such monitoring will be used to direct changes in diabetic management, resulting in improved treatment regimens and glycohemoglobin measurements.

Professional glucose monitoring is conducted after a minimum of 72-hours of wear. It may be repeated at a subsequent time depending on the patient's level of diabetic control.

Services for professional glucose monitoring should be billed using the above-listed codes with reporting no more than once per month per code. Associated technical services including, but not limited to, monitor applications, sensors, patient training, removal of monitor, and data, downloading are included in the reimbursement for ambulatory subcutaneous continuous blood glucose monitoring (95249, 95250).

The interpretation and reporting (95251) of data from a patient-owned continuous glucose monitor may be reported once every 30 days.

Continuous Glucose Monitors (CGM) With or Without Combined/Integrated Insulin Pump (E0784, A9276, A9277, A9278, S1034, S1035, S1036, S1037, A4238, E2102, E2103, A4239)

CDPHP considers continuous glucose monitoring, alone or in combination with an external insulin pump, medically necessary to detect trends and patterns in glucose levels over time to optimize glycemic control and reduce incidences of hyperglycemia and hypoglycemia in patients with diabetes.

CDPHP administers benefits for personal use of a continuous glucose monitoring device for individuals with diabetes (type I, type II, gestational, etc.) meeting the following criteria:

General Requirements

- Member demonstrates adherence to a physician-ordered diabetic treatment plan.
- Members who are initiating pump therapy for the first time must meet the criteria for an insulin infusion pump (please see External Ambulatory Insulin Infusion Pump, 1370/20.000457), as well as the criteria in this policy for continuous glucose monitors, when seeking approval for combined [CGM + pump] devices)
- The age of the patient is consistent with US FDA indications for the specific CGM device

Implantable Continuous Glucose Monitor (I-CGM) (0446T, 0447T, 0448T)

CDPHP considers implantable CGM's (i.e., Eversense) medically necessary for members who meet criteria for a continuous glucose monitor as noted above and one of the following:

- Physical disability, such as an impairment in vision, hearing, or dexterity;
- Any significant condition or situation requiring vibration alerts (e.g., patient lives alone and requires additional alarms to increase awareness of highs or lows).

Diabetic Education (G0108, G0109, S9465)

CDPHP administers benefits for diabetes self-management and training program rendered in an outpatient or office-based setting to include education regarding the following:

- Monitoring of blood glucose
- Nutrition
- Exercise
- Insulin treatment plan developed specifically for the patient who is insulin-dependent

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

The enrollee may self-refer for diabetes education counseling.

CDPHP administers benefits for diabetic educational counseling when all of the following criteria are met:

- The services are provided by a physician or hospital, registered dietitian (ADA), certified nutritionist, or certified diabetes educator (National Certification Board for Diabetes Educators).
- The services are medically necessary for the medical management of diabetes.
- Diabetic nutrition assessment/session must include nutritional counseling plus the evaluation of the diabetic condition, including history and examination as indicated, review of medical management, evaluation of appropriate diagnostic tests and procedures, and recommendations for the adjustment of therapeutic management. It must also include the calculation of selected nutrients/energy intake, such as carbohydrates, protein, fat, and kilocalories.
- CDPHP expects the registered dietitian, certified nutritionist, or certified diabetes educator will submit a consult report of education services to the physician managing the member's care.
- Diabetic education sessions are subject to applicable office visit cost-share as stated in the enrollee's contract.

Claims for diabetic education should be submitted using HCPCS codes S9465, G0108, or G0109. Codes G0108 and G0109 are to be billed in increments of 30 minutes per unit.

CDPHP will not separately reimburse for evaluation and management codes (99202-99239, 99281-99359) in conjunction with diabetes education (G0108, G0109, S9465) when billed by the same provider for the same date of service.

Diabetes Prevention Program (0403T, 0488T)

CDPHP administers benefits for members with pre-diabetes to participate in a recognized diabetes prevention lifestyle change program to help prevent or delay the onset of type 2 diabetes. The diabetes prevention program is a yearlong program to assist individuals in making real lifestyle changes such as eating healthier, incorporating physical activity into their daily lives, and improving problem solving and coping skills.

- *Refer to specific member contracts for availability of benefits relating to this program.*

Eye Exams for Diabetics

CDPHP administers benefits for vision care for enrollees with a diagnosis of diabetes to include:

- A self-referral for up to one routine diabetic eye examination once every 12 months.

Therapeutic Shoes for Diabetics A5500, A5501, A5503-A5507, Therapeutic Shoe Inserts: A5512, A5513, A5514

CDPHP administers benefits for therapeutic shoes, inserts, and/or modifications to therapeutic shoes that aid in the healing process and prevent further diabetic foot disease when all of the following criteria are met:

1. Patient is a diabetic; and

Description	ICD-10 codes effective 10/1/2015
Diabetes	E08.00-E13.9, O24.011-O24.93

2. Patient is being treated under a comprehensive plan of care for diabetes; and

3. Patient has one or more of the following conditions in one or both feet:
   - Partial or complete foot amputation
   - History of previous foot ulceration
   - History of pre-ulcerative calluses
   - Peripheral neuropathy with evidence of callus formation
   - Foot deformity
   - Poor circulation

For patients meeting above criteria, coverage is limited to one of the following within one calendar year:

- One pair of depth-inlay shoes (A5500) and three pairs of inserts (A5512, A5513, A5514) (not including the non-customized removable inserts provided with such shoes); **or**
- One pair of custom-molded shoes (A5501) (which includes inserts provided with these shoes) and two additional pairs of inserts (A5512, A5513, A5514).

A custom-molded shoe is indicated when the patient has a foot deformity that cannot be accommodated by a depth shoe.

A modification of a custom-molded or depth shoe may be covered as a substitute for an insert. Examples of the most common shoe modifications are rigid rocker bottoms (A5503), roller

bottoms (A5503), wedges (A5504), metatarsal bars (A5505), or offset heels (A5506). Other modifications to diabetic shoes (A5507) include flared heels. Payment for the modification(s) may not exceed the limit set for the inserts for which the individual is entitled.

A deluxe feature of a diabetic shoe (A5508) does not contribute to the therapeutic function of the shoe, and therefore is not covered.

Compression molding inserts (A5510) are considered non-covered, as they do not require total contact with the patient's foot at the time of fitting, but rather are molded to the patient's foot over time through the heat and pressure generated by wearing a shoe with the insert present.

Foot Orthotics

- CDPHP will provide coverage for custom foot orthotics (L3000-L3030) in lieu of therapeutic shoe inserts (A5512, A5513, A5514) for enrollees who meet all the criteria (1-3) outlined in the section above, *Therapeutic Shoes for Diabetics.*
- Benefits are limited to one pair of custom foot orthotics or three pairs of therapeutic shoe inserts within one calendar year.

Over-the-counter shoe inserts are not considered to be custom foot orthotics, and therefore, are not eligible for reimbursement.

Claims submitted for custom foot orthotics (L3000-L3030) will be processed as diabetic durable medical equipment when the enrollee has a diagnosis of diabetes and all of the required criteria (1-3) outlined in the section above are met.

Foot orthotics and shoe inserts (L3000-L3030, A5512-A5514) must be billed with modifier KX to ensure that coverage criteria are met, and that documentation exists to support the medical necessity.

EXCLUSIONS

Equipment repair or replacement due to misuse, neglect, and/or loss.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy with the following exception: The Diabetic Prevention Program (DPP) is not a covered benefit.

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy with the following exceptions: <u>Continuous Glucose Monitoring</u> E2103 (Non-adjunctive, non-implanted continuous glucose monitor or receiver) & A4239 (Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service) continuous glucose monitoring may be covered by Medicare when all the following criteria are met: 1. The beneficiary has diabetes mellitus; and, 2. The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription; and, 3. The CGM is prescribed in accordance with its FDA indications for use; and, 4. The beneficiary for whom a CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below: A. The beneficiary is insulin-treated; or, B. The beneficiary has a history of problematic hypoglycemia with documentation of at least one of the following: 1. Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or, 2. A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia 5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or Medicare-approved telehealth visit with the beneficiary to evaluate their diabetes control and determined that criteria (1)-(4) above are met E2102 (Adjunctive, non-implanted continuous glucose monitor or receiver) & A4238 (Supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service) are a covered benefit when:

- the above criteria is met AND the coverage criteria for an external insulin infusion pump is met as well (*please see External Ambulatory Infusion Pump, 1370/20.000457*)

***(Codes A9276, A9277 & A9278 are non-covered by Medicare)

As per NY Local Coverage Article, A52464, continuous glucose monitors (CGMs) are covered under the Durable Medical Equipment (DME) benefit [Social Security Act §1861(s)(6)].

Implantable Continuous Glucose Monitor (I-CGM) (0446T, 0447T, 0448T)

Therapeutic I-CGMs are considered reasonable and necessary by Medicare when all of the following coverage criteria (1-4) are met:

1. The beneficiary has diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and,
2. The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's caregiver) has sufficient training using the I-CGM prescribed as evidenced by providing a prescription; and,
3. The I-CGM is prescribed in accordance with its FDA indication for use; and,
4. The beneficiary for whom a I-CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below:
    A. The beneficiary is insulin-treated; or,
    B. The beneficiary has a history of problematic hypoglycemia with documentation of at least one of the following:
        i. Recurrent (more than one) level 2 hypoglycemic events (glucose < 54mg/dl (3.0mmol/L)) that persists despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or,
        ii. A history of one level 3 hypoglycemic event (glucose < 54mg/dl (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia.

I-CGM devices will not be considered reasonable and necessary for the following:

1. Short-term I-CGM (72 hours to 1 week) for diagnostic use.

<u>Medicare Diabetes Prevention Program</u>

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

Benefits are provided for the Medicare diabetes prevention program (MDPP) as outlined below.

The MDPP is a structured intervention with the goal of preventing type 2 diabetes in individuals with an indication of prediabetes.-The program consists of a minimum of 16 intensive "core" sessions of a Centers for Disease Control and Prevention (CDC) approved curriculum furnished over six months in a group-based, classroom-style setting that provides practical training in long-term dietary change, increased physical activity, and behavior change strategies for weight control. After completion of the core sessions, less intensive follow-up meetings are furnished monthly to help ensure participants maintain healthy behaviors. The primary goal of the program is at least 5-percent weight loss by participants.

Codes:

Code	Descriptor
G9886	Behavioral counseling for diabetes prevention, in-person, group, 60 minutes
G9887	Behavioral counseling for diabetes prevention, distance learning, 60 minutes
G9880	5 percent WL Achieved from baseline weight
G9881	9 percent WL Achieved from baseline weight
G9888	Maintenance 5 percent WL from baseline in months 7-12

Core Sessions:

- Beneficiaries may attend up to 16 weekly sessions during months 1-6 of the MDPP Core Services period.
- The MDPP Core Services period starts with the first claim for G9886 or G9887. Beneficiaries must attend one core session to initiate MDPP services.
- A supplier is paid based on the beneficiary's attendance, regardless of the beneficiary's weight loss.
- A supplier is paid performance payments if the beneficiary achieves weight-loss goals.

Core Maintenance Sessions:

- Beneficiaries may attend up to 6 monthly sessions during months 7-12 of the MDPP Core Services period.
- A supplier is paid based on the beneficiary's attendance, regardless of the beneficiary's weight loss.
- A supplier is paid performance payments if the beneficiary achieves weight-loss goals and/or continues to meet the 5% weight-loss goal at each session

Key Points to Remember:

- Three G-codes can be used when submitting claims for beneficiary achievement of performance milestones: 1) 5% weight loss (G9880), 2) 9% weight loss (G9881), and 3) maintenance of 5% weight loss in a core maintenance session (G9888).
- Note that codes G9880 and G9888 cannot be used with the same date of service (DOS), and the DOS for code G9880 must occur prior to any DOS submitted for G9888. Claims for G9888 will be rejected if 1) there is no claim for G9880 with a DOS prior to claim for G9888 and 2) DOS for G9888 is within the first 6 months of the MDPP services period.
- Suppliers may bill for a maximum of 22 sessions, including up to 16 weekly sessions in months 1-6, and up to 6 monthly sessions in months 7-12.
- Suppliers must use one of two G-codes (G9886 or G9887) when filing claims for attendance payments after every core and core maintenance session furnished to an MDPP beneficiary. Once 22 sessions have been paid for a beneficiary, any additional claims with DOS after the 22nd paid claim will be rejected, including out-of-sequence claims.
- Each HCPCS G-code should be listed with the corresponding session DOS, MDPP organizational NPI, and rendering provider NPI. Note that the coach is the rendering provider on the claim

Medicare Advantage members are eligible for MDPP services when all the following criteria are met:

- Enrolled in Medicare Part B
- Body mass index (BMI) of at least 25 (23 if self-identified as Asian) on the date of the first core session
- Meet 1 of 3 blood test requirements within the 12 months prior to

	attending the first core session: ○ A hemoglobin A1c test with a value between 5.7% and 6.4%, or ○ A fasting plasma glucose of 110-125 mg/dL, or ○ A 2-hour plasma glucose of 140-199 mg/dL (oral glucose tolerance test) • No previous diagnosis of diabetes prior to the date of the first core session (with exception of gestational diabetes) • Do not have end-stage renal disease (ESRD) • Have not previously received MDPP services (program is once-per-lifetime limit) Members may self-refer to a MDPP as a physician referral is not required. <u>Diabetes Self-Management Training</u> Benefits are provided for diabetes self-management training rendered by a participating provider (refer to section on *Diabetic Education*) for newly diagnosed diabetics up to 10 hours during a continuous 12-month period and up to two hours follow-up training in subsequent years. Diabetes self-management training is not subject to an office visit cost-share, as stated in the enrollee's contract. Benefits for Medicare Part D prescription drugs are available only to enrollees who have elected the CDPHP Medicare Advantage product with the Part D option. The CDPHP Medicare Advantage product does not cover any prescription drugs not covered by Medicare. In addition, for those individuals enrolled in the CDPHP Medicare Advantage product who have not elected the Part D option, CDPHP covers only those prescription drugs covered by Medicare Parts A and B, not those covered by Part D.
SELECT PLAN/HARP:	Subject to all terms and conditions noted above in the policy with the following exceptions: CDPHP utilizes the New York State Medicaid Management Information System Provider Manual (MMIS) to determine a medical or surgical supply versus durable medical equipment, orthotic, or prosthetic. Durable medical equipment is not subject to a deductible or copayment. Benefits are provided for medically necessary medical supplies, including insulin

	and diabetic supplies. Medically necessary prescription footwear and shoe modifications and additions are a covered benefit. Prescription footwear applies to all "L" codes listed in the prescription footwear section of the MMIS provider manual (4.6), as well as codes for diabetic shoes. Enrollees diagnosed with diabetes may self-refer to any participating provider of vision services (optometrist or ophthalmologist) for a dilated eye (retinal) examination once in any 12-month period. Continuous Glucose Monitoring (CGM) CDPHP utilizes the New York State Medicaid Management Information System (MMIS) Durable Medical Equipment Manual (section 4.1- Medical/Surgical Supplies) for coverage guidance: https://www.emedny.org/ProviderManuals/DME/PDFS/DME_Procedure_Codes.pdf Benefits are provided for adjunctive and non-adjunctive continuous glucose monitoring when criteria is met and should be billed to Medicaid Fee for Service. Diabetic Self-Management Training (DSMT) Benefits are provided for DSMT when rendered in a hospital outpatient department or free-standing diagnostic and treatment center and by one of the following NYS licensed, registered, or certified professionals affiliated with a DSMT program: • Registered Nurse • Registered Nurse Practitioner • Registered Dietician • Physician (MD or DO) • Pharmacist • Physician Assistant • Physical Therapist • Clinical Psychologist • Optometrist • Occupational Therapist • Podiatrist

	DSMT services are also allowed in an office-based setting when provided by one of the above licensed, registered, or certified health care professionals who is also certified as a Certified Diabetes Education (CDE) by the Certified Diabetes Care and Education Specialist (CBDCE). DSMT is covered for enrollees that are newly diagnosed with diabetes, have stable diabetes, or have diabetes with a medically complex condition such as poor diabetes control or another complicating factor. No more than 10 hours for newly diagnosed enrollees or enrollees with a medically complex condition will be allowed during a continuous six-month period. Enrollees with diabetes who are medically stable may receive up to one hour of DSMT in a continuous six-month period. DSMT services may be provided in individual sessions, or in group sessions of no more than eight patients. National Diabetes Prevention Program (NDPP) Services (0403T, G9880) This is an educational and support program designed to assist at-risk people from developing Type 2 diabetes. The program consists of group training sessions that focus on the long-term, positive effects of healthy eating and exercise. The goals for these lifestyle changes include modest weight loss and increased physical activity. NDPP sessions are taught using a trained lifestyle coach. • *Refer to specific member contracts for availability of benefits relating to this program.*

SOURCES

1. CDPHP Technology Assessment Team
2. NYS Diabetic Mandate
3. Other Payors
4. Contract Clarification
5. New York State Medicaid Redesign Team: Medicaid Managed Care Benefit Changes, 2011-2012, www.health.ny.gov
6. Medicare Diabetes Prevention program (MDPP) Expanded Model, https://innovation.cms.gov/initiatives/medicare-diabetes-prevention-program/Bode B, Gross

T, Thornton K, Mastrototaro J; Continuous Glucose Monitoring Used to Adjust Diabetes Therapy Improves Glycosylated Hemoglobin: A Pilot Study. Diabetes Research and Clinical Practice. 46 (1999) 183-190. Review.

7. Mastrototaro J, Levy R, Georges L-P, White M, Mestman J; Clinical Results from a Continuous Glucose Sensor Multi-Center Study. Journal of the American Diabetes Association. Diabetes Abstract Book, 59th Scientific Sessions June 1998. Abstract #0238.
8. Department of Health Division of Managed Care Response to Coverage Question for the Omnipod
   Diabetes Management System, Reference number: MA-00562, 7/22/10.
9. Wooldridge, J; Bergeron, J; Thorton, C: Preventing Diabetic Foot Disease: Lessons from the Medicare Therapeutic Shoe Demonstration. American Journal of Public Health, July 1996, 86(7), pp.
   Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity and Adults - The Evidence Report. The National Heart, Lung and Blood Institute (NHLBI) – National Institutes of Health. June 1998.
10. American Diabetes Association: Clinical Practice Recommendations 2000, www.diabetes.org.
11. Medicare Explained Part B Benefits section 370
12. New York State Department of Health: www.health.state.ny.us
13. DMERC Region A Medical Review Policy: Therapeutic Shoes for Patients with Diabetes, http://www.umd.nycpic.com/leavingRegionA_lmrp.html
14. Medicare Modernization Act, 2003.
15. GlucoWatch G2 Biographer Glucose Monitoring System Important Product News, http://www.glucowatch.com/
16. Division of Managed Care Response to Coverage Question. Reference number: MA-00552, response 2/9/10.
17. Provider (MMIS) Manual to the New York Medicaid, DME Manual, https://www.emedny.org/ProviderManuals/DME/index.aspx
18. NYS Department of Health Update, Policy and Billing Guidance: NYS Medicaid Expands Coverage to include Real Time Continuous Glucose Monitors for Individuals with Type I Diabetes, October 2017, https://www.health.ny.gov/health_care/medicaid/program/update/2017/oct17_mu.pdf
19. CMS Medicare Learning Network (MLN) Matters (MM)10436: New "K" Code for Therapeutic Shoe Inserts, https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10436.pdf
20. CMS Guidance Letter: Medical Supplies Associated with the Injection of Insulin, 1/5/18.
21. NYS Department of Health Update: Reimbursement of Continuous Glucose Monitoring for Individuals with Type I Diabetes, https://www.emedny.org/ProviderManuals/communications/CGM_Update_-_5-16-18.pdf
22. NYS DOH update https://www.health.ny.gov/health_care/medicaid/program/update/2021/no05_2021-04.htm#monitors

23. NYS DOH Update January 2022 Volume 38 https://health.ny.gov/health_care/medicaid/program/update/2022/no01_2022-01.htm#glucose

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POLICY APPROVAL DATES

New: 04/90

Revised: 10/92, 07/93, 12/94, 09/96, 03/98, 06/99, 07/99, 10/99, 06/00, 12/00, 01/01, 09/01, 01/02, 09/02, 04/03, 01/04, 06/05, 09/05, 11/05, 12/05, 09/07, 01/08, 01/09, 03/09, 09/09, 11/09, 01/10, 07/10, 01/11, 03/11, 09/11, 01/12, 01/13, 05/13, 01/14, 03/14, 05/14, 07/14, 09/14, 01/15, 07/15, 01/16, 07/17, 11/17, 01/18, 03/18, 05/18, 07/18, 11/18, 01/19, 01/20, 3/20, 7/20, 01/21, 03/21, 5/21, 7/21, 9/21, 11/21, 1/22, 3/22, 5/22, 7/22, 9/22, 11/22, 1/23, 3/23, 5/23, 11/23, 1/24, 5/24, 7/24, 1/25, 7/25, 9/25, 3/26

Reviewed: 10/95, 12/06, 01/17, 1/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
4/1/2026	Removed insulin requirement for CGM's and exclusion of CGM's for diagnosis of gestational diabetes.
10/1/2025	Updated CGM verbiage to indicate "insulin dependent" only. Removed Bridge payment code from Medicare Advantage section under Medicare Diabetes Prevention Program (MDPP). This payment was removed by CMS effective 1/1/2025. Under Medicare section, added LCA information for CGM's.

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

2/1/2025* *No change to effective date for this update	Clarified in the Child Health Plus section that the Diabetic Prevention Program is not a covered benefit.
2/1/2025	Removed information for foot orthotics for vascular disease as this is now in the foot care policy. Updated CGM criteria. Added coverage for implantable CGM's and updated Medicare implantable CGM criteria per updated LCD.
1/1/2024* *No change to effective date for this update	Under the Foot Orthotics section added information that was in the Foot Care policy regarding coverage indications. Added information regarding billing KX modifier with codes L3000-L3030 and A5512-A5514.
1/1/2024* *No change to effective date for this update	Updated the coding requirements for the Medicare Diabetes Prevention Program (MDPP) in the Medicare Advantage section.
1/1/2024	Removed termed code G0308 and G0309.
11/1/2023	Under Medicaid section- since CGM's are billed to Medicaid FFS (part of Medicaid carve out eff 4-1-23) removed criteria and provided link for the MMIS that outlines the criteria.
10/1/2023	Under Medicaid section updated CGM requirements per DOH mandate.
4/16/2023	Under the Position Statement for Diabetes Prevention Program, added the codes to bill for these services. Under Medicaid added info for National Diabetes Prevention Program. Under Medicare, updated CGM criteria which is effective 4/16/23.
1/1/2023 *No change to effective date of policy	Under Medicaid section 1. added updated CGM codes and guidance for A9276, A9277, and A9278.
1/1/2023	Added new CPT codes E2103 and A4239 and removed deleted codes K0553 and K0554

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

8/1/2022* No change to effective date	Under Medicare section for the Diabetes Prevention Program, added codes G9890, G9891 which are allowable under the program.
8/1/2022* No change to effective date	Added information to the Medicare CGM's section regarding coverage as a stand-alone device.
8/1/2022	For custom foot orthotics, expanded code range to include codes between L3000-L3030. Under the Medicare section, added coverage for Implantable Continuous Glucose Monitors.
04/01/2022* No change to effective date	CMS coverage update: Effective 2/28/2022, CMS will allow for coverage of a non-therapeutic (adjunctive) continuous glucose monitor (CGM) when it is being used with an integrated insulin pump system. New HCPCS codes (E2102 and A4238) effective 4/1/2022 for adjunctive CGM added to policy.
04/01/2022	Revised Select Plan/HARP section to expand CGM coverage to now include members who have type 2 diabetes and gestational diabetes.
02/01/2022	Added additional verbiage to policy regarding providers who can prescribe equipment, supplies, oral agents, and insulin: -"or other licensed Health Care Professional legally authorized to prescribe under Title 8 of the New York Education Law" Removed verbiage in the body of the policy that implantable monitors/implantable CGM devices are considered covered DME as these are listed under the exclusions section. Relocated CGM's for gestational diabetes to the exclusions section and removed the following exclusion: -Personal subcutaneous continuous blood glucose monitoring for children with diabetes
12/1/2021	Added quantity limits for diabetic test strips.
7/18/2021	Updated CGM criteria in the Medicare Advantage section in accordance with Medicare LCD update.

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

7/1/2021	Updated Select Plan/HARP section: effective 7/1/21, as per DOH updated guidance April 2021, CGM criteria changed to allow an enrolled Medicaid provider with experience in diabetes treatment to order the device and changed criteria of performing at least "four" finger stick glucose tests daily to "multiple". In addition, effective 4/1/2021, expanded the list of practitioners able to provide Diabetes Self-Management Training and clarified enrollees that are eligible for such training under Select Plan/HARP.
5/1/2021 (Effective date on policy remains the same)	In the Position Statement added verbiage in regards to code 95251 that was previously housed in the External Ambulatory Insulin Infusion Pump policy.
5/1/2021	Removed information under Medicaid in regards to National Diabetes Prevention Program (NDPP) as this language is now in the 2021 Member Handbook. Removed verbiage under Medicaid and Medicare in regards to Omnipod insulin pumps and V-Go insulin delivery systems as this information is housed in the External Ambulatory Insulin Infusion Pump policy.
4/1/2021	Updated verbiage in section on continued glucose monitoring to indicate a minimum of 72 hours.
7/15/20	Updated policy to include coverage of CGM for Type II diabetics when criteria in policy is met.
2/1/20 (Effective date on policy remains the same)	Added statement to Select Plan section to address coverage of Omnipod/Omnipod Dash as an acceptable alternative to an external ambulatory insulin infusion pump.
2/1/2020	Removed termed code K0903 and added code A5514 for shoe inserts. Removed requirement of finger sticks for individuals prescribed a therapeutic continuous glucose monitor. Made the following changes to the Select Plan section: • Added coverage for National Diabetes Prevention Program (NDPP) • Removed exclusion statement for non-coverage of Omnipod.

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: DIABETIC SERVICES: SUPPLIES, PHARMACEUTICALS, EQUIPMENT, EYE EXAM, EDUCATION, AND SHOES

	Added Omnipod Dash to the Medicare Section to the list of insulin delivery devices covered under Part D.

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MEDICAL POLICY

Medical Policy Title	**Disability Determination for Extension of Benefits After Coverage Termination**
Policy Number	**10.01.11**
Current Effective Date	**November 1, 2026**
Next Review Date	**August 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. For purposes of determining an individual's eligibility for an extension of benefits due to total disability upon termination of coverage, a Medical Director of the Health Plan will determine whether the individual was totally disabled before and on the date of termination. To request a total disability determination, the treating physician must submit certification of the former member's total disability at the time of termination and must include evidence that the total disability existed prior to the termination.

II. The Health Plan's Medical Director will base his/her disability determination upon the review of the former member's medical records and, if deemed necessary, discussion between the treating physician and the Health Plan's Medical Director or his/her appointed designee. In conducting the review, the Health Plan's Medical Director will be guided by the medical criteria stated in the Disability Evaluation under Social Security (Blue Book), published by the U.S. Social Security Administration.

III. When the Health Plan's Medical Director determines, in his/her sole discretion, that a former member was totally disabled prior to and at the time of termination of coverage, benefits will be provided only for services directly related to the total disability, assuming that the former member is otherwise eligible for an extension of benefits.

RELATED POLICIES

Not Applicable

POLICY GUIDELINE(S)

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

I. In order to be considered for an extension of benefits due to total disability after termination of coverage, the total disability must have existed prior to termination of the contract.

II. Extensions of benefits differ, depending upon whether a former member loses coverage under a group contract or individual contract and the reason for the loss of coverage. Please refer to the specific paragraph(s) in the Description section below for guidance.

DESCRIPTION

Under the Health Plan's subscriber contracts and certificates, when a member's coverage ends, benefits stop. However, when a Health Plan Medical Director determines that a former member is totally disabled on the date coverage terminates, and that the former member received services or care for the illness, condition, or injury that caused his or her total disability while covered under the subscriber contract, extended benefits may be available as follows.

Group Coverage Termination

I. When an individual who was covered under an insured group contract is determined to be totally disabled as of the date coverage terminates, extended benefits may continue for covered services to treat the total disability, if **ONE** of the following applies:

   A. Termination of employment, eligibility, or contract: When a former member's coverage is terminated due to termination of employment or termination of eligibility, or due to termination of the group contract, extended benefits will be provided during a period of total disability for a hospital stay commencing, or surgery performed, within 31 days from the date the coverage ended. The hospital stay and/or surgery must be for treatment of the injury, sickness, or pregnancy that caused the total disability.

   B. Termination of active employment: Unless coverage is provided for services in connection with the total disability under another health plan, if group coverage providing major medical-type benefits ended because the former member was no longer actively employed, extended benefits will be provided during a period of total disability for at least 12 months from the date coverage ended, but only for covered services to treat the injury, sickness, or pregnancy that caused the total disability.

II. Extended benefits terminate when all the benefits available have been exhausted, when a Health Plan Medical Director or his/her designee determines that the member is no longer totally disabled, or the maximum time period or the extended services have ended. The Health Plan will never provide more benefits than would have been provided, had the member remained covered under the contract.

Individual Coverage Termination

I. When an individual who was covered under an insured individual policy is determined to be totally disabled as of the date coverage terminates, benefits to treat the total disability will extend for 12 months or, if earlier, the end of the total disability.

Please refer to the former member's subscriber contract for the specific benefit extension that may be available to the former member.

SUPPORTIVE LITERATURE

Not Applicable

PROFESSIONAL GUIDELINE(S)

Not Applicable

REGULATORY STATUS

Under the New York State Insurance Regulations, certain benefits are required to be extended for a former Health Plan member who is totally disabled at the time coverage is terminated, but only when all of the requirements are met.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
No specific code(s)	

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HCPCS Codes

Code	Description
No specific code(s)	

ICD10 Codes

Code	Description
No specific code(s)	

REFERENCES

New York State Department of Financial Services. Compilation of Codes, Rules, and Regulations of the State of New York. (11 NYCRR §§ 52.17 (a)(15), 52.18 (b). Rules relating to content of forms for individual and group insurance.

Social Security Administration Office of Disability [internet]. Disability evaluation under Social Security. SSA Pub 64-039. 2008 Sep [accessed 2026 Jun 29]. Available from: https://www.ssa.gov/disability/professionals/bluebook/

SEARCH TERMS

Not applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Extension of benefits for total disability after disenrollment from Medicare is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 7/26

Revised:

Reviewed:

Date	Summary of Changes
11/1/2026	• New

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care for enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Duchenne muscular dystrophy (DMD) is a fatal X-linked genetic disorder that results in progressive and irreversible loss of muscle function, including the heart and lungs. Due to the X-linked nature of the disease, it almost exclusively affects males. In the United States, there are approximately 20,000 males with DMD which corressponds to one in 3,500-5,000 newborn boys. There is a poor prognosis to this condition; most patients with DMD are wheelchair bound by age 12, require breathing support by age 20, and die by age 30 due to respiratory or cardiac failure.

DMD is caused by mutations in the gene that encodes the dystrophin protein, a protein necessary for normal muscle maintenance and function. The most common mutations associated with DMD are large deletions where one or more exons are missing from the gene. The most common deletions are concentrated between exons 45 and 53. Approximately 13 percent of all DMD patients have mutations in exon 51, while about 8 percent of DMD patients have mutations in exon 53, and another 8 percent have mutations in exon 45.

Symptom management was the standard of care, and included corticosteriods because of their anti-inflammatory and immunomodulatory effects. Current FDA approved therapies for DMD inlcude the corticosteroid treatments Emflaza (deflazacort) and Agamree (vamorolone), the non-steroidal, histone deactylase inhibitor, Duvyzat (givinostat) as well as exon-skipping therapies including Exondys 51 (eteplirsen), Vyondys 53 (golodirsen), Viltepso (vitolarsen), and Amondys 45 (casimersen). The mechanism of exon-skipping therapy involves targeting the dystrophin mRNA, which allows for skipping of the mutated exons of the DMD gene that disrupts the downstream protein synthesis and nonfunctional dystrophin protein. Despite this innovative mechanism, there is little data to support that the demonstrated restoration of dystrophin slows the progression of the disease. In addition, the clinical benefits of these exon-skipping therapies have yet to be established.

Exondys 51 (eteplirsen) is an antisense oligonucleotide (ASO) developed as treatment for patients with DMD who have mutations in the gene encoding for dystrophin that are amenable to exon 51 skipping. Gene mutations with other exon deletions (e.g., exon 52 or exon 50) are also considered amenable to exon 51 skipping and therefore add to the potential eligible population for this treatment strategy. Exondys 51 was approved under the FDA accelerated approval pathway. This occurred despite the FDA Advisory Committee's recommendation against FDA approval. The approval was based on surrogate marker data; specifically, changes in treated-patient dystrophin levels compared to unmatched, historical disease-progression data from prior publications. No significant clinical improvements were identified. Therefore, continued approval for Exondys 51 is contingent upon demonstration of clinical benefit in confirmatory trials.

Vyondys 53 (golodirsen), also an antisense oligonucleotide, was developed as an exon 53-skipping agent for patients with DMD who have mutations in the gene encoding for dystrophin that are amenable to exon 53 skipping. As with Exondys 51, gene mutations with other exon deletions are considered ammenable to exon 53 skipping, and add to the eligible population. Furthermore, this agent was also approved under an accelerated approval based on an increase in dystrophin production in skeletal muscle. Therefore, continued approval is contingent upon demonstration of clinical benefit in confirmatory trials.

Viltepso, similar to Vyondys 53, is an antisense oligonucleotide, exon 53-skipping agent. It is indicated for patients with DMD who have mutations in the gene for dystrophin that are amendable to exon 53-skipping. This agent was approved under accelerated approval based on its ability to increase dystrophin levels. Notably, the initial published results for this agent have shown potential to increase dystrophin levels at a higher rate than Vyondys in a comparable patient population. While Vyondys demonstrated a dystrophin level change from 0.1% of normal at baseline to 1.02% of normal at the conclusion of the trial, Viltepso showed a change from 0.6% at baseline to 5.3% at the conclusion of the trial. Based on the lack of clinical significance of this data, continued approval for Vyondys is contingent upon demonstration of cinical benefit in confirmatory trials.

Amondys 45 (casimersen) is indicated for patients with DMD who have a confirmed mutation of the DMD gene that is amenable to exon 45 skipping. This specific mutation represents approximately 8% of the DMD patient population. The ESSENCE trial is currently underway with a completion date scheduled for April of 2024. Of note, the primary outcome of this trial is change in baseline in total distance walked during a 6-minute walk test (6MWT) at week 96 which presents the opportunity for findings with clinical application. Preliminary results have been discussed which indicate a subset of patients analyzed after 48 weeks of treatment had a mean dystrophin increase of 0.811%.

Summary	
Effective Date of Policy	8/13/2026
Indications	Duchenne Muscular Dystrophy
ICD10 Diagnosis Codes	G70
Availability	Eteplirsen: Solution for injection: 50 mg/mL Viltolarsen: Solution for injection: 50 mg/mL Golodirsen: Solution for injection: 50 mg/mL Casimersen: Solution for injection: 50 mg/mL
HCPCS codes	Exondys 51: J1428; Vyondys 53: J1429; Viltepso: J1427; Amondys 45: J1426
Duration	Initial approval: Three (3) months Continuation approval: Six (6) months

Required Criteria for Approval

All of the following conditions for the requested indication must be met in order to approve EXONDYS 51 (Eteplirsen), Viltepso (Viltolarsen), Vyondys 53 (Golodirsen), Amondys 45 (Casimersen) or any new ASO market entrant for the treatment of DMD:

Indication

Amondys 45 (casimersen)

Duchenne Muscular Dystrophy (FDA approval)
ICD10: G70

HCPCS: J1426

Criteria for Approval

1. Must have a diagnosis of DMD with a confirmed mutation of the DMD gene that is amenable to exon 45 skipping (see table below) **AND**

Exon 45 skip-amenable deletion mutation range[1,2]			
7-44	46-47	46-55	46-69
12-44	46-48	46-57	46-75
18-44	46-49	46-59	46-78
44	46-51	46-60	
46	46-53	46-67	

2. Must be on a stable dose of corticosteroids for at least 6 months prior to therapy or a documented reason not to be on corticosteroids **AND**
3. Documentation must indicate kidney function testing prior to starting therapy **AND**
4. Patient must not concurrently be on another exon skipping therapy for DMD **AND**
5. Amondys 45 will not be approved for use in patients that have previously been treated with Elevidys **AND**
6. All the below criteria must be met <u>(The below criteria are NOT applicable to Medicaid Managed Care)</u>
    a. Prescribed by or in consultation with a provider who specializes in the treatment of Duchenne Muscular dystrophy (DMD) and/or neuromuscular disorders **AND**
    b. The patients must be ambulatory and must have a baseline unassisted 6-minute walk test (6MWT) of at least 300 meters **AND**
    c. Must have stable cardiac function with left ventricular ejection fraction (LVEF) of > 40% **AND**
    d. Must have stable pulmonary function with forced vital capacity ≥ 50% of predicted and not require supplemental oxygen **AND**
    e. Dose must not exceed 30mg/kg infused over 35-60 minutes, once weekly **AND**
    f. Initial approval for new starts will be for 3 months.
    g. Continued approval in non-new starts for additional 6-month periods will require recent documentation that the patient continues to remain ambulatory with an unassisted 6MWT of at least 100 meters. In addition, the patient must meet the following criteria (Progress notes/test results must be dated after the most recent drug approval and within 3 months of the continuation period that is being requested):
        i. Must have stable cardiac function with left ventricular ejection fraction (LVEF) of > 40% **AND**
        ii. Must have stable pulmonary function with forced vital capacity ≥ 50% of predicted and not require supplemental oxygen **AND**
        iii. Must have a < 5% annual decline in percent predicted FVC (FVC% p)

Exondys 51 (eteplirsen)

Duchenne Muscular Dystrophy (FDA approval)
ICD10: G70

HCPCS: J1428

1. Must have a diagnosis of DMD with a confirmed mutation of the DMD gene that is amenable to exon 51 skipping (see below table) **AND**

Exon 51 skip-amenable deletion mutation range [12]			
3-50	19-50	33-50	47-50
4-50	21-50	34-50	48-50
5-50	23-50	35-50	49-50
6-50	24-50	36-50	50
9-50	25-50	37-50	51
10-50	26-50	38-50	52
11-50	27-50	39-50	52-61
13-50	28-50	40-50	52-63
14-50	29-50	41-50	52-64
15-50	30-50	42-50	52-66
16-50	31-50	43-50	52-76
17-50	32-50	45-50	

2. Must be on a stable dose of corticosteroids for at least 6 months prior to therapy or a documented reason not to be on corticosteroids **AND**
3. Patient must not concurrently be on another exon skipping therapy for DMD **AND**
4. Exondys 51 will not be approved for use in patients that have previously been treated with Elevidys **AND**
5. All the below criteria must be met <u>(The below criteria is NOT applicable to Medicaid Managed Care)</u>
    a. Prescribed by or in consultation with a provider who specializes in the treatment of Duchenne Muscular dystrophy (DMD) and/or neuromuscular disorders **AND**
    b. The patient must be ambulatory with a baseline unassisted 6-minutewalk test (6MWT) of at least 200 meters **AND**
    c. Must have stable cardiac function with left ventricular ejection fraction (LVEF) of > 40% **AND**
    d. Must have stable pulmonary function with forced vital capacity ≥ 50% of predicted and not require supplemental oxygen **AND**
    e. Dose must not exceed 30mg/kg of body weight infused once weekly **AND**
    f. Initial approval for new starts will be for 3 months. Continued approval in non-new starts for additional 6-month periods will require documentation that the patient continues to remain ambulatory with an unassisted 6MWT of at least 100 meters. In addition, the patient must meet the following criteria (Progress notes/test results must be dated after the most recent drug approval and within 3 months of the continuation period that is being requested):
        i. Must have stable cardiac function with left ventricular ejection fraction (LVEF) of > 40% **AND**
        ii. Must have stable pulmonary function with forced vital capacity ≥ 50% of predicted and not require supplemental oxygen **AND**
        iii. Must have a < 5% annual decline in percent predicted FVC (FVC% p)

Viltepso (viltolarsen)

Duchenne Muscular Dystrophy (FDA approval) ICD10: G70

HCPCS: J1427

1. Must have a diagnosis of DMD with a confirmed mutation of the DMD gene that is amenable to exon 53 skipping (see below table) **AND**

Exon 53 skip-amenable deletion mutation range[12]			
3-52	21-52	35-52	50-52
4-52	23-52	36-52	52
5-52	24-52	37-52	53
6-52	25-52	38-52	54-58
9-52	26-52	39-52	54-61
10-52	27-52	40-52	54-63
11-52	28-52	41-52	54-64
13-52	29-52	42-52	54-66
14-52	30-52	43-52	54-76
15-52	31-52	45-52	54-77
16-52	32-52	47-52	
17-52	33-52	48-52	
19-52	34-52	49-52	

2. Must be on a stable dose of corticosteroids for at least 3 months prior to therapy or a documented reason not to be on a corticosteroid **AND**
3. Documentation must indicate kidney function testing prior to starting therapy **AND**
4. Patient must not concurrently be on another exon skipping therapy for DMD **AND**
5. Viltepso will not be approved for use in patients that have previously been treated with Elevidys **AND**
6. All the below criteria must be met <u>(The below criteria are NOT applicable to Medicaid Managed Care)</u>
    a. Prescribed by or in consultation with a provider who specializes in the treatment of Duchenne Muscular dystrophy (DMD) and/or neuromuscular disorders **AND**
    b. The patients must be ambulatory and must have a baseline unassisted 6-minute walk test (6MWT) of at least 250 meters **AND**
    c. Must have stable cardiac function with left ventricular ejection fraction (LVEF) of > 40% **AND**
    d. Must have stable pulmonary function with forced vital capacity ≥ 50% of predicted and not require supplemental oxygen **AND**
    e. Dose must not exceed 80mg/kg infused over 60 minutes, once weekly **AND**
    f. Initial approval for new starts will be for 3 months
    g. Continued approval in non-new starts for additional 6-month periods will require recent documentation that the patients continue to be ambulatory with an unassisted 6MWT of at least 100 meters. In addition, the patient must meet the following criteria (Progress notes/test results must be dated after the most recent drug approval and within 3 months of the continuation period that is being requested):
        i. Must have stable cardiac function with left ventricular ejection fraction (LVEF) of > 40% **AND**
        ii. Must have stable pulmonary function with forced vital capacity ≥ 50% of predicted and not require supplemental oxygen **AND**
        iii. Must have a < 5% annual decline in percent predicted FVC (FVC% p)

Vyondys 53 (golodirsen)

Duchenne Muscular Dystrophy (FDA approval)
ICD10: G70

HCPCS: J1429

1. Must have a diagnosis of DMD with a confirmed mutation of the DMD gene that is amenable to exon 53 skipping (see below table) AND

Exon 53 skip-amenable deletion mutation range [12]			
3-52	21-52	35-52	50-52
4-52	23-52	36-52	52
5-52	24-52	37-52	53
6-52	25-52	38-52	54-58
9-52	26-52	39-52	54-61
10-52	27-52	40-52	54-63
11-52	28-52	41-52	54-64
13-52	29-52	42-52	54-66
14-52	30-52	43-52	54-76
15-52	31-52	45-52	54-77
16-52	32-52	47-52	
17-52	33-52	48-52	
19-52	34-52	49-52	

2. Must be on a stable dose of corticosteroids for at least 6 months prior to therapy or a documented reason not to be on corticosteroids AND
3. Documentation must indicate kidney function testing prior to starting therapy AND
4. Patient must not concurrently be on another exon skipping therapy for DMD AND
5. Vyondys 53 will not be approved for use in patients that have previously been treated with Elevidys AND
6. All the below criteria must be met (The below criteria are NOT applicable to Medicaid Managed Care)
    a. Prescribed by or in consultation with a provider who specializes in the treatment of Duchenne Muscular dystrophy (DMD) and/or neuromuscular disorders AND
    b. The patient must be ambulatory must have a baseline unassisted 6-minutewalk test (6MWT) of at least 250 meters AND
    c. Must have stable cardiac function with left ventricular ejection fraction (LVEF) of > 50% AND
    d. Must have stable pulmonary function with forced vital capacity ≥ 50% of predicted and not require supplemental oxygen AND
    e. Dose must not exceed 30 mg/kg infused IV over 35 to 60 minutes, once weekly
    f. Initial approval for new starts will be for 3 months.
    g. Continued approval in non-new starts for additional 6-month periods will require documentation that the patient continues to be ambulatory with an unassisted 6MWT of at least 100 meters. In addition, the patient must meet the following criteria (Progress notes/test results must be dated after the most recent drug approval and within 3 months of the continuation period that is being requested):
        i. Must have stable cardiac function with left ventricular ejection fraction (LVEF) of > 50% AND
        ii. Must have stable pulmonary function with forced vital capacity ≥ 50% of predicted and not require supplemental oxygen AND
        iii. Must have a < 5% annual decline in percent predicted FVC (FVC% p)

Policy Guidelines

1. Amondys 45, Exondys 51, Vyondys 53, and Viltepso are administered as an IV infusion and will be covered under the medical benefit.
2. Amondys 45, Exondys 51, Vyondys 53, and Viltepso will not be approved for patients who have lost ambulation or who have LVEF or FVC% predicted test results that indicate severe decompensation. These medications have only been evaluated in ambulatory patients, and it is unknown if patients with more advanced disease and greater muscle deterioration would receive any benefit with treatment. Pivotal studies do not provide adequate support to determine if the drug provides clinical benefit related to cardiac and respiratory complications, which can lead to morbidity and mortality in DMD. (Not applicable to **Medicaid Managed Care**)
3. Utilization Management are contract dependent. Refer to specific contract/benefit language for exclusions.
    a. Coverage criteria may be dependent on the contract renewal date.
    b. Coverage of drugs listed in this policy are contract dependent.
    c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit.
    d. Not all contracts/benefits cover all medical infusible drugs.

4. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging, and other objective or subjective measures of clinical benefit. For recertification, continued approval requires documentation demonstrating that the requested product is providing ongoing benefit to the patient, evidenced by improvement or stability in the disease state or condition, and that continued use remains medically necessary. Ongoing use of the requested product must continue to align with the current policy's preferred formulary. Recertification reviews may result in a requirement to trial more cost-effective treatment alternatives as they become available (e.g., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must remain consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
5. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
6. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
7. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications ca be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which ma include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in additio to LCD/NCD requirements.
8. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with Off-Label Uses of FDA Approved Drugs.
9. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may require prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.
10. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
11. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.
12. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
13. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html

References

		Updated	Accessed
1	Exondys 51 [Package Insert]. Cambridge (MA): Sarepta Therapeutics, Inc.; 2016.	12/24	1/25
2	*Efficacy Study Of AVI-4658 To Induce Dystrophin Expression In Selected Duchenne Muscular Dystrophy Patients - Study 202*. Clinicaltrials.gov., (NCT01540409 – Web Only)	11/16	04/17
3	*Efficacy, Safety, and Tolerability Rollover Study Of Eteplirsen In Subjects With Duchenne Muscular Dystrophy - Study 201*. Clinicaltrials.gov., (NCT01396239 – Web Only)	10/15	04/17
4	*Exon-Skipping For Duchenne* | Sarepta Therapeutics. Sarepta.com.	04/17	04/17
5	Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management Bushby, Katharine et al. The Lancet Neurology, Volume 9, Issue 1, 77 – 93	11/09	04/17
6	Application Number: 206488Orig1s000 Center for Drug Evaluation and Research (CDER), FDA.gov.	9/16	04/17
7	FDA Briefing Document: Peripheral and Central Nervous System Drugs Advisory Committee Meeting; NDA 206488 (Eteplirsen), FDA.	04/16	04/17
8	FDA Briefing Document: Peripheral and Central Nervous System Drugs Advisory Committee Meeting;	01/16	04/17

	NDA 206488 (Eteplirsen), FDA.		
9	Eteplirsen Approval Letter. FDA.gov.	09/16	04/17
10	Vyondys 53 (golodirsen) New Drug Review [Internet]. IPD Analytics. Dec 2019 [cited 2020 Jan 9]. Available from: https://secure.ipdanalytics.com/User/Pharma/RxStrategy/Search?q=vyondys		01/20
11	Vyondys 53 (golodirsen) Clinical Trial (NCT02310906) Available at: https://clinicaltrials.gov/ct2/show/NCT02310906		10/20
12	The Importance of Genetic Testing in Duchenne Muscular Dystrophy Genetic Testing Brochure, Sarepta Therapeutics, Inc. 2018 Available at: https://www.cureduchenne.org/wp-content/uploads/2016/11/Duchenne-Population-Potentially-Amenable-to-Exon-Skipping-11.10.16.pdf		01/20
13	Viltepso FDA Approval Letter. FDA; 2020 Aug. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2020/212154Orig1s000Approv.pdf		10/20
14	Safety, Tolerability, and Efficacy of Viltolarsen in Boys with Duchenne Muscular Dystrophy Amendable to Exon 53 Skipping. JAMA Neurol. 2020 Aug; 77(8): 1-10.		10/20
15	Viltepso [package insert]. Paramus (NJ): NS Pharma Inc.; 2020.	3/21	1/25
16	Analytics Market Forecast: Outlook for Amondys 45 [Internet]. IPD Analytics. Dec 2020 [cited 2020 Dec 21]. Available from: https://secure.ipdanalytics.com/User/Pharma/Drug/Amondys-45#870e9965-f9f7-4f01-b6b4-1f2165720d77	4/19	12/20
17	Study of SRP-4045 and SRP-4053 in DMD Patients (ESSENCE). Clinicaltrials.gov, (NCT02500381-Web Only)	1/23	1/23
18	Carvalho J. Casimersen Shows Promising Phase 3 Results for DMD, May Open Door for FDA New Drug Application. Muscular Dystrophy News Today. 2019 April; available from: https://musculardystrophynews.com/2019/04/05/sareptas-casimersen-shows-promising-results-phase-3-trial/	12/20	12/20
19	Amondys 45 [package insert]. Cambridge (MA): Sarepta Therapeutics, Inc.; 2021	7/24	1/25

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application.

SELECT PLAN/HARP: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 8/13/2026

New:
04/17

Revised:	Reviewed:
04/18, 2/20, 12/20, 2/21, 4/22, 4/25, 5/26, 8/26	04/19, 2/22, 4/23

Revision Date	Changes Made
4/22	Changed Select Plan/HARP applicability from "Subject to all terms and conditions noted in above application" to specific Inclusion Criteria listed to align with NYS Medicaid Fee-for-Service, as required.
4/25	Added requirement for baseline renal function assessment, baseline pulmonary assessment with FVC ≥ 50%, and baseline 6MWT greater than 300 meters. Continuation criteria updated with requirements for 6MWT, FVC/FVC rate of decline, and ejection fraction
5/2026	Reformatted policy to remove separated inclusion/exclusion sections and separate Medicaid criteria
8/2026	Changed considerations section to policy guidelines section

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

POLICY EFFECTIVE DATE:	8/1/2026
Policy Control #:	1370/20.000509
Next Annual Review:	November 2026

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

Multiple

DESCRIPTIONS

The Durable Medical Equipment, Prosthetics, and Orthotics policy is a resource compilation of durable medical equipment, prosthetics, orthotics, and medical supplies most frequently requested by vendors and/or providers. It is not all inclusive of codes contained in the HCPCS Level II Manual.

Durable medical equipment (DME) is defined as equipment which can withstand repeated use, is primarily and customarily used to serve a medical purpose, is generally not useful to a person in the absence of illness or injury; and is appropriate for use in the home.

Prosthetic devices are removable and not permanently implanted devices which replace all or part of a body organ, or replace all or part of a permanently non-functioning, absent, or malfunctioning body part (i.e., artificial limbs, eyes, post mastectomy breast prosthesis).

Orthotic devices are rigid or semi rigid devices which are used for the purpose of supporting a weak or deformed body part or to restrict or eliminate motion in a diseased or injured part of the body.

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Medical supplies are items other than drugs, prosthetic, or orthotic appliances, or DME used for the treatment of a specific medical condition which are consumable, non-reusable, disposable, and generally have no salvageable value (e.g., diapers, gauze pads, bandages). Reference should be made to specific contracts and/or summary plan designs for benefit availability.

RELATED POLICIES/DOCUMENTS

Prior Authorization Guideline, 1370/20.000425

POSITION STATEMENT

CDPHP utilizes CMS National Coverage Determinations (NCDs), Local Coverage Articles (LCAs), or Local Coverage Determinations (LCDs) as well as professional society guidelines and/or industry evidence based clinical resources when making medical necessity determinations for DME, Prosthetics/Orthotics, and medical supplies.

Purchase of DME, prosthetic and orthotic devices not exceeding an allowable amount of $1000 are administered without a prior authorization requirement when provided by a participating provider.

Prior authorization requirement applies to all the following:

- All rental items with the exception of the following:
  - Standard wheelchair rental (K0001-K0007)
  - Transport chairs (E1037-E1039)
  - Wheelchair accessory items (E0971- antitipping device, E0978- positioning belt/safety belt/pelvic strap and E0990- elevating leg rest, complete assembly)
  - Nebulizers (E0570 only)
  - TENS unit
  - Oxygen equipment and accessories (oximeter (E0445) will be allowed as a rental only and is not included in this prior authorization exception)
  - Negative pressure wound therapy electrical pump (E2402)
  - Home phototherapy devices for neonatal jaundice (E0202)
  - Enteral nutrition infusion pump (B9002)
  - Continuous Passive Motion Device (E0935) (exception, prior authorization is required for Medicare Advantage)

The following item may be rented for a period of up to 90 days without prior authorization (for any rental beyond this timeframe, prior authorization is required):

  - Hospital grade breast pump: E0604

- Total repairs exceeding an allowed amount of $1,000 on covered DME.

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

- *Each* purchased item exceeding an allowed amount of $1,000 (including diabetic DME) with the exception of the following:
  - CPAP/BiPAP machine purchase
  - TENS unit
  - Oxygen equipment and accessories
  - Insulin infusion pumps
  - Continuous glucose monitors and related supplies (A9276, A9277, A9278, S1034, S1035, S1036, S1037, A4238, E2102, E2103, A4239)
  - Scoliosis jacket/Thoracic Lumbar Sacral Orthoses (TLSO) (L1200, L1300, L1310) when billed with diagnosis of scoliosis (M41-M41.9).
  - L1832 - Jace Tri-brace
  - L1845 - Bledsoe brace
  - Ankle foot orthotic (AFO) codes: L1900, L1902, L1904, L1906, L1907, L1910, L1920, L1930, L1932, L1940, L1945, L1950, L1951, L1960, L1970, L1971, L1980, L1990, L2106, L2108, L2112, L2114, L2116, L2200, L2210, L2220, L2230, L2232, L2240, L2250, L2260, L2265, L2270, L2275, L2280, L2300, L2310, L2320, L2330, L2335, L2340, L2350, L2360, L2370,L2375, L4002, L4090, L4205, L4210, L4350, L4360, L4361, L4370, L4386, L4387, L4392, L4394, L4396, L4397, L4398, L4631
  - L3960 – Airplane splint/shoulder
  - L3000-L3030 Custom Foot Orthotics (NOTE: These items are only reimbursed If billed with a diagnosis of diabetes or peripheral vascular disease)
  - The following orthotic codes: L0456, L1200, L5020, L5301, L5321, L5585, L5611, L5643, L5649, L5651, L5673, L5681, L5700, L5701, L5705, L5781, L5828, L5840, L5845, L5964, L5968, L5981, L5987, L5988, L6110, L6721, L6884

CDPHP administers benefits for medically necessary repair, adjustment, replacement, or maintenance and servicing of a covered item if it is not covered under a manufacturer's warranty or purchase agreement. Repair, adjustment, or replacement where the total claim is under an allowable amount of $1000 do not require prior authorization. CDPHP reserves the right to determine whether replacement or repair of the item is more appropriate.

Repair or replacement of the following items do not require prior authorization even if exceeding an allowable amount of $1000:

- Covered foot orthotics

CDPHP administers benefits for ostomy, tracheostomy, and urological products that serve as a prosthetic device.

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POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

POLICY CONSIDERATIONS

DME, prosthetics/orthotics, and medical supplies are considered durable medical equipment and are subject to the terms and conditions of such as stated in the enrollee's contract.

Replacement of DME may be available in cases of loss, irreparable damage or wear, or when required because of a change in the enrollee's condition.

- Irreparable damage is damage that has been caused by a specific accident (e.g., wheelchair falling from a van) or natural disaster (e.g., flood or fire).
- Irreparable wear is the deterioration sustained from day-to-day usage over time. In cases involving irreparable wear, the useful lifetime of the equipment, which is five years, is taken into consideration (useful life of DME is considered no less than five years beginning with the date of delivery of the equipment to the member, not the actual age of the equipment). If the item of equipment has been in continuous use for the equipment's useful lifetime, the member may elect to obtain a new piece of equipment.
- Replacement due to wear is not covered during the reasonable useful lifetime of the equipment.

CDPHP follows coverage criteria from the Medicare NCD's, LCD's, or LCA's for the below listed items (please note that listed items with an asterisk (**) are only allowable for the Medicare Advantage line of business:

Refer to the link below for coverage guidelines:

Noridian - DME Jurisdiction A

Ankle-Foot/Knee-Ankle- Foot orthoses
Automatic external defibrillators
Bowel management devices
Canes and crutches
**Cervical traction devices
*For commercial products, E0849 is considered experimental
Cold therapy
Commodes
External breast prosthesis
External Infusion Pumps (*for external insulin infusion pump: see below)
**External Upper Limb Tremor Stimulator Therapy
*For commercial products, this device is considered experimental
Eye Prostheses
Facial Prostheses
Heating Pads and Heat Lamps

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

High Frequency Chest Wall Oscillation Devices
Hospital Beds and accessories
Infrared Heating Pads Systems
Intrapulmonary Percussive Ventilation System
Knee Orthoses
Lower limb prostheses
Manual wheelchair bases (Standard wheelchairs)
Mechanical in-exsufflation devices
Nebulizers
Negative pressure wound therapy pumps
Orthopedic footwear
Osteogenesis stimulators (Bone Growth Stimulators)
Ostomy supplies
Patient lifts
Power mobility devices (Power wheelchairs)
Pressure reducing support surfaces (group 1-3)
Respiratory assist devices
Seat lift mechanisms
Speech generating devices or augmentative communication devices
Spinal orthoses (TLSO and LSO)
Suction pumps
Surgical dressings
Tracheostomy care supplies
Tumor treatment field therapy
Urological supplies
Walkers
Wheelchair options/accessories
Wheelchair seating

Seat Elevation Equipment (Power Operated) on Power Wheelchairs:
Seat Elevation System NCD

Refer to the link below for NCD coverage guidelines on the below listed items that are either not covered or have coverage limitations:

CMS NCD: DME Reference List

Air cleaners
Air conditioners
Air fluidized bed
Alternating Pressure Pads, Mattresses, and Lamb's Wool Pads
Audible/Visible Signal/Pacemaker Monitors
Bathtub Lifts

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

Bathtub Seats
Bead beds
Bed Baths (home type)
Bed Lifters (bed elevators)
Bed boards
Bed Pans
Bed side rails
Beds- lounges (power or manual)
Bidet toilet seats
Blood glucose analyzers
Braille teaching texts
Canes
Carafes
Commodes
Continuous Passive Motion Devices
Crutches
Cushion lift power seats
Dehumidifiers
Diathermy machines
Digital electronic pacemaker monitor
Disposable sheets and bags
Elastic stockings
Electric Air cleaners
Electrical stimulation for wounds
Electrostatic machines
Elevators
Emesis basins
Esophageal dilators
Exercise equipment
Fabric supports
Face masks (surgical)
Fluidic breathing assisters
Fomentation devices
Gel flotation pads and mattresses
Grab bars
Heat and massage foam cushion pads
Heating and cooling plants
Heating pads
Heat lamps
Hot packs
Humidifier (room or central heating system types)
Hydraulic lifts
Incontinent pads

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

Injectors (hypodermic jet)
Intermittent positive pressure breathing machines
Iron lungs
Irrigating kits
Lamb's wool pads
Leotards
Lymphedema pumps
Massage devices
Mattresses
Mobile geriatric chairs
Muscle stimulators
Oscillating beds
Over bed tables
Paraffin bath units (portable)
Paraffin bath units (standard)
Parallel bars
Percussors
Portable room heaters
Portable whirlpool pumps
Postural drainage boards
Pressure leotards
Pulse tachometers
Raised toilet seats
Respirators
Rolling chairs
Safety rollers
Sauna baths
Seat lifts
Self-contained pacemaker monitors
Sitz baths
Speech teaching machines
Stairway elevators
**Standing tables (please see criteria below for Commercial products)
Steam packs
Support hose
Surgical leggings
Telephone alert systems
Toilet seats
Traction equipment
Trapeze bars
Treadmill exercisers
Ultraviolet cabinets
Urinals autoclavable

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

Vaporizers
Ventilators
Water and pressure pads and mattresses
Wheelchairs (manual)
Wheelchairs (power operated)
Wheelchairs (scooter/POV)
Wheelchairs (specially-sized)
Whirlpool Bath Equipment
Whirlpool pumps
White canes

For the following LCD/NCD items, please see specific CDPHP Resource Coordination or payment policies for coverage:

- Cochlear Implant:
  - Cochlear Implants and Auditory Brainstem Implants, 7.01.26
- Enteral/parenteral nutrition:
  - Nutritional Therapy: Oral/Enteral/Parenteral & Modified Solid Food Products, 1370/20.000480
- External infusion pumps: *for insulin infusion pump only:
  - External Ambulatory Insulin Infusion Pump, 1370/2.0000457
- Glucose monitors:
  - Diabetic Services: Supplies, Pharmaceuticals, Equipment, Eye Exam, Education and Shoes, 1370/20.000047
- Oral appliances for obstructive sleep apnea:
  - Obstructive Sleep Apnea: Diagnosis and Treatment, 1370/20.00006
- Oxygen and oxygen equipment or face masks (oxygen):
  - Oxygen and Oxygen Equipment, 1550/20.000148
- Positive Airway Pressure (PAP) Devices for the treatment of obstructive sleep apnea:
  - Obstructive Sleep Apnea: Diagnosis and Treatment, 1370/20.000060
- Refractive Lenses:
  - Contact Lenses, Intraocular Lenses & Eyeglasses for Medical Purposes, 1370/20.000164
- Therapeutic shoes for persons with Diabetes:
  - Diabetic Services: Supplies, Pharmaceuticals, Equipment, Eye Exam, Education and Shoes, 1370/20.000047
- Transcutaneous Electrical Joint Stimulation:
  - Electromagnetic and Pulsed Field Stimulation, 1.01.59
- Transcutaneous Electric Nerve Stimulators (TENS)
  - Non-Invasive Surface Electrical Stimulation for Pain and Rehabilitation, 1.01.61
- Vacuum erection devices (VED):
  - Erectile Dysfunction, 7.01.30

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

The following items are not addressed in a current Medicare LCD/NCD or CDPHP policy and may be covered if the criteria below is met:

Apnea Monitor (E0618, E0619)

Covered for infants up to 12 months of age with **any** of the following indications:

- Those who have experienced a brief resolved unexplained event (BRUE). If monitored due to BRUE, use of an apnea monitor is considered medically necessary until event free for two to three months.
- Those with tracheostomies or anatomic abnormalities of the face, tongue, jaw, or airway that make them vulnerable to airway compromise.
- Those with neurologic or metabolic disorders affecting respiratory control.
- Those with chronic lung disease (such as, bronchopulmonary dysplasia), particularly those requiring supplemental oxygen; continuous positive airway pressure; or mechanical ventilation.
- Those with apnea of prematurity, defined as sudden cessation of breathing that lasts for at least 20 seconds or is accompanied by bradycardia (heart rate less than 80 beats per minute) or oxygen (O2) desaturation (O2 saturation less than 90%) or cyanosis in an infant with early home discharge prior to term (38 weeks). Continued use is considered medically necessary up to 43 weeks postmenstrual age or event free for two weeks, whichever comes later.
- Those discharged home on a schedule of weaning narcotics.
- Those with bradycardia on caffeine, theophylline, or similar agents, until event free for two weeks off medication.
- Those with diagnosis of pertussis, with positive cultures. If monitored for pertussis, use of a monitor is considered medically necessary for up to one month post diagnosis.
- Those with diagnosis of gastroesophageal reflux disease (GERD) that results in apnea (at least 20 seconds), bradycardia (heart rate less than 80 beats per minute), or oxygen desaturation (O2 saturation less than 90% or cyanosis), until event free for six weeks.

Automatic Blood Pressure Cuff (A4670)

- Covered when there is a documented history of hypertension.

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

- Covered when part of an approved quality program
- Additional preventive coverage can be found in the payment policy Preventive Services Guidelines, 1550/20.000211.

Back-Up Equipment

- Coverage follows the Noridian guidelines available here: https://med.noridianmedicare.com/web/jadme/claims-appeals/billing-situations/back-up-equipment

Compression stockings, garments, wraps, bandages
Gradient compression stockings, garments and wraps are considered medically necessary for the following indications:

- Venous insufficiency
- Venous (stasis) ulcer(s);
- Varicose veins;
- Phlebitis/thrombophlebitis;
- Deep vein thrombosis (DVT) prophylaxis during pregnancy and postpartum, or immobilization due to surgery, trauma, or general debilitation;
- Orthostatic (postural) hypotension;
- Chronic lymphedema;
- Intractable lymphedema of the upper extremity subsequent secondary to lymph node dissection related to cancer surgery; and
- Edema following surgery, fracture, burns, or other trauma

The following codes will be allowed:

A6515-A6519, A6520-A6529, A6530, A6533-A6538, A6540-A6544, A6549, A6552-A6589, A6593, A6610, A6611, S8420-S8428.

We allow the above codes as follows:
- Daytime: 3 garments per affected body part every 6 months
- Nighttime: 2 garments per affected body part every 2 years

The following codes will be allowed when used as a primary or secondary dressing over wound(s) that are surgically created, modified or debrided:

- A6545, A6448-A6450, A6451-A6452, A6594-A6609

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

Codes A4490, A4495, A4500, A4510 are non-covered.

Cranial Remolding Orthosis (S1040- Prior authorization is required even if allowed amount is < $1000)

Covered for pediatric patients who have moderate to severe cranial asymmetry (plagiocephaly) associated with premature birth, restrictive intrauterine positioning, cervical abnormalities, birth trauma, torticollis, and/or sleeping positions for either of the following circumstances:

- Following surgical correction of synostotic plagiocephaly (i.e., craniosyntosis); or
- When a diagnosis of nonsynostotic plagiocephaly is documented and all the following criteria is met:
  - Infant is three to 18 months of age
  - Infant has not responded to a two-month trial of head positioning or other conservative therapies
  - Photographs and anthropometric measurements verifying moderate to severe nonsynostotic positional plagiocephaly.

Crutch substitute/knee walker (E0118)

Considered medically necessary when the below criteria has been met:

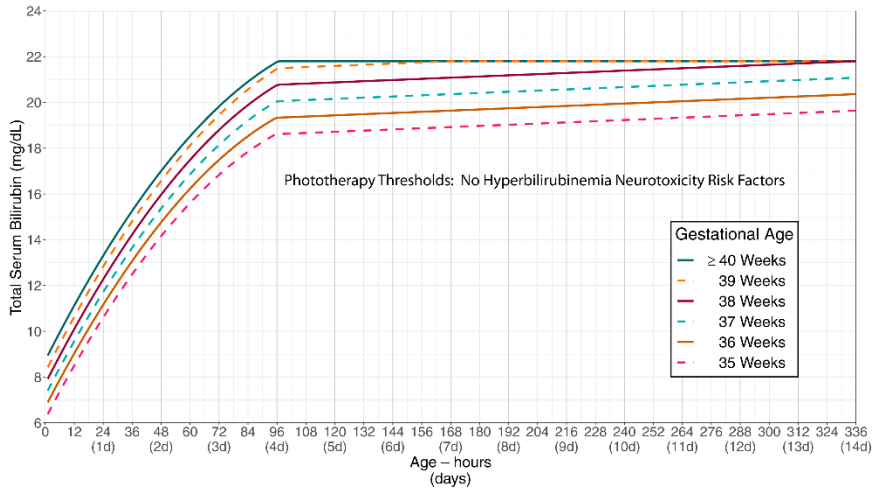
- There is a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADL) in the home, AND,
- The member is not a candidate for crutches or a manual wheelchair due to not having sufficient upper extremity function needed to safely use crutches or self-propel a manual wheelchair or there is no caregiver who is able to provide assistance with the wheelchair, AND
- The functional mobility deficit can be sufficiently resolved by use of a knee walker, AND,
- The member is able to safely use the knee walker

Home Phototherapy for neonatal hyperbilirubinemia (E0202)

For newborn infants who have already been discharged and then develop a total serum bilirubin (TSB) above the phototherapy threshold, treatment with a home LED-based phototherapy device rather than readmission to the hospital is an option for infants who meet the following criteria:

- Gestational age > 38 weeks
- > 48 hours old
- Clinically well with adequate feeding

- No known hyperbilirubinemia neurotoxicity risk factors
  - Gestational age < 38 week
  - Albumin < 3.0 g/dl
  - Isoimmune hemolytic disease (i.e., positive direct antiglobulin test), G6PD deficiency, or other hemolytic conditions
  - Sepsis
  - Significant clinical instability in the previous 24 hours
- No previous phototherapy
- TSB concentration no more than 1 mg/dL above the phototherapy treatment threshold (chart below)
- An LED-based phototherapy device will be available in the home without delay
- TSB can be measured daily



A microprocessor-controlled knee prosthesis (e.g., L5856)

Considered medically appropriate when ALL of the following criteria are met:
A. For persons with a knee disarticulation amputee OR transfemoral amputee;
B. Functional level 3 or above;
C. Lower level prosthetic devices (e.g., fluid, pneumatic, etc.) cannot be used or are insufficient to meet the functional needs of the individual in performing ADLs;
D. The patient has adequate cardiovascular and pulmonary reserve
E. The patient has received additional training for use of this technology and has demonstrated adequate cognitive ability to master use and care requirements;
F. The patient demonstrated a need to perform ALL of the following:

1. Long distance ambulation at variable rates;
2. Regular and frequent ambulation on uneven terrain (e.g., grass, gravel, or curbs); and
3. Regular and frequent ambulation on stairs or ramps;

G. Functional evaluation indicates that with training, use of a microprocessor-controlled knee prosthesis is likely to meet the functional needs of the individual.
H. Microprocessor-controlled knees are contraindicated for ANY of the following:

1. The patient's functional level is less than 3 or has limited ambulation due to poor balance or ataxia;
2. The patient is unable to tolerate the weight of the prosthesis;
3. The patient is unable to use the swing and stance features of the knee;
4. The patient is unable to change the prosthesis or has a condition that would cause inadequate fitting;
5. The patient has significant hip flexion contracture (over 20 degrees);
6. The patient has significant deformity of the remaining limb that would impair ability to stride;
7. The prosthesis will be used when the environmental conditions include excessive moisture or dust which invalidates the warranty.

A microprocessor-controlled ankle-foot prosthesis (L5973) (e.g., Proprio Foot, Ossur, Aliso Viejo, CA)
Considered **medically appropriate** when **ALL** of the following criteria are met:

A. For persons with a transtibial amputation;
B. Functional level of 3 or above;
C. Lower level prosthetic devices (e.g., SACH foot) cannot be used or are insufficient to meet the functional needs of the individual in performing ADLs;
D. The patient has adequate cardiovascular and pulmonary reserve;
E. The patient has received additional training for use of this technology and has demonstrated adequate cognitive ability to master use and care requirements;
F. The patient demonstrated a need to perform **ALL** of the following:

1. Long distance ambulation at variable rates;
2. Regular and frequent ambulation on uneven terrain (e.g., grass, gravel, or curbs); and
3. Regular and frequent ambulation on stairs or ramps;

G. Functional evaluation indicates that with training, use of a microprocessor-controlled ankle-foot prosthesis is likely to meet the functional needs of the individual.

The following lower extremity prosthetics or components are considered not medically necessary:

- **A.** Lower limb prosthetic devices for individuals with functional level 0
- **B.** A microprocessor-controlled ankle-foot with power assist (L5973 AND L5969)

Oximeter (E0445- Rental item only)

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

CDPHP allows rental (until purchase price is met) of an oximeter for members who require continuous monitoring will be covered in combination with oxygen therapy under the following circumstances:

- Weaning from oxygen.
- Changes in physical condition requiring adjustments in oxygen therapy.
- Maintaining oxygen levels within a narrow range.
- As part of a primary care provider's or physician specialist's treatment plan requiring frequent monitoring/assessment of oxygen levels that cannot be achieved using a "Spot check" oximeter.

Covered without oxygen therapy under the following circumstance:

- In cases of complex cardiac conditions, such as, but not limited to, univentricular heart or unrepaired cyanotic heart disease.

Pulse oximeter probes (A4606) are used with the oximeter (E0445) and are included in the reimbursement for the pulse oximeter rental.

Documentation Requirements for Oximeter for members who require continuous monitoring:

The following documentation is necessary to support prior approval of an oximeter:

- Diagnosis/medical condition justifying the need to monitor blood oxygen levels.
- Current oxygen orders, if applicable (Note: oxygen orders should be renewed every 12 months).
- Treatment plan listing the required parameters and interventions for abnormal readings, including corresponding oxygen titrations if applicable.
- Availability of caregivers trained to appropriately manage the listed treatment interventions.

If used with a ventilator, CPAP, BiPAP, or other respiratory assist device, the type, make, and model of the respiratory assist device must be provided to ensure oximetry is not already available on that device.

Pediatric Gait Trainer (E8000-E8002)

Gait trainers are considered medically necessary for therapeutic and functional ambulation when all the below criteria are met:

- Member is 18 years of age or younger;
- Member has an acquired injury (e.g., spinal cord, traumatic brain injury) or a chronic physical limitation that affects the ability to ambulate (e.g., cerebral palsy, neuromuscular disease, spina bifida);
- Member requires moderate to maximum support for ambulation and documentation shows that assistive devices have not been effective;

- There has been at least a one-month rental trial in which the member demonstrates capability of utilizing and tolerating the equipment safely.

Pediatric Safety Bed (E0328, E0316)

CDPHP will provide coverage of a pediatric hospital bed with enclosure frame when the below criteria is met:

1. There is a diagnosis-related cognitive/communication impairment or a severe behavioral disorder (e.g., traumatic brain injury, seizure disorder, autism)
2. Member has a risk to safety while in bed OR there is a risk to safety due to climbing out of bed/wandering
3. Other alternatives were tried and were unsuccessful or contraindicated (examples below):
    a. Putting a mattress on the floor
    b. Padding added to ordinary beds
    c. Transparent plastic shields
    d. Medications
    e. Helmets
    f. Door alarms

Replacement Batteries (Various Codes)

- Coverage will follow medical supplies section of member contract if available

Standing frame/table system (E0637, E0638, E0641, E0642)

A standing device is considered medically appropriate when BOTH of the following criteria are met:

- There is documentation that the standing device is necessary for the patient to be independent in one or more of the following activities of daily living (ADLs) in the patient's home:
    1. Eating;
    2. Personal hygiene;
    3. Toileting;
    4. Dressing;
    5. Transfer; AND
- The patient is unable to accomplish the activities identified in above with current durable medical equipment.

OR

A standing device is considered medically appropriate for decubitus ulcer management when BOTH of the following criteria are met:

- There is documentation that off-loading of a decubitus ulcer cannot be accomplished by other means; and
- The patient has completed a one-month trial using the standing device and has shown meaningful improvement after the trial period. Documentation from the referring provider that the patient has shown meaningful improvement during the trial period must be submitted, to be eligible for continued coverage.

Upper limb prostheses (L6000, L6010, L6020, L6050, L6055, L6100, L6110, L6120, L6130, L6200, L6205, L6250, L6300, L6310, L6320, L6350, L6360, L6370, L6400, L6450, L6500, L6550):

Prostheses that are worn externally and that temporarily or permanently replace all or part of an external body part that has been lost or damaged because of an injury or disease.

Vacuum drainage collection unit and tubing kit (A7048)
Covered for use in the home when provided in lieu of hospitalization or nursing home care.

CODING REQUIREMENTS AND REIMBURSEMENT

Supplies associated with DME/prosthetic/orthotic devices are covered when included in the purchase price.

All DME items must be billed with appropriate modifier to indicate purchase (NU), rental to purchase (NR), rental (RR) or used equipment that has been purchased (UE). Claims submitted without modifier will deny to resubmit with appropriate modifier.

When equipment is billed for purchase, the allowed amounts from any previously paid rental months will be subtracted from the purchase price. Payment for rental months will never exceed the total purchase price for the equipment.

DME Invoices

All DME items must be billed with appropriate modifier to indicate purchase (NU) or rental (RR). Claims submitted without modifier will deny to resubmit with appropriate modifier.

DME items not having a current CMS DME fee schedule or published NYS Medicaid fee schedule rate will be reimbursed at a rate established by CDPHP, which may be based on specific case review and/or submission of the actual manufacturers' invoice.

For items that are made by the DME vendor themselves and no manufacturer's invoice is available, an itemization of supplies utilized, and applicable charges is required in order to

consider reimbursement for the item.

CDPHP will reimburse DME items at the lesser of 150% of invoice cost or fee schedule unless otherwise stated in the provider contract.

When equipment is billed for purchase, the allowed amounts from any previously paid rental months will be subtracted from the purchase price.

Documentation Requests

CDPHP reserves the right to request medical records at any time including all dictated, handwritten notes, and the documents indicated below to support all the items billed on this claim. All pertinent information to meet policies and billing requirements must be included. Failure to supply full documentation indicated could result in partial or complete denial of services.

Required Documents*:

- Certificate of Medical Necessity (CMN) - Both initial and subsequent forms, if applicable

- Copy of unredacted manufacturer's invoice for items billed including: Product information
- Detailed Written Order (DWO)/Prescription/Fiscal Order or Standard Written Order (SWO)
- Dispensing Orders
- Face to Face Documents, if applicable
- Notes including progress notes pertinent to the DME requested
- Prior-Authorization form, if applicable
- Refill Documents
- Written Order Prior to Delivery (WOPD), if applicable
- DME Information Form (DIF)
- Model number and Manufacturer name
- Proof of Delivery (POD)/Delivery Documentation (Invoices and delivery receipts)

***Note:** Some of these documents may need to be obtained from the ordering physician while others may need to be obtained from the DME vendor who provided the equipment.

EXCLUSIONS

1. DME/Prosthetics/Orthotics designed for your comfort or convenience.
   The following list is not all inclusive but contains examples of items that are generally considered comfort or convenience:
   - Pools
   - Hot tubs

- Air conditioners
- Saunas
- Humidifiers
- Dehumidifiers
- Exercise equipment

2. Over-the-counter medical supplies.

3. Orthotic devices that are not rigid or semi rigid devices.

4. Repair or replacement of DME or a prosthetic/orthotic device due to loss, misuse, or neglect.

5. Repair or maintenance and servicing of equipment or device that is subject to the manufacturer's warranty.

6. Requests for a duplicate device to have available at various locations (e.g., one for home and one for school/work).

7. Equipment or devices prescribed solely for use during sports or employment.

8. Charges related to the shipping, handling and/or delivery of covered equipment or devices.

9. Battery powered walker (E0152) is considered non-covered since the capabilities relate to use of the walker outside the home and it does not serve as a purpose for use in the home.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	CDPHP utilizes the New York State Medicaid management information system provider manual (MMIS) to determine coverage availability and distinguish a medical/surgical supply versus durable medical equipment, prosthetic, or orthotic: http://www.emedny.org/providerManuals/Index.html
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy to include the following: • Medicare Advantage provides benefits for supplies that are

	necessary for effective use of a prosthetic.
SELECT PLAN/HARP	CDPHP utilizes New York State Medicaid management information system provider manual (MMIS) to determine coverage availability and distinguish a medical/surgical supply versus durable medical equipment, prosthetic, or orthotic. There are 2 guidelines that identify these benefits: Medical Supplies Procedure Codes & Coverage Guidelines (sections 4.1, 4.2, 4.3) are billed directly to Medicaid Fee for Service: Medical Supplies Procedure Codes DME Procedure Codes & Coverage Guidelines (sections 4.4, 4.5, 4.6, and 4.7) are billed to CDPHP: DME Procedure Codes

SOURCES

1. CMS Durable Medical Equipment LCD's
   https://med.noridianmedicare.com/web/jadme/policies/lcd/active
2. CMS National Coverage Determination (NCD) for Durable Medical Equipment Reference List (280.1)
   https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=190&ncdver=2&chapter=all&sortBy=title&bc=AAAAIAAAAAAA
3. NYS DOH Carve Out Update- April 2023:
   https://www.health.ny.gov/health_care/medicaid/program/update/2023/docs/mu_no5_mar23_speced.pdf

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POLICY APPROVAL DATES

New:	11/21
Revised:	5/22, 9/22,11/22, 1/23, 5/23, 7/23, 9/23, 11/23, 1/24, 3/24, 5/24, 9/24, 11/24, 1/25, 3/25, 5/25, 11/25, 3/26, 5/26, 7/26

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

Reviewed:

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
8/1/2026	Under "For the following LCD/NCD items, please see specific CDPHP Resource Coordination or payment policies for coverage", added new policy Electromagnetic and Pulsed Field Stimulation, 1.01.59 and Non-Invasive Surface Electrical Stimulation for Pain and Rehabilitation, 1.01.61
7/1/2026	Removed codes L5856 and L5973 from the list of items that do not require PA and added medical necessity criteria for these codes. Added information to code S1040 on prior authorization requirement.
3/1/2026	Added prior authorization DME information that was previous housed on the now obsolete Prior Authorization Guideline policy.
12/1/2025	Updated name and policy number for Cochlear implant and removed link to Medicare Non-Covered Items.
4/1/2025	Added new codes A6515-A6519, and A6611 to Compression stockings, garments, wraps, bandages section.
3/1/2025* No change to effective date of policy for this update	Added additional information for cervical traction devices previously housed in the Non-Covered Technology policy.
3/1/2025	Added criteria for pediatric safety beds.
2/1/2025	Added criteria for standing frames. Updated criteria for compression stockings. Under Noridian, removed Pneumatic Compression Devices as

	this LCD is retired. Clarified that Oximeter is rental item only.
1/1/2025 *No change to effective date of policy	Updated Medicaid section and provided links for DME/Supplies. Under Position Statement added: External Upper Limb Tremor Stimulator Therapy to the list. Added modifiers NR & UE to policy. Added additional coverage for automated blood pressure cuff (A4670) through quality programs.
1/1/2025	Added coverage criteria for oximeters.
8/1/2024	Added information on DME rental or purchase modifiers. Added statements regarding rentals converting to purchase. Added information on code A7048 Updated criteria for knee walker to remove "and/or other physical and mental capabilities".
5/1/2024	Added criteria for pediatric gait trainers Added criteria for automated blood pressure cuff (A4670)
4/1/2024	Added battery powered walker to exclusions
3/1/2024	Removed prior authorization exceptions from the Policy Considerations section as this information is housed in the RC Prior Authorization Guideline document. Updated lymphedema compression section.
1/1/2024	Replaced termed code K1013 with new code A4457 in Select Plan/HARP section.
12/1/2023	Updated link for coverage criteria for Seat Elevation Equipment (Power Operated) on Power Wheelchairs and added link for items that are considered non-covered.
11/1/2023* *No change to effective date for this update	Added coverage criteria for lymphedema gradient pressure sleeves/gauntlets/gloves (S8420-S8428). Added criteria for rental of home phototherapy devices for neonatal jaundice, and also identified there will be no PA

	requirement for these devices. Added that wheelchair accessory items E0971- antitipping device, E0978- positioning belt/safety belt/pelvic strap and E0990- elevating leg rest, complete assembly do not require PA for rental. Removed NCA link for Seat Elevation System and replaced with NCD link. Added link for products/codes that are non-covered.
11/1/2023	Added documentation requirements to Coding Requirements and Reimbursement section. Added section for items not otherwise addressed in a Medicare LCD/NCD or CDPHP policy. Added scoliosis jackets (L1300 & L1310) as not requiring a PA when billed with a diagnosis of scoliosis (M41-M41.9).
5/16/2023	Added new Medicare NCA link for Seat Lift Systems
5/1/2023	Under Policy Considerations added information on DME replacement. Added negative pressure wound therapy (E2402) as an item that does not have a rental PA requirement.
4/1/2023	Medicaid section updated to reflect the changes for the Medicaid RX/DME Carveout.
1/1/2023* *No change to effective date for this update	Updated Child Health Plus section to mirror Select Plan/HARP coverage.
1/1/2023* *No change to effective date for this update.	No coverage criteria changes made. Minor changes/clarifications made throughout policy.
1/1/2023	Under Policy Considerations, added information on Nebulizers, standard wheelchairs, and transports chairs.
5/1/2022	Added references to maintenance and servicing coverage.
1/1/2022	New policy

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RESOURCE COORDINATION POLICY

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POLICY EFFECTIVE DATE:	11/1/2026
Policy Control #:	1370/20.000509
Next Annual Review:	November 2026

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

Multiple

DESCRIPTIONS

The Durable Medical Equipment, Prosthetics, and Orthotics policy is a resource compilation of durable medical equipment, prosthetics, orthotics, and medical supplies most frequently requested by vendors and/or providers. It is not all inclusive of codes contained in the HCPCS Level II Manual.

Durable medical equipment (DME) is defined as equipment which can withstand repeated use, is primarily and customarily used to serve a medical purpose, is generally not useful to a person in the absence of illness or injury; and is appropriate for use in the home.

Prosthetic devices are removable and not permanently implanted devices which replace all or part of a body organ, or replace all or part of a permanently non-functioning, absent, or malfunctioning body part (i.e., artificial limbs, eyes, post mastectomy breast prosthesis).

Orthotic devices are rigid or semi rigid devices which are used for the purpose of supporting a weak or deformed body part or to restrict or eliminate motion in a diseased or injured part of the body.

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Medical supplies are items other than drugs, prosthetic, or orthotic appliances, or DME used for the treatment of a specific medical condition which are consumable, non-reusable, disposable, and generally have no salvageable value (e.g., diapers, gauze pads, bandages). Reference should be made to specific contracts and/or summary plan designs for benefit availability.

RELATED POLICIES/DOCUMENTS

Prior Authorization Guideline, 1370/20.000425

POSITION STATEMENT

CDPHP utilizes CMS National Coverage Determinations (NCDs), Local Coverage Articles (LCAs), or Local Coverage Determinations (LCDs) as well as professional society guidelines and/or industry evidence based clinical resources when making medical necessity determinations for DME, Prosthetics/Orthotics, and medical supplies.

Purchase of DME, prosthetic and orthotic devices not exceeding an allowable amount of $1000 are administered without a prior authorization requirement when provided by a participating provider.

Prior authorization requirement applies to all the following:

- All rental items with the exception of the following:
  - Standard wheelchair rental (K0001-K0007)
  - Transport chairs (E1037-E1039)
  - Wheelchair accessory items (E0971- antitipping device, E0978- positioning belt/safety belt/pelvic strap and E0990- elevating leg rest, complete assembly)
  - Nebulizers (E0570 only)
  - TENS unit
  - Oxygen equipment and accessories (oximeter (E0445) will be allowed as a rental only and is not included in this prior authorization exception)
  - Negative pressure wound therapy electrical pump (E2402)
  - Home phototherapy devices for neonatal jaundice (E0202)
  - Enteral nutrition infusion pump (B9002)
  - Continuous Passive Motion Device (E0935) (exception, prior authorization is required for Medicare Advantage)

The following item may be rented for a period of up to 90 days without prior authorization (for any rental beyond this timeframe, prior authorization is required):

  - Hospital grade breast pump: E0604

- Total repairs exceeding an allowed amount of $1,000 on covered DME.

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

- *Each* purchased item exceeding an allowed amount of $1,000 (including diabetic DME) with the exception of the following:
  - CPAP/BiPAP machine purchase
  - TENS unit
  - Oxygen equipment and accessories
  - Insulin infusion pumps
  - Continuous glucose monitors and related supplies (A9276, A9277, A9278, S1034, S1035, S1036, S1037, A4238, E2102, E2103, A4239)
  - Scoliosis jacket/Thoracic Lumbar Sacral Orthoses (TLSO) (L1200, L1300, L1310) when billed with diagnosis of scoliosis (M41-M41.9).
  - L1832 - Jace Tri-brace
  - L1845 - Bledsoe brace
  - Ankle foot orthotic (AFO) codes: L1900, L1902, L1904, L1906, L1907, L1910, L1920, L1930, L1932, L1940, L1945, L1950, L1951, L1960, L1970, L1971, L1980, L1990, L2106, L2108, L2112, L2114, L2116, L2200, L2210, L2220, L2230, L2232, L2240, L2250, L2260, L2265, L2270, L2275, L2280, L2300, L2310, L2320, L2330, L2335, L2340, L2350, L2360, L2370,L2375, L4002, L4090, L4205, L4210, L4350, L4360, L4361, L4370, L4386, L4387, L4392, L4394, L4396, L4397, L4398, L4631
  - L3960 – Airplane splint/shoulder
  - L3000-L3030 Custom Foot Orthotics (NOTE: These items are only reimbursed If billed with a diagnosis of diabetes or peripheral vascular disease)
  - The following orthotic codes: L0456, L1200, L5020, L5301, L5321, L5585, L5611, L5643, L5649, L5651, L5673, L5681, L5700, L5701, L5705, L5781, L5828, L5840, L5845, L5964, L5968, L5981, L5987, L5988, L6110, L6721, L6884

CDPHP administers benefits for medically necessary repair, adjustment, replacement, or maintenance and servicing of a covered item if it is not covered under a manufacturer's warranty or purchase agreement. Repair, adjustment, or replacement where the total claim is under an allowable amount of $1000 do not require prior authorization. CDPHP reserves the right to determine whether replacement or repair of the item is more appropriate.

Repair or replacement of the following items do not require prior authorization even if exceeding an allowable amount of $1000:

- Covered foot orthotics

CDPHP administers benefits for ostomy, tracheostomy, and urological products that serve as a prosthetic device.

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POLICY CONSIDERATIONS

DME, prosthetics/orthotics, and medical supplies are considered durable medical equipment and are subject to the terms and conditions of such as stated in the enrollee's contract.

Replacement of DME may be available in cases of loss, irreparable damage or wear, or when required because of a change in the enrollee's condition.

- Irreparable damage is damage that has been caused by a specific accident (e.g., wheelchair falling from a van) or natural disaster (e.g., flood or fire).
- Irreparable wear is the deterioration sustained from day-to-day usage over time. In cases involving irreparable wear, the useful lifetime of the equipment, which is five years, is taken into consideration (useful life of DME is considered no less than five years beginning with the date of delivery of the equipment to the member, not the actual age of the equipment). If the item of equipment has been in continuous use for the equipment's useful lifetime, the member may elect to obtain a new piece of equipment.
- Replacement due to wear is not covered during the reasonable useful lifetime of the equipment.

CDPHP follows coverage criteria from the Medicare NCD's, LCD's, or LCA's for the below listed items (please note that listed items with an asterisk (**) are only allowable for the Medicare Advantage line of business:

Refer to the link below for coverage guidelines:

Noridian - DME Jurisdiction A

Ankle-Foot/Knee-Ankle- Foot orthoses
Automatic external defibrillators
Bowel management devices
Canes and crutches
**Cervical traction devices
*For commercial products, E0849 is considered experimental
Cold therapy
Commodes
External breast prosthesis
External Infusion Pumps (*for external insulin infusion pump: see below)
**External Upper Limb Tremor Stimulator Therapy
*For commercial products, this device is considered experimental
Eye Prostheses
Facial Prostheses
Heating Pads and Heat Lamps

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High Frequency Chest Wall Oscillation Devices
Hospital Beds and accessories
Infrared Heating Pads Systems
Intrapulmonary Percussive Ventilation System
Knee Orthoses
Lower limb prostheses
Manual wheelchair bases (Standard wheelchairs)
Mechanical in-exsufflation devices
Nebulizers
Negative pressure wound therapy pumps
Orthopedic footwear
Osteogenesis stimulators (Bone Growth Stimulators)
Ostomy supplies
Patient lifts
Power mobility devices (Power wheelchairs)
Pressure reducing support surfaces (group 1-3)
Respiratory assist devices
Seat lift mechanisms
Speech generating devices or augmentative communication devices
Spinal orthoses (TLSO and LSO)
Suction pumps
Surgical dressings
Tracheostomy care supplies
Urological supplies
Walkers
Wheelchair options/accessories
Wheelchair seating

Seat Elevation Equipment (Power Operated) on Power Wheelchairs:
Seat Elevation System NCD

Refer to the link below for NCD coverage guidelines on the below listed items that are either not covered or have coverage limitations:

CMS NCD: DME Reference List

Air cleaners
Air conditioners
Air fluidized bed
Alternating Pressure Pads, Mattresses, and Lamb's Wool Pads
Audible/Visible Signal/Pacemaker Monitors
Bathtub Lifts
Bathtub Seats

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

Bead beds
Bed Baths (home type)
Bed Lifters (bed elevators)
Bed boards
Bed Pans
Bed side rails
Beds- lounges (power or manual)
Bidet toilet seats
Blood glucose analyzers
Braille teaching texts
Canes
Carafes
Commodes
Continuous Passive Motion Devices
Crutches
Cushion lift power seats
Dehumidifiers
Diathermy machines
Digital electronic pacemaker monitor
Disposable sheets and bags
Elastic stockings
Electric Air cleaners
Electrical stimulation for wounds
Electrostatic machines
Elevators
Emesis basins
Esophageal dilators
Exercise equipment
Fabric supports
Face masks (surgical)
Fluidic breathing assisters
Fomentation devices
Gel flotation pads and mattresses
Grab bars
Heat and massage foam cushion pads
Heating and cooling plants
Heating pads
Heat lamps
Hot packs
Humidifier (room or central heating system types)
Hydraulic lifts
Incontinent pads
Injectors (hypodermic jet)

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

Intermittent positive pressure breathing machines
Iron lungs
Irrigating kits
Lamb's wool pads
Leotards
Massage devices
Mattresses
Mobile geriatric chairs
Muscle stimulators
Oscillating beds
Over bed tables
Paraffin bath units (portable)
Paraffin bath units (standard)
Parallel bars
Percussors
Portable room heaters
Portable whirlpool pumps
Postural drainage boards
Pressure leotards
Pulse tachometers
Raised toilet seats
Respirators
Rolling chairs
Safety rollers
Sauna baths
Seat lifts
Self-contained pacemaker monitors
Sitz baths
Speech teaching machines
Stairway elevators
**Standing tables (please see criteria below for Commercial products)
Steam packs
Support hose
Surgical leggings
Telephone alert systems
Toilet seats
Traction equipment
Trapeze bars
Treadmill exercisers
Ultraviolet cabinets
Urinals autoclavable
Vaporizers
Ventilators

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

Water and pressure pads and mattresses
Wheelchairs (manual)
Wheelchairs (power operated)
Wheelchairs (scooter/POV)
Wheelchairs (specially-sized)
Whirlpool Bath Equipment
Whirlpool pumps
White canes

For the following LCD/NCD items, please see specific CDPHP Resource Coordination or payment policies for coverage:

- Cochlear Implant:
  - Cochlear Implants and Auditory Brainstem Implants, 7.01.26
- Enteral/parenteral nutrition:
  - Nutritional Therapy: Oral/Enteral/Parenteral & Modified Solid Food Products, 1370/20.000480
- External infusion pumps: *for insulin infusion pump only:
  - External Ambulatory Insulin Infusion Pump, 1370/2.0000457
- Glucose monitors:
  - Diabetic Services: Supplies, Pharmaceuticals, Equipment, Eye Exam, Education and Shoes, 1370/20.000047
- Lymphedema Pumps:
  - Powered Compression Devices/Lymphedema Pump, 1.01.17
- Oral appliances for obstructive sleep apnea:
  - Obstructive Sleep Apnea: Diagnosis and Treatment, 1370/20.00006
- Oxygen and oxygen equipment or face masks (oxygen):
  - Oxygen and Oxygen Equipment, 1550/20.000148
- Positive Airway Pressure (PAP) Devices for the treatment of obstructive sleep apnea:
  - Obstructive Sleep Apnea: Diagnosis and Treatment, 1370/20.000060
- Refractive Lenses:
  - Contact Lenses, Intraocular Lenses & Eyeglasses for Medical Purposes, 1370/20.000164
- Therapeutic shoes for persons with Diabetes:
  - Diabetic Services: Supplies, Pharmaceuticals, Equipment, Eye Exam, Education and Shoes, 1370/20.000047
- Transcutaneous Electrical Joint Stimulation:
  - Electromagnetic and Pulsed Field Stimulation, 1.01.59
- Transcutaneous Electric Nerve Stimulators (TENS)
  - Non-Invasive Surface Electrical Stimulation for Pain and Rehabilitation, 1.01.61

- Tumor Treatment Field Therapy:
  - Tumor-Treatment Fields Therapy, 6.01.45
- Vacuum erection devices (VED):
  - Erectile Dysfunction, 7.01.30

The following items are not addressed in a current Medicare LCD/NCD or CDPHP policy and may be covered if the criteria below is met:

Apnea Monitor (E0618, E0619)

Covered for infants up to 12 months of age with **any** of the following indications:

- Those who have experienced a brief resolved unexplained event (BRUE). If monitored due to BRUE, use of an apnea monitor is considered medically necessary until event free for two to three months.

- Those with tracheostomies or anatomic abnormalities of the face, tongue, jaw, or airway that make them vulnerable to airway compromise.

- Those with neurologic or metabolic disorders affecting respiratory control.

- Those with chronic lung disease (such as, bronchopulmonary dysplasia), particularly those requiring supplemental oxygen; continuous positive airway pressure; or mechanical ventilation.

- Those with apnea of prematurity, defined as sudden cessation of breathing that lasts for at least 20 seconds or is accompanied by bradycardia (heart rate less than 80 beats per minute) or oxygen (O2) desaturation (O2 saturation less than 90%) or cyanosis in an infant with early home discharge prior to term (38 weeks). Continued use is considered medically necessary up to 43 weeks postmenstrual age or event free for two weeks, whichever comes later.

- Those discharged home on a schedule of weaning narcotics.

- Those with bradycardia on caffeine, theophylline, or similar agents, until event free for two weeks off medication.

- Those with diagnosis of pertussis, with positive cultures. If monitored for pertussis, use of a monitor is considered medically necessary for up to one month post diagnosis.

- Those with diagnosis of gastroesophageal reflux disease (GERD) that results in apnea (at least 20 seconds), bradycardia (heart rate less than 80 beats per minute), or oxygen desaturation (O2 saturation less than 90% or cyanosis), until event free for six weeks.

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

Automatic Blood Pressure Cuff (A4670)

- Covered when there is a documented history of hypertension.
- Covered when part of an approved quality program
- Additional preventive coverage can be found in the payment policy Preventive Services Guidelines, 1550/20.000211.

Back-Up Equipment

- Coverage follows the Noridian guidelines available here: https://med.noridianmedicare.com/web/jadme/claims-appeals/billing-situations/back-up-equipment

Compression stockings, garments, wraps, bandages
Gradient compression stockings, garments and wraps are considered medically necessary for the following indications:

- Venous insufficiency
- Venous (stasis) ulcer(s);
- Varicose veins;
- Phlebitis/thrombophlebitis;
- Deep vein thrombosis (DVT) prophylaxis during pregnancy and postpartum, or immobilization due to surgery, trauma, or general debilitation;
- Orthostatic (postural) hypotension;
- Chronic lymphedema;
- Intractable lymphedema of the upper extremity subsequent secondary to lymph node dissection related to cancer surgery; and
- Edema following surgery, fracture, burns, or other trauma

The following codes will be allowed:

A6515-A6519, A6520-A6529, A6530, A6533-A6538, A6540-A6544, A6549, A6552-A6589, A6593, A6610, A6611, S8420-S8428.

We allow the above codes as follows:

- Daytime: 3 garments per affected body part every 6 months
- Nighttime: 2 garments per affected body part every 2 years

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

The following codes will be allowed when used as a primary or secondary dressing over wound(s) that are surgically created, modified or debrided:

- A6545, A6448-A6450, A6451-A6452, A6594-A6609

Codes A4490, A4495, A4500, A4510 are non-covered.

Cranial Remolding Orthosis (S1040- Prior authorization is required even if allowed amount is < $1000)

Covered for pediatric patients who have moderate to severe cranial asymmetry (plagiocephaly) associated with premature birth, restrictive intrauterine positioning, cervical abnormalities, birth trauma, torticollis, and/or sleeping positions for either of the following circumstances:

- Following surgical correction of synostotic plagiocephaly (i.e., craniosyntosis); or
- When a diagnosis of nonsynostotic plagiocephaly is documented and all the following criteria is met:
    - Infant is three to 18 months of age
    - Infant has not responded to a two-month trial of head positioning or other conservative therapies
    - Photographs and anthropometric measurements verifying moderate to severe nonsynostotic positional plagiocephaly.

Crutch substitute/knee walker (E0118)

Considered medically necessary when the below criteria has been met:

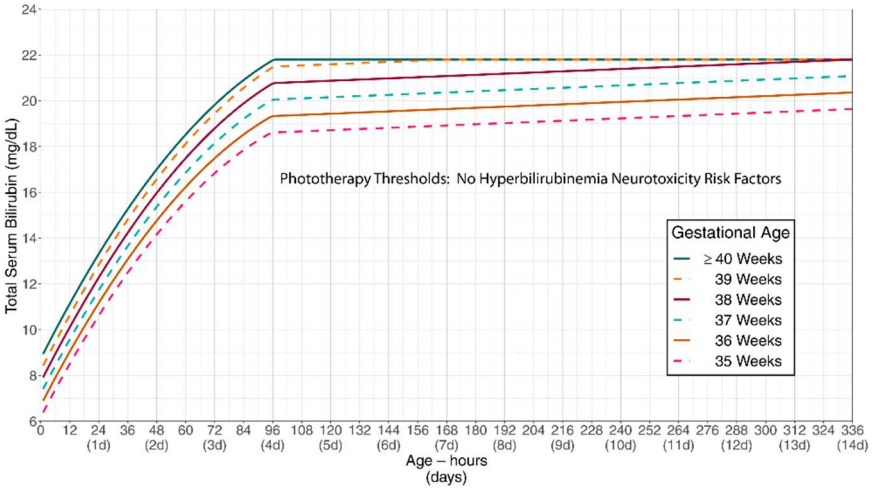
- There is a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADL) in the home, AND,
- The member is not a candidate for crutches or a manual wheelchair due to not having sufficient upper extremity function needed to safely use crutches or self-propel a manual wheelchair or there is no caregiver who is able to provide assistance with the wheelchair, AND
- The functional mobility deficit can be sufficiently resolved by use of a knee walker, AND,
- The member is able to safely use the knee walker

Home Phototherapy for neonatal hyperbilirubinemia (E0202)

For newborn infants who have already been discharged and then develop a total serum bilirubin (TSB) above the phototherapy threshold, treatment with a home LED-based phototherapy device rather than readmission to the hospital is an option for infants who meet the following

criteria:

- Gestational age > 38 weeks
- > 48 hours old
- Clinically well with adequate feeding
- No known hyperbilirubinemia neurotoxicity risk factors
    - Gestational age < 38 week
    - Albumin < 3.0 g/dl
    - Isoimmune hemolytic disease (i.e., positive direct antiglobulin test), G6PD deficiency, or other hemolytic conditions
    - Sepsis
    - Significant clinical instability in the previous 24 hours
- No previous phototherapy
- TSB concentration no more than 1 mg/dL above the phototherapy treatment threshold (chart below)
- An LED-based phototherapy device will be available in the home without delay
- TSB can be measured daily



A microprocessor-controlled knee prosthesis (e.g., L5856)

Considered medically appropriate when ALL of the following criteria are met:
A. For persons with a knee disarticulation amputee OR transfemoral amputee;
B. Functional level 3 or above;
C. Lower level prosthetic devices (e.g., fluid, pneumatic, etc.) cannot be used or are insufficient to meet the functional needs of the individual in performing ADLs;

D. The patient has adequate cardiovascular and pulmonary reserve
E. The patient has received additional training for use of this technology and has demonstrated adequate cognitive ability to master use and care requirements;
F. The patient demonstrated a need to perform ALL of the following:
    1. Long distance ambulation at variable rates;
    2. Regular and frequent ambulation on uneven terrain (e.g., grass, gravel, or curbs); and
    3. Regular and frequent ambulation on stairs or ramps;
G. Functional evaluation indicates that with training, use of a microprocessor-controlled knee prosthesis is likely to meet the functional needs of the individual.
H. Microprocessor-controlled knees are contraindicated for ANY of the following:
    1. The patient's functional level is less than 3 or has limited ambulation due to poor balance or ataxia;
    2. The patient is unable to tolerate the weight of the prosthesis;
    3. The patient is unable to use the swing and stance features of the knee;
    4. The patient is unable to change the prosthesis or has a condition that would cause inadequate fitting;
    5. The patient has significant hip flexion contracture (over 20 degrees);
    6. The patient has significant deformity of the remaining limb that would impair ability to stride;
    7. The prosthesis will be used when the environmental conditions include excessive moisture or dust which invalidates the warranty.

A microprocessor-controlled ankle-foot prosthesis (L5973) (e.g., Proprio Foot, Ossur, Aliso Viejo, CA)
Considered **medically appropriate** when **ALL** of the following criteria are met:

A. For persons with a transtibial amputation;
B. Functional level of 3 or above;
C. Lower level prosthetic devices (e.g., SACH foot) cannot be used or are insufficient to meet the functional needs of the individual in performing ADLs;
D. The patient has adequate cardiovascular and pulmonary reserve;
E. The patient has received additional training for use of this technology and has demonstrated adequate cognitive ability to master use and care requirements;
F. The patient demonstrated a need to perform **ALL** of the following:
    1. Long distance ambulation at variable rates;
    2. Regular and frequent ambulation on uneven terrain (e.g., grass, gravel, or curbs); and
    3. Regular and frequent ambulation on stairs or ramps;
G. Functional evaluation indicates that with training, use of a microprocessor-controlled ankle-foot prosthesis is likely to meet the functional needs of the individual.

The following lower extremity prosthetics or components are considered not medically necessary:

A. Lower limb prosthetic devices for individuals with functional level 0

B. A microprocessor-controlled ankle-foot with power assist (L5973 AND L5969)

Oximeter (E0445- Rental item only)

CDPHP allows rental (until purchase price is met) of an oximeter for members who require continuous monitoring will be covered in combination with oxygen therapy under the following circumstances:

- Weaning from oxygen.
- Changes in physical condition requiring adjustments in oxygen therapy.
- Maintaining oxygen levels within a narrow range.
- As part of a primary care provider's or physician specialist's treatment plan requiring frequent monitoring/assessment of oxygen levels that cannot be achieved using a "Spot check" oximeter.

Covered without oxygen therapy under the following circumstance:

- In cases of complex cardiac conditions, such as, but not limited to, univentricular heart or unrepaired cyanotic heart disease.

Pulse oximeter probes (A4606) are used with the oximeter (E0445) and are included in the reimbursement for the pulse oximeter rental.

Documentation Requirements for Oximeter for members who require continuous monitoring:

The following documentation is necessary to support prior approval of an oximeter:

- Diagnosis/medical condition justifying the need to monitor blood oxygen levels.
- Current oxygen orders, if applicable (Note: oxygen orders should be renewed every 12 months).
- Treatment plan listing the required parameters and interventions for abnormal readings, including corresponding oxygen titrations if applicable.
- Availability of caregivers trained to appropriately manage the listed treatment interventions.

If used with a ventilator, CPAP, BiPAP, or other respiratory assist device, the type, make, and model of the respiratory assist device must be provided to ensure oximetry is not already available on that device.

Pediatric Gait Trainer (E8000-E8002)

Gait trainers are considered medically necessary for therapeutic and functional ambulation when all the below criteria are met:

- Member is 18 years of age or younger;

- Member has an acquired injury (e.g., spinal cord, traumatic brain injury) or a chronic physical limitation that affects the ability to ambulate (e.g., cerebral palsy, neuromuscular disease, spina bifida);
- Member requires moderate to maximum support for ambulation and documentation shows that assistive devices have not been effective;
- There has been at least a one-month rental trial in which the member demonstrates capability of utilizing and tolerating the equipment safely.

Pediatric Safety Bed (E0328, E0316)

CDPHP will provide coverage of a pediatric hospital bed with enclosure frame when the below criteria is met:

1. There is a diagnosis-related cognitive/communication impairment or a severe behavioral disorder (e.g., traumatic brain injury, seizure disorder, autism)
2. Member has a risk to safety while in bed OR there is a risk to safety due to climbing out of bed/wandering
3. Other alternatives were tried and were unsuccessful or contraindicated (examples below):
    a. Putting a mattress on the floor
    b. Padding added to ordinary beds
    c. Transparent plastic shields
    d. Medications
    e. Helmets
    f. Door alarms

Replacement Batteries (Various Codes)

- Coverage will follow medical supplies section of member contract if available

Standing frame/table system (E0637, E0638, E0641, E0642)

A standing device is considered medically appropriate when BOTH of the following criteria are met:

- There is documentation that the standing device is necessary for the patient to be independent in one or more of the following activities of daily living (ADLs) in the patient's home:
    1. Eating;
    2. Personal hygiene;
    3. Toileting;
    4. Dressing;
    5. Transfer; AND
- The patient is unable to accomplish the activities identified in above with current durable

medical equipment.

OR

A standing device is considered medically appropriate for decubitus ulcer management when BOTH of the following criteria are met:

- There is documentation that off-loading of a decubitus ulcer cannot be accomplished by other means; and
- The patient has completed a one-month trial using the standing device and has shown meaningful improvement after the trial period. Documentation from the referring provider that the patient has shown meaningful improvement during the trial period must be submitted, to be eligible for continued coverage.

Upper limb prostheses (L6000, L6010, L6020, L6050, L6055, L6100, L6110, L6120, L6130, L6200, L6205, L6250, L6300, L6310, L6320, L6350, L6360, L6370, L6400, L6450, L6500, L6550):

Prostheses that are worn externally and that temporarily or permanently replace all or part of an external body part that has been lost or damaged because of an injury or disease.

Vacuum drainage collection unit and tubing kit (A7048)

Covered for use in the home when provided in lieu of hospitalization or nursing home care.

CODING REQUIREMENTS AND REIMBURSEMENT

Supplies associated with DME/prosthetic/orthotic devices are covered when included in the purchase price.

All DME items must be billed with appropriate modifier to indicate purchase (NU), rental to purchase (NR), rental (RR) or used equipment that has been purchased (UE). Claims submitted without modifier will deny to resubmit with appropriate modifier.

When equipment is billed for purchase, the allowed amounts from any previously paid rental months will be subtracted from the purchase price. Payment for rental months will never exceed the total purchase price for the equipment.

DME Invoices

All DME items must be billed with appropriate modifier to indicate purchase (NU) or rental (RR). Claims submitted without modifier will deny to resubmit with appropriate modifier.

DME items not having a current CMS DME fee schedule or published NYS Medicaid fee schedule

rate will be reimbursed at a rate established by CDPHP, which may be based on specific case review and/or submission of the actual manufacturers' invoice.

For items that are made by the DME vendor themselves and no manufacturer's invoice is available, an itemization of supplies utilized, and applicable charges is required in order to consider reimbursement for the item.

CDPHP will reimburse DME items at the lesser of 150% of invoice cost or fee schedule unless otherwise stated in the provider contract.

When equipment is billed for purchase, the allowed amounts from any previously paid rental months will be subtracted from the purchase price.

Documentation Requests

CDPHP reserves the right to request medical records at any time including all dictated, handwritten notes, and the documents indicated below to support all the items billed on this claim. All pertinent information to meet policies and billing requirements must be included. Failure to supply full documentation indicated could result in partial or complete denial of services.

Required Documents*:

- Certificate of Medical Necessity (CMN) - Both initial and subsequent forms, if applicable

- Copy of unredacted manufacturer's invoice for items billed including: Product information
- Detailed Written Order (DWO)/Prescription/Fiscal Order or Standard Written Order (SWO)
- Dispensing Orders
- Face to Face Documents, if applicable
- Notes including progress notes pertinent to the DME requested
- Prior-Authorization form, if applicable
- Refill Documents
- Written Order Prior to Delivery (WOPD), if applicable
- DME Information Form (DIF)
- Model number and Manufacturer name
- Proof of Delivery (POD)/Delivery Documentation (Invoices and delivery receipts)

***Note:** Some of these documents may need to be obtained from the ordering physician while others may need to be obtained from the DME vendor who provided the equipment.

EXCLUSIONS

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

1. DME/Prosthetics/Orthotics designed for your comfort or convenience.
   The following list is not all inclusive but contains examples of items that are generally considered comfort or convenience:
   - Pools
   - Hot tubs
   - Air conditioners
   - Saunas
   - Humidifiers
   - Dehumidifiers
   - Exercise equipment

2. Over-the-counter medical supplies.

3. Orthotic devices that are not rigid or semi rigid devices.

4. Repair or replacement of DME or a prosthetic/orthotic device due to loss, misuse, or neglect.

5. Repair or maintenance and servicing of equipment or device that is subject to the manufacturer's warranty.

6. Requests for a duplicate device to have available at various locations (e.g., one for home and one for school/work).

7. Equipment or devices prescribed solely for use during sports or employment.

8. Charges related to the shipping, handling and/or delivery of covered equipment or devices.

9. Battery powered walker (E0152) is considered non-covered since the capabilities relate to use of the walker outside the home and it does not serve as a purpose for use in the home.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	CDPHP utilizes the New York State Medicaid management information system provider manual (MMIS) to determine coverage availability and distinguish a medical/surgical supply versus durable medical equipment, prosthetic, or orthotic: http://www.emedny.org/providerManuals/Index.html

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy to include the following: • Medicare Advantage provides benefits for supplies that are necessary for effective use of a prosthetic.
SELECT PLAN/HARP	CDPHP utilizes New York State Medicaid management information system provider manual (MMIS) to determine coverage availability and distinguish a medical/surgical supply versus durable medical equipment, prosthetic, or orthotic. There are 2 guidelines that identify these benefits: Medical Supplies Procedure Codes & Coverage Guidelines (sections 4.1, 4.2, 4.3) are billed directly to Medicaid Fee for Service: Medical Supplies Procedure Codes DME Procedure Codes & Coverage Guidelines (sections 4.4, 4.5, 4.6, and 4.7) are billed to CDPHP: DME Procedure Codes

SOURCES

1. CMS Durable Medical Equipment LCD's
   https://med.noridianmedicare.com/web/jadme/policies/lcd/active
2. CMS National Coverage Determination (NCD) for Durable Medical Equipment Reference List (280.1)
   https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=190&ncdver=2&chapter=all&sortBy=title&bc=AAAAIAAAAAAA

3. NYS DOH Carve Out Update- April 2023:
   https://www.health.ny.gov/health_care/medicaid/program/update/2023/docs/mu_no5_mar23_speced.pdf

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POLICY APPROVAL DATES

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

New: 11/21

Revised: 5/22, 9/22,11/22, 1/23, 5/23, 7/23, 9/23, 11/23, 1/24, 3/24, 5/24, 9/24, 11/24, 1/25, 3/25, 5/25, 11/25, 3/26, 5/26, 7/26

Reviewed:

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
11/1/2026	Under "For the following LCD/NCD items, please see specific CDPHP Resource Coordination or payment policies for coverage", added new policy Powered Compression Devices/Lymphedema Pump, 1.01.17
8/1/2026	Under "For the following LCD/NCD items, please see specific CDPHP Resource Coordination or payment policies for coverage", added new policy Electromagnetic and Pulsed Field Stimulation, 1.01.59 and Non-Invasive Surface Electrical Stimulation for Pain and Rehabilitation, 1.01.61
7/1/2026	Removed codes L5856 and L5973 from the list of items that do not require PA and added medical necessity criteria for these codes. Added information to code S1040 on prior authorization requirement.
3/1/2026	Added prior authorization DME information that was previous housed on the now obsolete Prior Authorization Guideline policy.
12/1/2025	Updated name and policy number for Cochlear implant and removed link to Medicare Non-Covered Items.
4/1/2025	Added new codes A6515-A6519, and A6611 to Compression stockings, garments, wraps, bandages section.
3/1/2025* No change to effective date of policy for this	Added additional information for cervical traction devices previously housed in the Non-Covered Technology policy.

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

update	
3/1/2025	Added criteria for pediatric safety beds.
2/1/2025	Added criteria for standing frames. Updated criteria for compression stockings. Under Noridian, removed Pneumatic Compression Devices as this LCD is retired. Clarified that Oximeter is rental item only.
1/1/2025 *No change to effective date of policy	Updated Medicaid section and provided links for DME/Supplies. Under Position Statement added: External Upper Limb Tremor Stimulator Therapy to the list. Added modifiers NR & UE to policy. Added additional coverage for automated blood pressure cuff (A4670) through quality programs.
1/1/2025	Added coverage criteria for oximeters.
8/1/2024	Added information on DME rental or purchase modifiers. Added statements regarding rentals converting to purchase. Added information on code A7048 Updated criteria for knee walker to remove "and/or other physical and mental capabilities".
5/1/2024	Added criteria for pediatric gait trainers Added criteria for automated blood pressure cuff (A4670)
4/1/2024	Added battery powered walker to exclusions
3/1/2024	Removed prior authorization exceptions from the Policy Considerations section as this information is housed in the RC Prior Authorization Guideline document. Updated lymphedema compression section.
1/1/2024	Replaced termed code K1013 with new code A4457 in Select Plan/HARP section.

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

12/1/2023	Updated link for coverage criteria for Seat Elevation Equipment (Power Operated) on Power Wheelchairs and added link for items that are considered non-covered.
11/1/2023* *No change to effective date for this update	Added coverage criteria for lymphedema gradient pressure sleeves/gauntlets/gloves (S8420-S8428). Added criteria for rental of home phototherapy devices for neonatal jaundice, and also identified there will be no PA requirement for these devices. Added that wheelchair accessory items E0971- antitipping device, E0978- positioning belt/safety belt/pelvic strap and E0990- elevating leg rest, complete assembly do not require PA for rental. Removed NCA link for Seat Elevation System and replaced with NCD link. Added link for products/codes that are non-covered.
11/1/2023	Added documentation requirements to Coding Requirements and Reimbursement section. Added section for items not otherwise addressed in a Medicare LCD/NCD or CDPHP policy. Added scoliosis jackets (L1300 & L1310) as not requiring a PA when billed with a diagnosis of scoliosis (M41-M41.9).
5/16/2023	Added new Medicare NCA link for Seat Lift Systems
5/1/2023	Under Policy Considerations added information on DME replacement. Added negative pressure wound therapy (E2402) as an item that does not have a rental PA requirement.
4/1/2023	Medicaid section updated to reflect the changes for the Medicaid RX/DME Carveout.
1/1/2023* *No change to effective date for this update	Updated Child Health Plus section to mirror Select Plan/HARP coverage.
1/1/2023* *No change to effective date for this update.	No coverage criteria changes made. Minor changes/clarifications made throughout policy.

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: DURABLE MEDICAL EQUIPMENT, PROSTHETICS/ORTHOTICS & MEDICAL SUPPLIES

1/1/2023	Under Policy Considerations, added information on Nebulizers, standard wheelchairs, and transports chairs.
5/1/2022	Added references to maintenance and servicing coverage.
1/1/2022	New policy

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Policy/Procedure Name: Elahere (mirvetuximab soravtansine-gynx) **Control Number: 1350/20.000470**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Ovarian cancer includes cancers that start in cells from the ovary, fallopian tube, or peritoneum. These cancers are grouped together often because they are treated using similar therapies. In the United States, approximately 20,000 patients are diagnosed with ovarian cancer a year and of those, 13,000 result in death. Most of the time, the disease has already advanced at the time of diagnosis. Surgery and platinum-based combination chemotherapy, with or without bevacizumab is typically used for treatment depending on the stage. Platinum-resistant ovarian cancer, (PROC) occurs in about 15 to 30% of women with ovarian cancer. Recurrence is frequent and up to 80% of patients will acquire progressive resistance over time.

If a patient has recurrence within six months after completion of platinum-based chemotherapy it is classified as PROC. Currently, there is no standardized treatment for PROC however, NCCN guidelines recommend non-platinum-based agents such as bevacizumab (if not previously received), docetaxel, oral etoposide, gemcitabine, weekly paclitaxel with or without pazopanib, liposomal doxorubicin with or without bevacizumab, weekly paclitaxel with or without bevacizumab, or topotecan with or without bevacizumab.

The folate receptor 1 (FOLR1) is elevated in 70 to 80% of ovarian cancers and highly expressed in up to 40% of all high-grade ovarian cancers. This receptor serves as an ideal target for therapies such as Elahere because it has limited expression in normal tissues. Elahere is an antibody-drug conjugate (ADC). The antibody is a chimeric immunoglobulin G1 (IgG1) directed against FRα. The small molecule, DM4, is a microtubule inhibitor attached to the antibody via a cleavable linker. Upon binding to FRα, mirvetuximab soravtansine-gynx is internalized followed by intracellular release of DM4 via proteolytic cleavage. DM4 disrupts the microtubule network within the cell, resulting in cell cycle arrest and apoptotic cell death.

In the SOROYA trial, all patients were required to have received prior bevacizumab treatment and be positive for FRα expression as defined by the Ventana FOLR1 Assay. The overall response rate was 31.7% and the median duration of response was 6.9 months. The most common (≥ 20%) adverse reactions, including laboratory abnormalities, were vision impairment, fatigue, nausea, increased alanine aminotransferase, keratopathy, abdominal pain, decreased lymphocytes, peripheral neuropathy, diarrhea, decreased albumin, constipation, increased alkaline phosphatase, dry eye, decreased magnesium, decreased leukocytes, decreased neutrophils, and decreased hemoglobin.

Summary

Effective Date of Policy:	2/1/2023
Indications	FRα-positive, platinum resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer
ICD10 Diagnosis Codes	C56.9, C57.0, C48.2
Availability	Injection: 100 mg/20 mL (5 mg/mL) in a single-dose vial
Duration	Six months
Limitations	Elahere contains a black box warning for ocular toxicity. It can cause severe ocular toxicities, including visual impairment, keratopathy, dry eye, photophobia, eye pain, and uveitis.

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy:

	Inclusion Criteria	Recommended Dosing Regimen
Indication (FDA approval) Treatment of adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary	• Enrollee ≥ 18 years old • Therapy is requested by an oncology specialist • Enrollee has diagnosis of FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer through the following:	• 6 mg/kg adjusted ideal body weight administered as an intravenous infusion every three weeks until disease progression or unacceptable toxicity • Premedication includes corticosteroid, antihistamine, antipyretic, antiemetic,

peritoneal cancer	○ Tumor must be positive for FRα expression as defined by the Ventana FOLR1 Assay (≥ 75% positive tumor cells) ○ Enrollee must have platinum-resistant disease defined as: ▪ Members who have only had one line of platinum-based therapy must have received at least four cycles of platinum, must have had a response and then progressed between > three months and ≤ six months after the date of the last dose of platinum ▪ Patients who have received two or three lines of platinum therapy must have progressed on or within six months after the date of the last dose of platinum • Patients must have received at least one but no more than three prior systemic lines of anticancer therapy, including at least one line of therapy containing bevacizumab, and for whom single-agent therapy is appropriate as the next line of treatment ○ See NCCN guidelines for recommended therapies for treatment • Enrollee has documentation of an ophthalmic exam including visual acuity and slit lamp exam prior to treatment initiation, every other cycle for the first eight cycles, and as clinically indicated ○ Enrollee will receive artificial tears and ophthalmic topical corticosteroids	ophthalmic topical steroids, and lubricating eye drops.

Exclusion Criteria

Therapy will not be authorized if any of the above Inclusion Criteria are not met OR any of the below noted Exclusion Criteria are met:

- Members with active or chronic corneal disorders, history of corneal transplantation, or active ocular conditions requiring ongoing treatment/monitoring, such as uncontrolled glaucoma, wet age-related macular degeneration requiring intravitreal injections, active diabetic retinopathy with macular edema, macular degeneration, presence of papilledema, and/or monocular vision

Continuation Criteria

- Requests will be reviewed per criteria every six months
- Therapy will be reauthorized if clinical documentation supports ongoing disease stability and acceptable adverse reaction tolerability
  - See above for ocular toxicity black box warning

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.

References

		Updated	Accessed
1.	Elahere [package insert]. Waltham, MA. ImmunoGen, Inc., October 2024	10/24	11/24
2.	IPD Analytics. Elahere (mirvetuximab soravtansine-gynx). New Drug Review. 2022 Dec.		1/23
3.	National Comprehensive Cancer Network®. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer V.3.2024. © National Comprehensive Cancer Network, Inc. 2024. All rights reserved. To view the most recent and complete version of the guideline, go online to NCCN.org.	7/24	11/23
4.	ImmunoGen Announces FDA Accelerated Approval of ELAHERE™ (mirvetuximab soravtansine-gynx) for the Treatment of Platinum-Resistant Ovarian Cancer. ImmunoGen Inc. Nov 2022. Accessed at https://immunogen.com on December 27, 2022.		1/23
5.	Garcia, A., & Singh, H. (2013). Bevacizumab and ovarian cancer. Therapeutic advances in medical oncology, 5(2), 133–141. https://doi.org/10.1177/1758834012467661		1/23

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE CHOICES: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 2/12/2026

New: 2/2023

Revised	Reviewed
	2/24, 2/25, 2/26

Revision Date	Changes Made

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MEDICAL POLICY

Medical Policy Title	**Electromagnetic and Pulsed Field Stimulation**
Policy Number	**1.01.59**
Current Effective Date	**August 1, 2026**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

I. The following forms of electromagnetic and pulsed field stimulation are **investigational**:

A. Peripheral Magnetic Stimulation, including Transcutaneous Electro Magnetic Peripheral Nerve Stimulation (mPNS) (e.g., Axon Therapy, MagVenture Pain Therapy) for chronic neuropathic pain;

B. Pulsed Electrical Stimulation (PES), including BioniCare when used to facilitate repair of cartilage in patients with arthritis (e.g., MedRelief ST Series, and Jstim1000);

C. Targeted Electromagnetic Field Stimulation (e.g., SofPulse);

D. Electromagnetic Stimulation (e.g., OrthoCor Active Knee System);

RELATED POLICIES

Corporate Medical Policy

1.01.58 Cranial and Auricular Neuromodulation

1.01.60 Implantable and Invasive Neuromodulation Systems

1.01.61 Non-Invasive Surface Electrical Stimulation for Pain and Rehabilitation

1.01.62 Specialized Neuromodulation for Specific Conditions

7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

7.01.10 Sacral Nerve Stimulation

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

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Peripheral sensory nerve fibers are classified according to their diameter, myelination, and conduction velocity. A fibers are sub-classified into A-alpha, A-beta, and A-delta types. These types of fibers are large, fast, myelinated and have the lowest activation threshold. When activated, they inhibit pain transmission in the spinal cord via proprioceptive and motor afferent signals. B fibers are small, lightly myelinated and carry preganglionic autonomic signals. They are activated after A fibers, but before C fibers and can contribute to responses in the autonomic nervous system such as vasodilation or sympathetic modulation when stimulated. They aren't often the primary targets in pain treatment. C fibers are the smallest of the fibers with the highest activation threshold and have limited capability to be selective in terms of blocking currents through the nerves.

Canonical Erlanger-Gasser Classification of fiber types in sensory peripheral nerves (Olausson et al 2024)

Fiber Type	**Function**	**Average Diameter (µm)**	**Average conduction velocity (m/s)**
Aα (A-alpha)	Myelinated, Primary muscle spindles, Golgi tendon organs	15	100
Aβ (A-beta)	Myelinated, Cutaneous touch and pressure afferents	8	50
Aδ (A-delta)	Myelinated, Cutaneous temperature (cold) and 'fast' pain	<3	15
C	Unmyelinated, Cutaneous pain ('slow' pain) and temperature (warmth and cold)	1	1

Magnetic stimulation of peripheral nerves (mPNS) has been described in the literature as a pain-free alternative to electrical stimulation. mPNS does not require tissue contact yet has a deeper penetration depth. It uses a time-varying field to generate currents through electromagnetic induction, easily targeting Aδ fibers rather than Aβ fibers through electrodes at the skin's surface (Sayed et al 2023). The activation of the Aδ fibers is thought to impact sharp pinprick type pain (Olausson et al 2024).

Neuralace Medical, the creator of Axon Therapy differentiates its device from PNS by using "low frequency magnetic pulses to engage sensory, pain, and motor fibers mechanistically" and reports to provide "long-term relief for the root cause of post-trauma and post-surgical neuropathic pain."

MagVenture Pain Therapy devices (Tonika Elektronik A/S) are intended for use in the hospital and

clinics.

Targeted Electromagnetic Field (e.g., SofPulse, OrthoCor)

Electrical and electromagnetic stimulation are being investigated to improve functional status, as well as to relieve pain related to osteoarthritis and rheumatoid arthritis that are unresponsive to other standard therapies. Noninvasive electrical stimulators generate a weak electrical current within the target site using pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. In capacitive coupling, small skin pads or electrodes are placed on either side of the knee or wrist. Electrical stimulation is provided by an electronic device that noninvasively delivers a subsensory low-voltage, monophasic electrical field to the target site of pain. Pulsed electromagnetic fields are delivered via treatment coils placed over the skin. Combined magnetic fields deliver a time-varying field by superimposing that field onto an additional static magnetic field.

In basic research studies, pulsed electrical stimulation has been shown to alter chondrocyte-related gene expression in vitro and to have regenerative effects in animal models of cartilage injury. It is proposed that the device treats the underlying cause of the disease by stimulating the joint tissue and improving the overall health of the joint and that it provides a slow-acting, but longer-lasting improvement in symptoms. Therefore, pulsed electrical stimulation is proposed to be similar to bone stimulator therapy for fracture nonunion.

The OrthoCor Active Knee System (OrthoCor Medical; acquired by Caerus Corp) uses pulsed electromagnetic field energy at a radiofrequency of 27.12 MHz to treat pain. The OrthoCor Knee System is classified as a short-wave diathermy device for use other than applying therapeutic deep heat. It is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue and for the treatment of muscle and joint aches and pain associated with overexertion, strains, sprains, and arthritis. the SofPulse (also called Torino II, 912-M10, and Roma; Ivivi Health Sciences, renamed Amp Orthopedics) was cleared for marketing as a short-wave diathermy device that applies electromagnetic energy at a radiofrequency of 27.12 MHz. The device is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue.

SUPPORTIVE LITERATURE

Soliman and colleagues (2025) conducted a meta-analysis of 313 double-blind randomized controlled trials (RCTs) evaluating participants of any age with neuropathic pain. A total of 284 studies were pharmacological, while only 29 were related to neuromodulation. Included in the analysis were any pharmacological or neuromodulation intervention if administered for at least 3 weeks of follow up if after a single administration, had at least 3 weeks of follow up. The primary efficacy outcome was the proportion of responders (defined as having at least a 50% reduction in baseline pain intensity. The primary safety outcome was the number of participants who withdrew from the treatment due to adverse events. Duration of the included trials was 3-24 weeks, with a median of 8 weeks. Given the low certainty of evidence, authors were not able to confidently make treatment recommendations for specific populations, and there were no evidence of superiority to any of the drugs included in head-to-head trials. Tri-cyclic antidepressants, serotonin and norepinephrine reuptake inhibitors (SNRIs)

and α2δ-ligands are recommended as first line treatments, followed by topical treatments. Regarding neuromodulation (which included 29 sham-controlled trials of both invasive and non-invasive techniques) trials, the majority of results were inconclusive, stating a need for large, double-blind sham controlled, parallel trials over clinically relevant timeframes to examine efficacy and safety.

Pulsed Electrical Stimulation

PES has been investigated over several decades. There have been no clinical studies to date that have developed standardized stimulation parameters, provided accurate comprehensive reporting of electrical conditions, or consistent clinical results (Zimmerman et al 2024). Given this, conclusions cannot be formulated as to its ability to positively impact the net health outcome.

Pulsed Electromagnetic Fields

Yang et al (2020) published a systematic review evaluating the effects of pulsed electromagnetic field therapy on pain, stiffness, physical function, and quality of life in patients with osteoarthritis. The meta-analysis included 15 small, sham- or placebo-controlled studies published between 1993 and 2016. Only two studies were deemed to be at low risk of bias. Overall, the quality of evidence was deemed low or very low. A statistically significant beneficial treatment effect was noted for pain (standardized mean difference [SMD], 1.06; 95% confidence interval [CI], 0.61 to 1.51), stiffness (SMD, 0.37; 95% CI, 0.07 to 0.67), and physical function (SMD, 0.46; 95% CI, 0.14 to 0.78), but not quality of life (SMD, 1.49; 95% CI, -0.06 to 3.04). Only pain outcomes were considered clinically significant. Studies were limited to the short-term effects of pulsed electromagnetic field therapy, with study follow-up durations ranging from 10 days to 12 weeks. Additionally, the high levels of heterogeneity across the outcome measures made harmonization difficult, the included studies had small sample sizes, and there was a lack of an intention-to-treat analysis in many of the included studies.

Tong et al (2022) conducted a systematic review of 11 randomized trials in which patients with osteoarthritis received pulsed electromagnetic fields or control treatment. Of the studies, six had a sham group and five studies used other treatments including hot packs, TENS, physiotherapy, and ultrasound. Many of the trials described below were included in the analysis, along with some additional studies. Risk of bias was high in six studies, moderate in two studies, and low in three studies. The main outcomes measured the efficacy of pulsed electromagnetic field stimulation on osteoarthritis-related soreness, stiffness, and physical function assessed by visual analog scale (VAS) and/or Western Ontario and McMaster University Arthritis Index (WOMAC) scores. Compared to controls, pulsed electromagnetic field stimulation significantly reduced pain (SMD, 0.71; 95% CI, 0.08 to 1.34; p=.03; I^2=93%). There were also significant differences in stiffness (SMD, 1.34; 95% CI, 0.45 to 2.23; p=.003; I^2=99%) and physical function (SMD, 1.52; 95% CI, 0.49 to 2.55; p=.004; I^2=95%) with pulsed electromagnetic field stimulation. All three outcomes were significantly better with pulsed electromagnetic field stimulation compared to sham treatment but not compared to other treatments. Limitations of the analysis included the small number of studies, high heterogeneity, and the combined analysis of sham and other interventions.

Yabroudi et al (2024) evaluated the effects of pulsed electromagnetic field therapy combined with progressive resistance exercise (PRE) in improving physical function and pain in patients with knee osteoarthritis. Patients were randomized to receive either 24 sessions of pulsed electromagnetic field therapy plus PRE (n=17) or PRE alone (n=17). Compared to baseline assessments, both groups scored higher on post-treatment, 3-month, and 6-month follow-up scores of Knee Injury and Osteoarthritis Outcome Score (KOOS) and Numeric Pain Rating Scale (NPRS). Both groups were also able to complete the 5-times chair stand test and walking speed test faster at post-treatment timepoints compared to baseline; however, none of the discussed study outcomes were significantly different between the pulsed electromagnetic field therapy plus PRE or PRE alone groups.

de Paula Gomes et al (2020) conducted a prospective, randomized, sham-controlled trial evaluating the effects of an exercise program alone or combined with electrophysical modalities in patients with knee osteoarthritis (N=100). Patients were equally allocated into five groups (n=20): exercise, exercise plus sham, exercise plus interferential current therapy (ICT), exercise plus pulsed shortwave diathermy therapy (SDT), and exercise plus photobiomodulation. Patients received treatment three times weekly for a duration of eight weeks. A significant improvement in WOMAC function and pain scores was observed in the exercise-only group compared to all other groups, including SDT. The addition of ICT, SDT, or photobiomodulation did not result in any clinically meaningful benefits. No long-term follow-up assessments were performed after the eight-week treatment period and use of analgesics was not controlled in the study.

Magnetic Peripheral Nerve Stimulation (mPNS)

Kapural et al 2025, conducted a vendor funded randomized controlled trial to assess the safety and efficacy of mPNS in combination with conventional medical management (CMM) in patients with post-traumatic or post-surgical pain. A total of 65 patients were randomized (CMM+mPNS n=35, CMM n=30) and evaluated for one year. Patients in the CMM alone group were allowed to crossover to the treatment group at 90 days. The primary efficacy endpoint was subjects with ≥50% pain relief at day 90, without an increase in pain medication. The treatment protocol included three consecutive daily sessions in the first week, followed by a weekly session for the remainder of the month for a total of six treatments. Assessments included the visual analog scale (VAS), average change in pain score from baseline, reduction in morphine-equivalent daily dose (MEDD), initiation of new pain medication, and increases in new pain medication. Secondary outcomes included patient reported quality of life outcomes (European Quality of Life 5 Dimensions 3 Level [EQ-5D-3L]) at 365 days, the Patient Global Impression of Change (PGIC) scores and Pain Disability Index (PDI) scores. At the 90-day mark, 71% of the subjects were considered responders in the CMM +mPNS cohort vs. 13% in the CMM group ($p<0.0001$). At the end of the study, 94% of participants were responders in the CMM+mPNS cohort and 69.2% in the crossover group. Improvements were noted in the EQ-5D-3L and PGIC responder rates. Treatment -related adverse events were reported by seven participants in the CMM+mPNS, three in CMM alone, and five in crossover participants. None of the adverse events led to withdrawal and were mostly composed of mild skin irritation and short-term increases in pain around the treatment area. A primary limitation of the study was the design-it was not originally designed as a crossover study at 90 days but was added on IRB-approved protocol revision. Additionally, the authors note that a stipend was provided to the mPNS+CMM subjects to enhance retention. Prior to

the stipend increase only 3/14 subjects completed day 365. The retention rate increased from 21.4% to 76.5% after the stipend increase. Longer studies, with sound methodology are needed to determine if the use of mPNS improves the net health outcome.

PROFESSIONAL GUIDELINE(S)

In 2019, the American College of Rheumatology released guidelines for the management of osteoarthritis of the hand, hip, and knee. The guidelines do not mention pulsed electrical or electromagnetic stimulation, but they recommend against transcutaneous electrical stimulation for patients with knee and/or hip osteoarthritis.

In 2019, the Osteoarthritis Research Society International published updated evidence-based consensus guidelines for the nonsurgical management of knee, hip, and polyarticular osteoarthritis. Sixty treatment modalities were evaluated for three patient groups: knee-only, hip, and multijoint osteoarthritis. Neuromuscular electrical stimulation was considered " strongly recommended against" for all groups due to low quality evidence from trials with small sample sizes and insufficient duration of follow-up. Electromagnetic therapy was considered "strongly recommended against" for all groups due to low quality evidence and an implausible biological mechanism.

In 2021, the American Academy of Orthopaedic Surgeons published updated guidelines on the treatment of osteoarthritis of the knee. The guidelines noted that there was only one study "that examined the use of a wearable pulsed electromagnetic field device for pain management in subjects with knee osteoarthritis." The strength of recommendation was downgraded to "limited" from inconclusive since there is only this single "moderate" quality study recommending for or against the intervention."

In 2021, the American College of Rheumatology released updated recommendations for the treatment of rheumatoid arthritis. All recommended treatments were pharmacologic. Use of electrical stimulation for treating rheumatoid arthritis was not addressed.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates stimulation devices as medical devices. All electrical stimulation devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 March 26]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Mar 26]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).

- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0766T (E/I)	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, initial treatment, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve
0767T (E/I)	Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, initial treatment, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; each additional nerve (List separately in addition to code for primary procedure)
97039 (*E/I)	Unlisted modality (specify type and time if constant attendance) (*E/I when utilized for any of the modalities addressed within this policy.)
97139	Unlisted therapeutic procedure (specify)

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HCPCS Codes

Code	Description
97139	Unlisted therapeutic procedure (specify)
E0761	Nonthermal pulsed high frequency radiowaves, high peak power electromagnetic energy treatment device
E0762 (E/I)	Transcutaneous electrical joint stimulation device system, includes all accessories
E0769 (E/I)	Electrical stimulation or electromagnetic wound treatment device, not otherwise classified
E1399	Durable medical equipment, miscellaneous

ICD10 Codes

Code	Description
All Diagnoses	

REFERENCES

American Academy of Orthopaedic Surgeons (AAOS) [Internet]. Clinical practice guideline: osteoarthritis of the knee. 2021 Aug 31 [accessed 2026 April 06]. Available from: https://www.aaos.org/quality/quality-programs/osteoarthritis-of-the-knee/

Bannuru RR, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. Osteoarthritis and Cartilage. 2019 June 20;27(2019):1578-1589.

De Paula Gomes CAF, et al. Exercise program combined with electrophysical modalities in subjects with knee osteoarthritis: a randomized, placebo-controlled clinical trial. BMC Musculoskeletal Disorders. 2020;21(258):1-11.

Fraenkel L, et al. 2021 American College of Rheumatology guideline for the treatment of rheumatoid arthritis. Arthritis Care and Research. 2021 July;73(7):924-939.

Kapural L, et al. Efficacy and safety of magnetic peripheral nerve stimulation for treatment of neuropathic pain; one year follow up of long-term outcomes. J Pain Research. 2025 Aug 30;2025(18):4471-4481.

Kolasinski SL, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the management of osteoarthritis of the hand, hip, and knee. Arthritis Care Res. 2020 Feb;72(2):149-162.

Olausson H, et al. Slow touch and ultrafast pain fibres: revisiting peripheral nerve classification. Clinical Neuropsychology. 2024 May 03;163(2024):255-262.

Tong J, et al. The efficacy of pulsed electromagnetic fields on pain, stiffness, and physical function in osteoarthritis: a systematic review and meta-analysis. Pain Res and Management. 2022 May 09;22:1-11.

Yabroudi MA, et al. Effects of the combination of pulsed electromagnetic field with progressive resistance exercise on knee osteoarthritis: a randomized controlled trial. J Back and Musculoskeletal Rehab. 2024 Jan;37(1):55-65.

Yang X, et al. Effects of pulsed electromagnetic field therapy on pain, stiffness, physical function, and quality of life in patients with osteoarthritis: a systematic review and meta-analysis of randomized placebo-controlled trials. Physical Therapy. 2020 Apr 06;100(7): 1118-1131.

Zimmerman J, et al. Electrical stimulation for cartilage tissue engineering- a critical review from an engineer's perspective. Heliyon. 2024 Sep 23;10(2024):e38112.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD-Electrical Stimulation (ES) and Electromagnetic Therapy for the Treatment of Wounds (270.1) [accessed 2026 Apr 06]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 7/26 **Revised**: **Reviewed**:	
Date	**Summary of Changes**
8/1/2026	• New policy in conjunction with other new policies 1.01.58, 1.01.60, 1.01.61, & 1.01.62, which will replace Neuromuscular/Functional Electrical Stimulation policy 1370/20.000073 which is being made obsolete.

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Policy/Procedure Name: Elevidys (Delandistrogene moxeparvovec) **Control Number: 1350/20.000485**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Duchenne muscular dystrophy (DMD) results from mutation of the DMD (also known as Dystrophin) gene, the largest known human gene, which is carried on the X chromosome. DMD affects about 1 in 3,300 boys. Although histologic and laboratory evidence of myopathy may be seen at birth, the clinical onset of skeletal muscle weakness usually does not become evident until early childhood, average age at diagnosis is approximately five years.

Therapy for DMD includes exon-skipping agents (for those with specific DMD mutations) which were approved through accelerated approval pathway. Importantly, the confirmatory trials demonstrating clinical benefit has yet to be verified. The four exon-skipping anti-sense oligonucleotide agents that are available include Exondys-51 (Eteplirsen), Viltepso (Viltolarsen), Vyondys 53 (Golodirsen), and Amondys 45 (Casimersen). In addition to exon-skipping agents, corticosteroids remain a primary pharmacologic treatment for DMD.

Elevidys (formerly SRP-9001) is an adeno-associated virus (AAV) vector-based gene therapy product FDA approved for treatment of ambulatory patients aged 4-5 years with DMD with a confirmed mutation in the DMD gene. Elevidys encodes a novel protein, Sarepta's micro-dystrophin. Elevidys was approved under the accelerated pathway, and continued approval may be contingent upon verification and description of clinical benefit as confirmed in clinical trials.

According to the FDA Briefing Document for the Cellular, Tissue, and Gene Therapies Advisory Committee Meeting[1],

> Sarepta's micro-dystrophin is a novel, engineered protein; no epidemiologic or pathophysiologic evidence of its function is available. The protein differs in important ways from both the endogenous shortened forms of dystrophin in patients with [Becker muscular dystrophy] BMD, and the internally-truncated dystrophins expressed through exon-skipping drugs. Measurement of levels of Sarepta's micro-dystrophin in muscle tissue only provides information about expression of the transgene product in cells transduced by SRP-9001, rather than insight into a pharmacologic effect on a biomarker in the pathway of the disease.
>
> Having reviewed nonclinical data and three clinical studies, including a randomized, double-blinded, placebo-controlled trial demonstrating expression of Sarepta's micro-dystrophin at week 12 following infusion of SRP-9001, FDA notes that the clinical studies conducted to date do not provide unambiguous evidence that SRP-9001 is likely beneficial for ambulatory patients with DMD. It is challenging to conclude with reasonable certainty from the data provided by the Applicant either that SRP-9001 is likely effective for younger patients, or that it is likely ineffective for older patients or those with somewhat poorer functional status. Additionally, FDA has safety concerns related to the possibility of administering an ineffective gene therapy.

Following the discussion topics, the panel was asked to vote on whether SRP-9001 was deserving of accelerated approval, while considering the benefits and risks of the treatment, and using micro-dystrophin expression at week 12 as a surrogate end point. The panel voted 8–6 (8 Yes; 6 No; 0 Abstain) in favor of the agent. Importantly two "YES" votes came from a patient and consumer representative.

Therapy was investigated in Study 102 (NCT03769116), a randomized, double-blind, placebo controlled trial, described in two parts (part 1 described below, part 2 included treatment of the Part 1 placebo arm with SRP-9001). In the 48-week randomized, double-blind, placebo-controlled Part 1, 41 ambulatory subjects with DMD 4-7 years old were studied. Subjects either had a confirmed frameshift mutation or premature stop codon mutation between exons 18 to 58 in the DMD gene and were randomized in a 1:1 ratio to receive either a single intravenous infusion of SRP-9001 (N=20) at the intended dose of 1.33×10^{14} vg/kg or placebo (N=21). However, in the SRP-9001 group it was retrospectively determined, eight subjects received the intended dose, six subjects received approximately two-thirds of the intended dose (8.94×10^{13} vg/kg), and six subjects received about half of the intended dose (6.29×10^{13} vg/kg) and this was driven by a change in the analytical method. Randomization was stratified by age (4-5 years old vs 6-7 years old).

One primary objective was evaluation of the effect of SRP-9001 on North Star Ambulatory Assessment (NSAA) total scores, a validated rating scale used to measure the impact of Duchenne muscular dystrophy on ambulatory performance. It is important to note that NSAA is process and effort dependent, susceptible to bias. Baseline NSAA scores were 19.8 in the SRP-9001 group versus 22.6 in the placebo group. Based on the study analysis, the least square mean changes in the NSAA total score from baseline to week 48 were 1.7 (0.6 standard error) and 0.9 (0.6 standard error) for SRP-9001 and placebo, respectively. **The LS mean (SE) treatment difference (0.8 [0.9]) at week 48 between**

SRP-9001 and placebo is not statistically significant (95% confidence interval [CI]: -1.0, 2.7; p=0.37). Age was an important factor in this study, in the subgroup of 4-5 years of age, a more significant difference in NSAA scoring from baseline to week 48 was demonstrated (4.3 (SE 0.7) vs 1.9 (SE 0.7), p = 0.0172), although not prespecified and listed as hypothesis-generating only.

The micro-dystrophin outcomes of Study 102 were based on different dose levels of SRP-9001: half of intended dose (6.29×10^{13} vg/kg, SRP-9001-DL1), two-thirds of intended dose (8.94×10^{13} vg/kg, SRP9001-DL2), and intended dose (1.33×10^{14} vg/kg, SRP-9001-DL3). At Week 12 of Study 102 Part 1, the mean (SD) change from baseline levels of Sarepta's micro-dystrophin (% of control) were 3.6 (5.7), 28.2 (52.2), and 43.4 (48.6) for subjects receiving SRP-9001-DL1, SRP-9001-DL2, and SRP-9001-DL3, respectively. At week 12 of Study 102 Part 2, the mean (SD) change from baseline levels of Sarepta's micro-dystrophin (% of control) were 10.6 (17.0), 10.4 (14.7), and 43.5 (55.6) for subjects receiving SRP9001-DL1, SRP-9001-DL2, and SRP-9001-DL3, respectively.

Safety was evaluated in the aforementioned studies, and importantly no deaths occurred during any of the studies. The most frequent adverse reactions (incidence ≥5%) observed in the studies include vomiting (61%), nausea (40%), acute liver injury (37%), pyrexia (24%), and thrombocytopenia (12%). Acute serious liver injury were reported in the clinical trials, however all resolved without clinical sequelae spontaneously or with additional corticosteroid treatment. One case of immune-mediated myositis was reported, presenting with muscle weakness, dysphagia, dysphonia, and other findings. The symptoms partially resolved with supportive care, plasmapheresis, and corticosteroid treatment. As a result, Sarepta has proposes that SRP-9001 be contraindicated in patients with any deletion that fully includes exons 9 through 13 in the DMD gene (due to the mutations involved in the affected subject). Lastly, myocarditis and elevated troponin-I were experienced by a few subjects within the clinical trials, though none of these events were associated with acute cardiac imaging changes from baseline, at this time the long-term effects of increased troponin-I and the associated risk of myocarditis on the underlying pathologic process of DMD, is unknown.

Ongoing Phase 3 trial, EMBARK (NCT05096221) is being proposed as a confirmatory trial, and the FDA is considering a non-age restriction, depending on the results of that study.

On June 15, 2025, Sarepta Therapeutics announced a suspension of commercial shipments of Elevidys for non-ambulatory patients with Duchenne muscular dystrophy (DMD), following two treatment-related deaths attributed to acute liver failure. Both fatalities occurred in non-ambulatory patients over the age of 15.

On July 18, 2025, The U.S. Food and Drug Administration announced it has placed Sarepta Therapeutics investigational gene therapy clinical trials for limb girdle muscular dystrophy on clinical hold following three deaths potentially related to these products and new safety concerns that the study participants are or would be exposed to an unreasonable and significant risk of illness or injury. The FDA has also revoked Sarepta's platform technology designation..

On July 21, 2025 Sarepta Therapeutics then notified the U.S. Food and Drug Administration (FDA) of its decision to voluntarily and temporarily pause all shipments of ELEVIDYS (delandistrogene moxeparvovec) for Duchenne muscular dystrophy in the United States, effective close of business Tuesday, July 22, 2025. This occurred after the 4th reported death in an 8-year-old boy. Sarepta then resumed shipping Elevidys for ambulatory patients after the FDA recommended removing the voluntary pause and resume shipment for ambulatory patients.

Summary	
Effective Date of Policy:	6/7/2023
Indications	Duchenne Muscular Dystrophy in patients 4-5 years of age
ICD10 Diagnosis Codes	G71.01
Availability	*Suspension for intravenous infusion; nominal concentration of 1.33 x 10^{13}vg/mL*
Duration	Not applicable, if approved, only one lifetime administration will be authorized.

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy:

Specific Indication	Inclusion Criteria	Recommended Dosing Regimen
Duchenne Muscular Dystrophy (pending FDA approval) ICD10: G71.01	• Therapy is prescribed by neurologist with expertise in the treatment of DMD • Enrollee has diagnosis of DMD with confirmed frameshift mutation (deletion or duplication) or premature stop codon mutation between exons 18 to 58 in the DMD gene • Enrollee is between four and five years of age	• Therapy involves a one-time intravenous infusion of Delandistrogene moxeparvovec • Dosing and administration considerations per FDA prescribing information.

	• Enrollee is ambulatory, walking without the assistance of durable medical equipment or wheelchair • Enrollee has baseline anti-AAVrh74 total binding antibody titer ≤ 1:100 • Enrollee has baseline NorthStar Ambulatory Assessment (NSAA) score documented in medical record, and physician agrees to post infusion clinical monitoring (see Considerations section for details) • Enrollee will not concurrently, or post administration of Elevidys, receive any exon-skipping ASO agents, including but not limited to, Exondys-51 (Eteplirsen), Viltepso (Viltolarsen), Vyondys 53 (Golodirsen), and Amondys 45 (Casimersen) • Enrollee has not previously received Delandistrogene moxeparvovec or any other gene therapy to treat DMD	• Enrollee will not concurrently, or post administration of Elevidys, receive any exon-skipping ASO agents, including but not limited to, Exondys-51 (Eteplirsen), Viltepso (Viltolarsen), Vyondys 53 (Golodirsen), and Amondys 45 (Casimersen)

Exclusion Criteria

- Enrollee has elevated anti-AAVrh74 total binding antibody titers > 1:100
- Enrollee is unable to walk without assistance or enrollee is wheelchair-dependent

Continuation Criteria

- Not applicable, if approved, only one lifetime administration will be authorized

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department
- In clinical trials, baseline corticosteroid therapy was increased by 1mg/kg of prednisone equivalent daily and continued at this level for at least 60 days after infusion, unless clinical indicated otherwise
- Physician acknowledges that CDPHP will request documentation, not more frequently than biannually, of follow-up patient assessments including serial NSAA assessments or other clinical assessments while the patient is under the care of the physician

References

		Updated	Accessed
1	FDA Briefing Document, BLA #125781, delandistrogene moxeparvovec. Cellular, Tissue and Gene Therapies Advisory Committee Meeting. May 12, 2023. Briefing Document available at: https://www.fda.gov/media/168021/download ; https://www.fda.gov/media/168022/download Final Roster available at: https://www.fda.gov/media/168381/download Meeting Broadcast available at: https://www.youtube.com/watch?v=k33d4h-CpGU	5/23	6/23
2	SRP-9001 (Delandistrogene Moxeparvovec) Clinical Trial (NCT05096221). Last Update: 11/15/22. Available at: https://clinicaltrials.gov/ct2/show/NCT05096221	11/22	6/23
3	SRP-9001 (Delandistrogene Moxeparvovec) Clinical Trial (NCT03769116). Last Update: 7/1/22. Available at: https://clinicaltrials.gov/ct2/show/NCT03769116	7/22	6/23
4	Klimchak AC, et al. Assessing the value of delandistrogene moxeparvovec (SRP-9001) gene therapy in patients with Duchenne muscular dystrophy in the United States. J Mark Access Health Policy. 2023; 11(1):2216518.	5/23	6/23
5	IPD Analytics RxBrief: Central Nervous System Gene Therapy for Duchenne Muscular Dystrophy. Published May 2021. Subscription required.	5/21	6/23
6.	Elevidys (prescribing information). Cambridge, MA; Sarepta Therapeutics, Inc.	8/24	5/25
7.	Sarepta Therapeutics Announces Voluntary Pause of ELEVIDYS Shipments in the U.S. Available at: https://investorrelations.sarepta.com/news-releases/news-release-details/sarepta-therapeutics-announces-voluntary-pause-elevidys	7/25	8/25
8.	FDA Requests Sarepta Therapeutics Suspend Distribution of Elevidys and Places Clinical Trials on Hold for Multiple Gene Therapy Products Following 3 Deaths. Available at: https://www.fda.gov/news-events/press-announcements/fda-requests-sarepta-therapeutics-suspend-distribution-elevidys-and-places-clinical-trials-hold	7/25	8/25

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE CHOICES:	Subject to all terms and conditions noted in above application.
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 9/10/25

New: 6/7/2023

Revised	Reviewed
9/25	6/24, 6/25, 9/25

Date	Note

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Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care for enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background/Literature Summary

Macular telangiectasia (Mac Tel) is a disease that causes abnormalities of capillaries of the fovea or perifoveal region that are associated with loss of outer nuclear layers and the ellipsoid zone, Eventually, these abnormalities can progress to cystic cavitation-like changes in all retinal layers, or to development of full-thickness macular hole or subretinal neovascularization in advanced stages.

Mac Tel is divided into 2 main types:

- **Type 1**: blood vessels dilate and tiny aneurysms form, which leak and cause macular edema and damages macular cells. The disease almost always occurs in one eye, which differentiates it from Type 2.
- **Type 2**: blood vessels around the fovea become abnormal and may dilate and there may be macular neovascularization. Tissue in the macula or the fovea may thin out or form a scar, causing loss of detail vision. Type 2 affects both eyes but not always with the same severity.

In the United States, MacTel type 2 has a prevalence of about 0.1% in individuals over 40 years of age.

On March 5, 2025, the FDA approved Neurotech Pharmaceuticals' Encelto (revakinagene taroretcel-lwey, previously known as NT-501) for the treatment of adults with idiopathic macular telangiectasia (MacTel) type 2. Encelto is the first FDA-approved treatment for MacTel type 2.

Encelto (revakinagene taroretcel-lwey) is an encapsulated, cell-based gene therapy that consists of allogenic retinal pigment epithelial (RPE) cells that secrete recombinant human ciliary neurotrophic factor (rhCNTF). rhCNTF is a neurotrophic factor endogenously produced by neurons and glia that promotes photoreceptor survival by initiating a protective signaling cascade. Although the full mechanism of action of Encelto is not fully understood, the proposed mechanism involves slowing the progression of ellipsoid zone (EZ) loss, which is a marker of photoreceptor degeneration, and increases retinal integrity in MacTel type 2.

The approval of Encelto was based on results from two Phase 3, randomized, multicenter studies (Study 1: NTMT-03-A [NCT03316300] and Study 2: NTMT-03-B [NCT03319849]). Of a combined 228 patients, those who were treated with Encelto (Study 1, n = 58; Study 2, n = 59) demonstrated a statistically significant reduction in the rate of change in ellipsoid zone area loss over 24 months compared with that of patients who received sham treatment. Results for the mean change in aggregate retinal sensitivity loss from baseline to 24 months were statistically significant in Study 1 but not in Study 2. Best-corrected visual acuity (BCVA) was essentially the same between the Encelto-treated group and the sham-treated group.

Adverse events occurring more frequently than sham included conjunctival hemorrhage (31%), delayed dark adaptation (23.1%), suture-related complications (15.4%), and vitreous hemorrhage (8.5%). Rare but serious adverse events have occurred with Encelto, including suture-related complications in five patients and an implant extrusion in one patient.

Summary

Effective Date of Policy:	8/13/2026
ICD10 Diagnosis Codes	H35.0 Macular Telangiectasia
HCPCS	J3403
Dosage Forms	Intravitreal implant
Duration	Initial approval: 6 months Continuation approval: not applicable

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Criteria

1. Must be 18 years of age or older AND
2. Must be prescribed by and administered by an ophthalmologist AND
3. Must have a diagnosis of idiopathic macular telangiectasia type 2 (MacTel) AND
4. Provider must indicate which eye(s) will be treated AND
5. For the eye(s) being treated, the following must be true (a, b, c, and d):
    a. Must have evidence of fluorescein leakage typical of MacTel on fluorescein angiography AND
    b. Must have at least one of the following features (i, ii, iii, iv, or v):
        i. Hyperpigmentation that is outside of a 500-micron radius from the center of the fovea
        ii. Retinal opacification
        iii. Crystalline deposits
        iv. Right-angle vessels
        v. Inner/outer lamellar cavities AND
    c. Must have an Inner Segment - Outer Segment (IS/OS) Photo Receptor (PR) break (area of IS/OS loss) in ellipsoid zone (EZ) between 0.16 mm^2 and 2.00 mm^2 as measured by spectral domain optical coherence tomography (SD-OCT) AND
    d. Must have best corrected visual acuity (BCVA) of 54-letter score or better as measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) chart OR have a BCVA of 20/80 or better as measured by the Snellen Chart.
        i. Documentation within the last 6 months must be provided. AND
6. Must not have evidence of intraretinal neovascularization or subretinal neovascularization (SRNV), as evidenced by hemorrhage, hard exudate, subretinal fluid or intraretinal fluid in either eye AND
7. Encelto will not be authorized in patients with MacTel type 1 AND
8. Encelto will not be authorized for any non-FDA approved indication AND
9. Encelto will be limited to a single implant per eye per lifetime. Approval duration will be for 6 months to allow time for procedure to take place.

Policy Guidelines

1. Utilization Management is contract dependent. Refer to specific contract/benefit language for exclusions.
    a. Coverage criteria may be dependent on the contract renewal date.
    b. Coverage of drugs listed in this policy are contract dependent.
    c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit
    d. Not all contracts/benefits cover all medical infusible drugs.
2. Unless otherwise indicated within drug specific criteria, the drugs listed in this policy are administered by a health care professional and therefore are covered under the medical benefit.
3. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of busine including Medicare Advantage.
4. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS permits a Medicare Advantage Organization (MAO) to establish its own coverage determinations in accordance with 42 CFR § 422.101(b)(6). Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan. Step therapy requirements may be imposed in addition to LCD/NCD requirements.
5. Clinical documentation must be submitted for each request (initial and recertification [if applicable]) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging and other objective or subjective measures of clinical benefit.

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6. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
7. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
8. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
9. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.
10. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.
11. The requested site of care may impact approval timeframe and is subject to review.
12. The following applies to all gene and cellular therapies unless otherwise specified within the drug-specific coverage criteria:
    a. Administration, Retreatment, and Treatment with Additional or Other Gene/Cellular Therapies
        i. One-Time Administration
            1. Most gene and cellular therapies, whether autologous, allogeneic ("off-the-shelf"), or in vivo gene-transfer therapies, are designed and studied as one-time treatments.
            2. Repeat dosing, reinfusion, or sequential therapy with other gene or cellular products has not been established as safe, effective, or clinically appropriate.
        ii. Retreatment/Repeat Administration
            1. Retreatment with the same gene or cellular therapy product is considered experimental and investigational because:
                a. Clinical trials evaluated these therapies as single-administration interventions
                b. Safety, efficacy, and durability of a second administration have not been established
                c. Risks immune activation, insertional mutagenesis, or vector immunity may be increased with repeat dosing
        iii. Treatment with an Additional or Other Gene/Cellular Therapy
            1. Treatment with an additional or different gene or cellular therapy after prior exposure to any gene or cellular therapy is currently considered experimental and investigational as there is lack of evidence demonstrating the following (a-c):
                a. Anticipated clinical benefit beyond available standard therapies
                b. Safety of sequential administration
                c. Justification for selecting a second gene/cellular intervention after a prior one
            2. This includes, but is not limited to:
                a. Switching between CAR-T products (e.g., CD19 → CD19 or CD19 → BCMA)
                b. Switching between autologous and allogeneic cellular therapies
                c. Sequential use of CAR-T, TCR-T, NK-cell therapies, or other genetically engineered cell therapies
                d. Receiving a gene therapy after previous gene or cellular therapy exposure

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e. Receiving an in vivo gene therapy following any prior vector-based therapy

iv. Prior Gene/Cell Therapy Exposure

1. An is generally not eligible for additional gene or cellular therapy if they have previously received:
   a. Any autologous cellular therapy (e.g., CAR-T, TCR-T, TIL),
   b. Any allogeneic genetically modified cellular therapy,
   c. Any in vivo gene therapy (e.g., AAV, lentiviral vector)
   d. Any ex vivo gene-modified cell product
   e. Are being considered for any other gene or cellular therapy without documented evidence supporting safety and anticipated benefit.

References

		Updated	Accessed
1	Encelto (revakinagene taroretcel-lwey) [prescribing information]. Neurotech Pharmaceuticals, Inc. Cumberland, RI.	3/2025	8/2025
2	Turbert D, et al. What is macular telangiectasia? American Academy of Ophthalmology website. Available at: https://www.aao.org/eye-health/diseases/macular-telangiectasia	9/2024	8/2025
3	A Study to Determine the Safety and Efficacy of NT-501 in Macular Telangiectasia Type 2 – Protocol A. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/study/NCT03316300	9/2024	8/2025
4	A Study to Determine the Safety and Efficacy of NT-501 in Macular Telangiectasia Type 2 - Protocol B. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/study/NCT03319849	9/2024	8/2025
5	Roger A. Goldberg, MD: Pooled Visual Function Data of NT-501 for MacTel. HCP Live. Available at: https://www.hcplive.com/view/roger-a-goldberg-md-pooled-visual-function-data-nt-501-mactel	10/2024	8/2025

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GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

SELECT PLAN/HARP: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 8/13/2026

New: 9/2025

Revised	Reviewed
8/2026	

Revision Date	Changes Made
12/2025	Added criteria applicable to Medicaid and Medicare, updated rationale for Commercial
8/2026	Updated to medically necessary for Commercial and aligned criteria Updated policy guidelines

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MEDICAL POLICY

Medical Policy Title	**Endometrial Ablation**
Policy Number	**4.01.01**
Current Effective Date	**November 1, 2026**
Next Review Date	**February 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.

(Link to Product Disclaimer)

Please refer to Corporate Medical Policy #3.01.22 Gender Affirming Behavioral Health and Medical Services for those members with a diagnosis of gender dysphoria.

POLICY STATEMENT(S)

I. Endometrial ablation is considered **medically appropriate** when **ALL** of the following criteria are met:

A. The patient has experienced menorrhagia/menometrorrhagia ("abnormal uterine bleed") for greater than three (3) menstrual cycles;

B. The patient has been treated with and has failed to respond to hormone therapy (contraceptives, progestin) for three consecutive menstrual cycles, or there is a contraindication to hormone therapy;

C. The symptoms are severe enough to warrant surgical intervention (e.g., hysterectomy);

D. The symptoms interfere with activities of daily living (ADLs) or results in anemia that is unresponsive to treatment;

E. The results of a Pap smear within the past 12 months are within normal limits;

F. Endometrium is normal within the last six (6) to 12 months, as evidenced by **ONE** of the following:

1. Hysteroscopy with dilation and curettage (D & C);
2. Transvaginal ultrasound; **or**
3. Sonohysterogram;

G. The patient is not pregnant, and there is no desire for future pregnancy; **and**

H. The device is approved by the U.S. Food and Drug Administration (FDA).

Contraindications:

I. Contraindications for endometrial ablation include:
   1. Known or suspected endometrial carcinoma or pre-malignant change of the endometrium (e.g., pre-cancerous endometrial abnormalities);
   2. Enlarged uterus (e.g., greater than 10 cm in length or comparable to 12 or more weeks of gestation;
   3. Any anatomic or pathologic condition in which weakness of the myometrium could exist (e.g., history of previous classical cesarean section(s), transmural myomectomy, history of previous endometrial ablation procedure or endometrial resection);
   4. The patient is on medications that could thin the myometrial muscles, such as long-term steroid use (except for inhaler or nasal therapy for asthma);
   5. Uterine prolapse;
   6. Submucosal myomas;
   7. Active genital or urinary tract infection (e.g., cervicitis, vaginitis, endometritis, salpingitis, or cystitis);
   8. Pregnancy or desire to become pregnant in the future;
   9. Intrauterine device (IUD) in place; **or**
   10. Active pelvic inflammatory disease.

J. Thermal balloon endometrial ablation is contraindicated in patients who have a history of latex allergy or who have demonstrated sensitivity to latex material.

K. Microwave ablation is contraindicated in patients who have **ALL** of the following:
   1. Essure contraceptive micro-inserts in place;
   2. Myometrial thickness less than 10 mm; **and**
   3. Uterine sounding length less than 6 cm.

II. Other methods of endometrial ablation (e.g., chemoablation, photodynamic endometrial ablation) are considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

Gender Reassignment Therapies, 1370/20.000447

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Individuals with abnormal uterine bleeding (menorrhagia) should be screened for possible reasons for the condition, and, if results appear positive, further hematologic work-up should be

performed. Examples of "red flags" indicating that further work-up should be completed for a patient include:

A. A relative who has an inherited bleeding disorder,
B. Prolonged bleeding from small wounds or following dental procedures,
C. Heavy and prolonged bleeding following surgical procedures,
D. Easy bruising,
E. Spontaneous nosebleeds,
F. Blood in the stool or bleeding ulcer requiring urgent medical care,
G. Anemia requiring transfusion,
H. Heavy menses resulting in anemia,
I. Passing of large clots with menses or soaking more than one pad hourly, or
J. Heavy bleeding during or following childbirth.

DESCRIPTION

Endometrial ablation is a method of treating abnormal uterine bleed through destruction of the endometrial lining. Endometrial ablation is an alternative to hysterectomy for women with abnormal uterine bleed from benign causes, who have found medical therapy ineffective or contraindicated.

In addition, in order to exclude other conditions, thyroid stimulating hormone (TSH) and human chorionic gonadotropin (HCG) testing are often performed prior to endometrial ablation, to confirm that these are within normal limits.

Several devices have been developed that utilize various modalities to accomplish endometrial ablation, including, but not limited to laser therapy, resecting loop rollerball using electric current, thermal ablation using a liquid-filled balloon, microwave, electrode array or cryosurgical device.

Thermal fluid-filled balloon, cryosurgical endometrial ablation, instillation of heated saline, and radiofrequency ablation can be performed without general anesthesia in a physician's office and do not require hysteroscopic guidance. Microwave ablation with the Microwave Endometrial Ablation System (MEA) may also be performed in a physician's office but does require use of the hysteroscope.

Methods that utilize direct hysteroscopic visualization include, but are not limited to:

I. Hydrothermal (e.g., Hydro ThermAblator, Genesys HTA System);
II. Neodymium-yttrium aluminum garnet (Nd-YAG) laser;
III. Resectoscope/resecting loop; and
IV. Rollerball.

Methods that do not utilize direct hysteroscopic visualization include, but are not limited to:

I. Cryoablation (e.g., Her Option);

II. Laser interstitial hyperthermy;

III. Microwave (e.g., MEA System, Minitouch 3.8);

IV. Radiofrequency (e.g., NovaSure); and

V. Thermal balloon (e.g., ThermaChoice).

SUPPORTIVE LITERATURE

Several studies have been published that address the various techniques of endometrial ablation as an alternative to hysterectomy for the treatment of abnormal uterine bleed (menorrhagia). In summary, the studies show that endometrial ablation has become the surgical treatment of choice for dysfunctional uterine bleeding when hysterectomy is not desired. In the short-term, hysteroscopic and non-hysteroscopic endometrial ablation techniques have been proven to be safe and effective in reducing excessive menstrual bleeding, when specific criteria are met.

In a 2017 article by Klebanoff et al, the authors sought to determine the incidence and predictors of failed standard of care associated with second-generation endometrial ablation. "Failed" is defined as need for surgical re-intervention. The retrospective cohort study was conducted on subjects undergoing second-generation endometrial ablation between October 2003 and March 2016. Second-generation devices utilized during the study period included the radiofrequency ablation device (RFA), hydrothermal ablation device (HTA), and uterine balloon ablation system (UBA). Of the 5,936 women participating in the study, the surgical re-intervention rate was found to be 15.6%. Age, ethnicity, and radiofrequency ablation were significant risk factors for failed endometrial ablation, and menorrhagia was the leading indication for re-intervention.

Deehan et al (2024) conducted a systematic review and meta-analysis to evaluate the clinical efficacy, safety, and cost-effectiveness of endometrial ablation or resection (E:A/R) compared to hysterectomy for the treatment of heavy menstrual bleeding. Twelve randomized controlled trials (RCTs) with 2,028 women (hysterectomy: n=977 vs. n=1,051) were included in the analysis. Authors concluded that (E:A/R) offers alternatives to hysterectomy. Both procedures have high effectiveness rates, impact on QoL, and safety. Hysterectomy is associated with greater improvement in the bleeding symptoms, both subjectively and objectively, and higher patient-satisfaction up-to two years. However, it has longer operating times, longer recovery periods, and higher rates of postoperative complications. On the other hand, (E:A/R) has lower initial cost than hysterectomy but the need for further surgery is common; therefore, there is no difference in the costs in the long-follow-up. These results should be interpreted with caution due to the heterogeneity of the trials included. An adequately powered and carefully-planned non-inferiority RCT comparing between the different methods of (E:A/R) to those of hysterectomy with long term follow-up periods is required to inform the surgeons, patients, and decision makers with the most clinically-effective and cost-effective surgical treatment for heavy menstrual bleeding.

Marchand et al (2024) conducted a network meta-analysis to determine the efficacy of first- and second-generation ablation techniques compared with medical treatment, invasive surgery and

different modalities of the endometrial ablation (EA) techniques themselves. 49 RCTs that compared 8,038 premenopausal women with abnormal uterine bleeding (AUB) receiving the intervention of second-generation EA techniques were included in the study. The uterine balloon ablation had significantly higher amenorrhoea rates than other techniques in both short (hydrothermal ablation (risk ratio (RR)=0.51, 95%CI 0.37; 0.72), microwave ablation (RR=0.43, 95%CI 0.31; 0.59), first-generation techniques (RR=0.44, 95%CI 0.33; 0.59), endometrial laser intrauterine therapy (RR=0.18, 95%CI 0.10; 0.32) and bipolar radio frequency treatments (RR=0.22, 95%CI 0.15; 0.31)) and long-term follow-up (microwave ablation (RR=0.11, 95%CI 0.01; 0.86), bipolar radio frequency ablation (RR=0.12, 95%CI 0.02; 0.90), first generation (RR=0.12, 95%CI 0.02; 0.90) and endometrial laser intrauterine thermal therapy (RR=0.04, 95%CI 0.01; 0.36)). When calculating efficacy based only on calculated bleeding scores, the highest scores were achieved by cryoablation systems (p-score=0.98). Authors concluded that most second-generation EA systems were superior to first-generation systems but that there is no evidence at this time that any one of the examined second-generation systems is clearly superior to the others.

PROFESSIONAL GUIDELINE(S)

The American College of Obstetricians and Gynecologists (ACOG) issued a committee opinion (number 557) in 2013 on the management of acute abnormal bleeding in nonpregnant women of reproductive age. ACOG recommended medical management as first-line treatment and stated that surgical management be considered for patients who failed or are not suitable for medical management, or who are not clinically stable. Endometrial ablation was listed as a surgical option, along with dilation and curettage, uterine artery embolization, and hysterectomy. ACOG also stated that endometrial ablation should only be considered for patients who have failed other treatments or have a contraindication when women have no plans for future childbearing, and when endometrial and uterine cancer have been ruled out as the cause of acute uterine bleeding.

The World Professional Association for Transgender Health (WPATH) is a 501(c)(3) non-profit, interdisciplinary professional and educational organization that promotes evidence-based care, education, research, advocacy, public policy and respect in transgender health. WPATH publishes documents supporting medical necessary and appropriate care for transgender or transition-related treatments. These are known as the Standards of Care (SOC). WPATHs SOC states that menstrual suppression may impact gender dysphoria and can function as an initial step allowing for "…further exploration of gender-related goals of care, prioritization of other mental health care, or both, especially for those who experience worsening gender dysphoria from unwanted uterine bleeding." Testosterone therapy typically causes cessation of menstruation within six months, but is impacted by the dose, route, frequency, body habitus, and other co-occurring medical conditions that may exist. Residual bleeding can occur after hormone therapy. Endometrial ablation can be offered for those that decline hysterectomy and/or hormone therapy (e.g., nonbinary) or in situations where those considerations may be contraindicated. The American College of Obstetricians and Gynecologists agrees with WPATHs statement regarding the impact of menstrual suppression to decrease gender dysphoria associated with menses, public restroom use for menstrual hygiene and its impact on individuals' attitudes and safety.

REGULATORY STATUS

Several first-generation hysteroscopically aided and second-generation non-hysteroscopically aided devices have been approved by the FDA as a safe and effective alternative to hysterectomy in premenopausal patients with heavy menstrual bleeding due to benign causes for whom childbearing is complete. In 2021, the FDA published guidelines listing contraindications for endometrial ablation which include, but are not limited to, pregnancy, previous endometrial ablation or endometrial resection, previous cesarean section, or infection at the time of treatment.

In 1997, the U.S. Food and Drug Administration (FDA) approved ThermaChoice, the first non-hysteroscopic ablation device to treat excessive uterine bleeding (menorrhagia) due to benign (non-cancerous) causes. The ThermaChoice Uterine Balloon Therapy System (Gynecare) consists of a balloon that is inserted through the neck of the cervix and into the uterus.

In 2001, the FDA approved the Her Option Uterine Cryoblation Therapy System (CryoGen Inc.) uses a cryoprobe capable of producing temperatures down to minus 148˚F (minus 100˚C) at the tip. This extreme cold is applied to the tissue for 10 mins to freeze and destroy the uterine lining. Ultrasound is used to guide and monitor the procedure.

Also, in 2001, the FDA approved the NovaSure-Endometrial Alation System, which utilizes a metallized mesh electrode array that is introduced into the uterine cavity, applying bipolar electrical energy that creates heat to ablate the endometrium.

In 2003, the FDA approved the Microsulis Microwave Endometrial Ablation (MEA) System. The MEA system is a surgical device that uses microwave energy to treat excessive menstrual bleeding by destroying tissue lining the uterus (womb). Endometrial ablation is a minimally invasive surgery that can be a viable alternative to hysterectomy.

The Genesys HTA – Hydro-Thermal Ablation System, FDA approved in 2010, is a hysteroscopic thermal ablation device intended to ablate the endometrial lining of the uterus in premenopausal women with menorrhagia due to benign causes for whom childbearing is complete.

In 2023, the Minitouch 3.8 Era System (Minitouch System) received the Premarket approval (PMA) from the FDA. This device is intended for ablation of the endometrial lining of the uterus for the treatment of menorrhagia caused by non-malignant conditions in pre-menopausal women who do not wish to become pregnant in the future.

The U.S. Food and Drug Administration (FDA) regulates ablation devices as medical devices. All ablation devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Jan 7]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Jan 7]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
58353	Endometrial ablation, thermal, without hysteroscopic guidance
58356	Endometrial cryoablation with ultrasonic guidance, including endometrial curettage, when performed
58563	Hysteroscopy, surgical; with endometrial ablation (e.g., endometrial resection, electrosurgical ablation, thermoablation)

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Medically Appropriate codes for when criteria are met under Policy Statement I:

Code	Description
F64.0-F64.9	Gender identity disorders (code range)
N92.0	Excessive and frequent menstruation with regular cycle
N92.1	Excessive and frequent menstruation with irregular cycle
N92.4	Excessive bleeding in the premenopausal period
N93.8	Other specified abnormal uterine and vaginal bleeding
N93.9	Abnormal uterine and vaginal bleeding, unspecified
Z87.890	Personal history of sex reassignment

Contraindicated conditions under Policy Statement III (not an all-inclusive list of codes):

Code	Description
D07.0	Carcinoma in situ of endometrium
D25.0	Submucous leiomyoma of uterus
N81.2	Incomplete uterovaginal prolapse
N81.3	Complete uterovaginal prolapse
N81.4	Uterovaginal prolapse, unspecified
N85.00	Endometrial hyperplasia, unspecified
N85.02	Endometrial intraepithelial neoplasia [EIN]
N85.2	Hypertrophy of uterus

REFERENCES

American College of Obstetricians and Gynecologists [Internet]. Committee Opinion Number 557: Management of acute abnormal uterine bleeding in nonpregnant reproductive-aged women. 2013 Apr; reaffirmed 2019 [accessed 2025 Jan 12]. Available from: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2013/04/management-of-acute-abnormal-uterine-bleeding-in-nonpregnant-reproductive-aged-women

American College of Obstetricians and Gynecologists [Internet]. Practice Bulletin #823: Health care for transgender and gender diverse individuals. 2021 Mar [accessed 2025 Jan 7]. Available from: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals.

American Society for Reproductive Medicine. Indications and options for endometrial ablation. Fertil Steril. 2008 Nov;90(5 Suppl):S236-40.

Deehan C, et al. Endometrial ablation and resection versus hysterectomy for heavy menstrual bleeding: an updated systematic review and meta-analysis of effectiveness and complications. Obstet Gynecol Sci. 2023 Sep;66(5):364-384.

Klebanoff J, et al. Incidence and predictors of failed second-generation endometrial ablation. Gynecol Surg. 2017;14(1):26.

Marchand GJ, et al. First and second-generation endometrial ablation devices: a network meta-analysis. BMJ Open. 2024 May 28;14(5).

National Institute for Clinical Excellence [Internet]. Photodynamic endometrial ablation. 2004 Mar 24 [accessed 2025 Jan 07]. Available from: https://www.nice.org.uk/guidance/ipg47

National Institute for Health and Care Excellence [Internet]. Photodynamic endometrial ablation. 2024 March 2004 [accessed 2025 Jan 07]. Available from: https://www.nice.org.uk/guidance/ipg47

Oderkerk TJ, et al. Risk of hysterectomy after endometrial ablation: a systematic review and meta-analysis. Obstet Gynecol. 2023 Jul 1;142(1):51-60.

United States Food & Drug Administration [Internet]. Endometrial ablation for heavy menstrual bleeding. 2021 Oct. [updated 2021 Oct 25; accessed 2025 Jan 07]. Available from: https://www.fda.gov/medical-devices/surgery-devices/endometrial-ablation-heavy-menstrual-bleeding

World Professional Association for Transgender Health (WPATH) [Internet]. Standards of care for the health of transsexual, transgender, and gender nonconforming people. 2022 Sept 15. [accessed 2025 Jan 07]. Available from: https://www.tandfonline.com/doi/full/10.1080/26895269.2022.2100644

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Endometrial ablation is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 7/26

Revised:

Reviewed:

Date	Summary of Changes

11/1/2026	• New

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Policy/Procedure Name: Enjaymo (sutimlimab-jome) **Control Number: 1350/20.000452**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

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Background

Cold agglutinin disease (CAD) is rare form of autoimmune hemolytic anemia. It is characterized by premature hemolysis of red blood cells by cold agglutinins. Cold agglutinins are autoantibodies that trigger hemolysis at low temperatures (optimum temperature of 3-4 degrees Celsius). When red blood cells are exposed to temperatures below normal core body temperature, they can be recognized by the cold agglutinins, and the cold agglutinins bind to the I surface antigen on red blood cells and agglutination, or clumping occurs, and the classical complement pathway is activated. This destruction of red blood cells results in hemolytic anemia and increases patient's requirement of red blood cell transfusions. Symptoms of CAD include fatigue, shortness of breath, dizziness, palpitations or chest pain, acrocyanosis (discoloration of extremities), and Raynaud's phenomenon (coldness of the fingers and toes). Cold agglutinin disease can be primary (unknown cause) or secondary to infection, rheumatologic disease, or active hematologic malignancy. Secondary CAD may also be referred to as cold agglutinin syndrome (CAS). Primary CAD has an incidence of one individual per million per year. Because of the pathophysiology of the disease, diagnosis typically occurs during the winter months, and prevalence may be higher in cooler climates. CAD typically affects adults between 40 and 80 years old.

For patients with secondary CAD, treating the underlying cause is the mainstay of therapy. For patients with primary CAD who are asymptomatic, watch and wait is the preferred treatment option. Nonpharmacological treatment for CAD, especially in mild cases, can include avoiding exposure to cold temperatures. For patients experiencing symptoms such as fatigue, Raynaud's phenomenon, and decreased hemoglobin levels, historically, off-label rituximab in combination with bendamustine has been a first line therapy. In a prospective trial from 2017, the combination has showed a 71% overall response ratio with 40% of patients achieving complete response. Median response to treatment was 1.9 months, but even longer time to best response was seen to take a median of seven months. Ninety percent of responders did not relapse after 32 months. Follow-up data on these same patients was published in 2020 and even higher response rate and complete response were noted, 78% and 53% of participants, respectively. Seventy-seven percent of these patients were still in remission after five years.

Enjaymo is a humanized monoclonal antibody that inhibits the C1 complex of the classical complement pathway, which is responsible for hemolysis among patients with CAD. Specifically, Enjaymo binds to complement protein C1 which prevents the deposition of complement proteins that induce phagocytosis on the surface of red blood cells. This inhibition prevents hemolysis from occurring in patients with CAD. Initially, Enjaymo was approved based on a 26-week, open label, single arm Phase III study (CARDINAL) in 24 CAD patients with a history of transfusion led to FDA approval in early 2022. The primary endpoint encompassed an increase from baseline hemoglobin level of > 2g/dL or a hemoglobin level > 12 g/dL at the treatment assessment time point in conjunction with no blood transfusion or additional CAD treatment during weeks five through 26. 71% of patients remained transfusion free during weeks 5 through 26 and 54% of patients reached the composite primary endpoint. The mean increase in hemoglobin level at week three was 2.29 g/dL, and 3.18 g/dL at the treatment assessment time point. It is important to note, that treatment with Enjaymo does not influence symptoms such as coldness in fingers or toes. It is also a chronic treatment, as opposed to historical rituximab containing regimens.

In January 2023, the FDA expanded the approved indication of Enjaymo based on the 26-week phase III, randomized, double-blind, placebo-controlled CADENZA trial. The expanded indication now includes adults without a transfusion history who have CAD. CADENZA assessed safety and efficacy of Enjaymo in 42 total patients (22 in the treatment group and 20 in the placebo group) with CAD without recent (within 6 months prior to enrollment) transfusion history. Composite primary endpoint criteria (hemoglobin increase ≥ 1.5 g/dL at treatment assessment timepoint [mean of weeks 23, 25, 26], avoidance of transfusion, and study-prohibited CAD therapy [weeks 5-26]) were met by 16 patients (73%) on Enjaymo, and 3 patients (15%) on placebo (odds ratio, 15.9 [95% confidence interval, 2.9, 88.0; $P < .001$]).

Summary

Effective Date of Policy:	9/10/2025
Indications	Cold agglutinin disease, Cold autoimmune hemolytic anemia
ICD10 Diagnosis Codes	D59.12
Availability	1,100 mg/22 mL (50 mg/mL) in a single-dose vial
J - Code	J1302

Duration	See continuation criteria

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy:

Specific Indication	Inclusion Criteria	Recommended Dosing Regimen
Indication Cold autoimmune hemolytic anemia (FDA approval) ICD10: D59.12	1. Enrollee is at least 18 years old 2. The prior authorization is being obtained by a hematologist or prescriber who specializes in the treatment of cold agglutinin disease 3. Enrollee must be ≥ 39 kg 4. There is a confirmed diagnosis of primary CAD: a. Cold agglutinin titer ≥ 1:64 at 4⁰ Celsius b. Prescriber attestation that enrollee has chronic hemolysis (i.e. not a result of a transient cause such as infection) c. Positive polyspecific direct antiglobulin test (DAT) d. Monospecific DAT shows both of the following: i. C3d DAT: strongly positive ii. IgG DAT: ≤ 1+ 5. Presence of at least one of the following symptoms associated with CAD: a. Symptomatic anemia b. Acrocyanosis c. Raynaud's phenomenon 6. Secondary CAD has been ruled out (cold agglutinin syndrome secondary to infection, rheumatologic disease, or active hematologic malignancy) 7. Hemoglobin ≤ 10 g/dL a. Consideration may be given to patients who are symptomatic with hemoglobin > 10 mg/dL 8. Trial and failure, contraindication, OR clinically significant intolerance to at least six months of treatment with rituximab in combination with bendamustine or rituximab monotherapy if not a candidate for bendamustine	• Initially administered intravenously weekly for the first two weeks, then administered every two weeks thereafter ○ 39 to less than 75 kg ▪ 6,500 mg ○ 75 kg or more ▪ 7,500 mg

Exclusion Criteria

Therapy will not be covered if any of the above noted inclusion criteria are not met or if any of the below exclusion criteria are met

- Coverage will not be provided for Secondary CAD (i.e., cold agglutinin syndrome secondary to infection, rheumatologic disease, or active hematologic malignancy)
- Enrollee must not be receiving combination therapy with rituximab or another complement inhibitor

Continuation Criteria

- Requests will be reviewed per criteria every six months
- Enrollee positively responds to therapy as evidenced by an increase in hemoglobin of at least 2 g/dL or a hemoglobin level ≥ 12 g/dL AND has been transfusion free after the first 5 weeks of treatment

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department
- Patients should be vaccinated against encapsulated bacteria at least two weeks prior to treatment, according to the most current Advisory Committee on Immunization Practices (ACIP) Recommendations for patients with persistent completement deficiencies

References

		Updated	Accessed
1.	Jäger U, Barcellini W, Broome CM, et al. Diagnosis and treatment of autoimmune hemolytic anemia in adults: Recommendations from the First International Consensus Meeting. Blood Rev. 2020. May; 41:100648.	05/2020	07/2024
2.	Berentsen S. How I treat cold agglutinin disease. *Blood*. 2021;137(10):1295–1303. doi:10.1182/blood.2019003809	03/2021	07/2024
3.	Berentsen S, et al. Cold agglutinin disease revisited: a multinational, observational study of 232 patients. *Blood*. 2020;136(4):480–488. doi:10.1182/blood.2020005674	07/2020	07/2024
4.	Enjaymo™ [package insert]. Waltham, MA: Bioverativ USA Inc.; February 2024	02/2024	07/2024
5.	IPD Analytics. Enjaymo (sutimlimab-jome). New Drug Approval Review. March 2022. Accessed June 1, 2022.	03/2022	06/2022
6.	Roth A, Barcellini W, D'Sa S, et al. Sutimlimab in Cold Agglutinin Disease. N Engl J Med. 2021;384(14):1323-1334.	04/2021	07/2024
7.	Berentsen, S., Randen, U., Oksman, M., Birgens, H., Tvedt, T., Dalgaard, J., Galteland, E., Haukås, E., Brudevold, R., Sørbø, J. H., Næss, I. A., Malecka, A., & Tjønnfjord, G. E. (2017). Bendamustine plus rituximab for chronic cold agglutinin disease: results of a Nordic prospective multicenter trial. *Blood*, *130*(4), 537–541. https://doi.org/10.1182/blood-2017-04-778175	05/2017	07/2024
8.	Röth A, Berentsen S, Barcellini W, et al. Sutimlimab in patients with cold agglutinin disease: results of the randomized placebo-controlled phase 3 CADENZA trial. *Blood* 2022; 140 (9): 980–991.	9/2022	7/2024

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE CHOICES:	Subject to all terms and conditions noted in above application.
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 9/10/25

New: 06/2022

Revised	Reviewed
9/24	9/25

Revision Date	Changes Made
9/24	Updated J code, removed requirement for transfusion in the past 6 months due to FDA expanded indication

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Policy/Procedure Name: Enzyme Replacement Therapy for Fabry Disease **Control Number: 1350/20.000490**

Disclaimer Notice

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Background

Fabry disease is a rare, X-linked, progressive genetic disorder characterized by a defective gene (GLA) that causes a deficiency of the enzyme alpha-galactosidase A (α-Gal A). Without alpha-Gal A, patients may experience progressive cardiovascular, neurologic, and renal complications, which are potentially fatal. There are two types of Fabry disease, Type 1 (classic, more severe, shorter life span) and Type 2 (atypical, later-onset, less severe, increased lifespan in comparison).

Treatment for Fabry disease focuses on enzyme replacement therapy (ERT) and related products. Galafold (migalastat) was approved by the FDA in 2018, for the treatment of adults with Fabry disease who have a genetic mutation determined to be amenable to treatment with Galafold based on laboratory data. It is estimated that 35%–50% of patients with Fabry disease may have an amenable GLA variant. Galafold differs from ERT in that it increases the activity of the deficient enzyme rather than replacing it. Currently available ERT includes Fabrazyme (agalsidase beta), approved in 2003, to be used in those at least two years of age. Elfabrio represents the third agent for Fabry disease, providing PEGylated exogenous source of alpha-Gal A enzyme. In comparison to Fabrazyme, Elfabrio was designed as a "biobetter", to have a longer half-life, lower immunogenicity, and an improved safety profile.

Summary

Effective Date of Policy:	2/25/2026
Indications	See agents below
ICD10 Diagnosis Codes	E75.21
HCPCS Code	Fabrazyme: J0180 Elfabrio: J2508
Availability	*See below*
Duration	Initial: 1 year Continuation: 2 years

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy:

Specific Drug	Inclusion Criteria	Recommended Dosing

Fabrazyme (agalsidase beta)
 	
Indication
Treatment of adult and pediatric patients two years of age and older with confirmed Fabry disease
 	
(FDA approval)
ICD10: E75.21
 	
HCPCS: J0180
	• Enrollee is at least two years of age
	• Therapy is prescribed by geneticist, nephrologist, or other physician who specializes in the treatment of Fabry disease
	• Enrollee has confirmed Fabry disease as follows:
	  ○ Male patients:
	  ▪ Enzyme assay test in leukocytes, plasma, fibroblasts, or dried blood spots demonstrating complete deficiency or less than 3% of normal of alpha-galactosidase A activity (alpha-Gal A) OR
	  ▪ Documented GLA gene mutation by gene sequencing.
	  ○ Female patients:
	  ▪ Documented GLA gene mutation by gene sequencing is required for diagnosis
	• Must have clinical symptoms of disease as noted below (except for classically affected males)
	  ○ Males: Classically affected of any age with complete deficiency or less than 3% of normal alphaGal A activity treatment should begin treatment at time of diagnosis. Classically affected pediatric males typically begin treatment between 8–13 years of age.
		• Dosing: 1 mg/kg every two weeks administered as an intravenous infusion
		• See FDA prescribing information for additional administration details.

	○ Atypically affected Males with residual alpha-Gal A activity (3-35% of normal mean): institute treatment if significant symptoms (see below) or evidence of progression of organ involvement ○ Females (all ages): Monitor; institute treatment if significant symptoms (see below) or evidence of progression of organ involvement • Enrollee has clinical manifestations of disease including: ○ Neuropathic pain, acroparesthesias (excruciating pain the hands and feet which occur with exercise, fevers, stress) ○ Angiokeratomas (clusters of red to blue rash-liked discolorations on the skin) ○ Anhidrosis or hypohidrosis (absent or markedly decreased sweating) ○ Gastrointestinal symptoms (abdominal pain, cramping, frequent bowel movements) ○ Corneal dystrophy (star-burst pattern of cornea seen by slit lamp ophthalmologic examination) ○ Cardiovascular complications (arrhythmias, left ventricular hypertrophy, hypertrophic cardiomyopathy) ○ Renal complications (progressive proteinuria, renal insufficiency, renal failure) ○ Cerebrovascular disease (transient ischemic attack, stroke) • For new starts on Formularies 3, 4, and CHP only: Enrollee must have experienced serious side effects or drug failure to Galafold (migalastat) except in the following circumstances: ○ Pediatric patients between the ages of 8 years old to less than 18 years old ○ Patients with severe, classical phenotype who demonstrate no alpha galactosidase activity OR ○ those who exhibit severe clinical Fabry disease symptoms (as previously noted) where the provider has determined that Fabrazyme is medically necessary. ○ Patients with estimated glomerular filtration rate (eGFR) < 30 mL/min/1.73 m2 OR end-stage renal disease (ESRD) ○ Patients who do not have an amenable GLA gene mutation for treatment with Galafold based on the human embryonic kidney (HEK) 293 assay • Will not be used concomitantly receive Galafold (migalastat) or Elfabrio (pegunigalsidase alfa) • Current body weight and requested dose regimen must be submitted for initial review and each recertification request	
Elfabrio (pegunigalsidase alfa) **Indication** Treatment of adults with confirmed Fabry disease (FDA approval) ICD10: E75.21 HCPCS: J2508	• Enrollee is at least 18 years of age • Therapy is prescribed by geneticist, nephrologist, or other physician who specializes in the treatment of Fabry disease • Enrollee has confirmed Fabry disease as follows: ○ Male patients: ▪ Enzyme assay test in leukocytes, plasma, fibroblasts, or dried blood spots demonstrating complete deficiency or less than 3% of normal of alpha-galactosidase A activity (alpha-Gal A) OR ▪ Documented GLA gene mutation by gene sequencing.	• Dosing: 1 mg/kg every two weeks administered as an intravenous infusion • See FDA prescribing information for additional administration details.

- Female patients:
  - Documented GLA gene mutation by gene sequencing is required for diagnosis

- Must have clinical symptoms of disease as noted below (except for classically affected males)
  - Males: Classically affected of any age with complete deficiency or less than 3% of normal alphaGal A activity treatment should begin treatment at time of diagnosis. Classically affected pediatric males typically begin treatment between 8–13 years of age.
  - Atypically affected Males with residual alpha-Gal A activity (3-35% of normal mean): institute treatment if significant symptoms (see below) or evidence of progression of organ involvement
  - Females (all ages): Monitor; institute treatment if significant symptoms (see below) or evidence of progression of organ involvement
- Enrollee has clinical manifestations of disease including:
  - Neuropathic pain, acroparesthesias (excruciating pain the hands and feet which occur with exercise, fevers, stress)
  - Angiokeratomas (clusters of red to blue rash-liked discolorations on the skin)
  - Anhidrosis or hypohidrosis (absent or markedly decreased sweating)
  - Gastrointestinal symptoms (abdominal pain, cramping, frequent bowel movements)
  - Corneal dystrophy (star-burst pattern of cornea seen by slit lamp ophthalmologic examination)
  - Cardiovascular complications (arrhythmias, left ventricular hypertrophy, hypertrophic cardiomyopathy)
  - Renal complications (progressive proteinuria, renal insufficiency, renal failure)
  - Cerebrovascular disease (transient ischemic attack, stroke)
- For new starts on Formularies 3, 4, and CHP only: Enrollee must have experienced serious side effects or drug failure to Galafold (migalastat) except in the following circumstances:
  - Pediatric patients between the ages of 8 years old to less than 18 years old
  - Patients with severe, classical phenotype who demonstrate no alpha galactosidase activity OR
  - those who exhibit severe clinical Fabry disease symptoms (as previously noted) where the provider has determined that Fabrazyme is medically necessary.
  - Patients with estimated glomerular filtration rate (eGFR) < 30 mL/min/1.73 m2 OR end-stage renal disease (ESRD)
  - Patients who do not have an amenable GLA gene mutation for treatment with Galafold based on the human embryonic kidney (HEK) 293 assay
- Will not be used concomitantly receive Galafold (migalastat) or Fabrazyme (agalsidase beta)
- Current body weight and requested dose regimen must be submitted for initial review and each recertification request

Exclusion Criteria

Therapy will not be approved if any of the above Inclusion Criteria are not met OR any of the below Exclusion Criteria are met:

- Enrollee has non-compliance with > 50% of treatments and/or failure to regularly attend follow up visits
- Enrollee has persistent life threatening or severe infusion reactions that do not respond to prophylaxis (e.g., anaphylaxis)
- End stage renal disease without an option for kidney transplantation, in combination with advanced heart failure (NYHA Class IV)
- End stage Fabry disease or other comorbidities with a life expectancy of less than one year
- Cognitive decline of any cause
- Lack of treatment response for one year, when the primary indication for ERT is neuropathic pain while receiving maximum supportive care

Continuation Criteria

- Requests will be reviewed per criteria every six months
- Enrollee continues to meet above noted Inclusion Criteria and does not meet any Exclusion Criteria
- Enrollee has disease response as demonstrated by improvement or stabilization of the disease including neuropathic pain and/or the rate of decline of the estimated glomerular filtration rate (eGFR)

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department

References

		Updated	Accessed
1	Elfabrio [package insert]. Parma, Italy; Chiesi Farmaceutici S.p.A.; May 2023. Accessed August 2023.	5/2024	8/2025
2	Fabrazyme [package insert]. Cambridge, MA; Genzyme Corporation.	7/2024	8/2025
3	National Organization for Rare Disorders. Fabry Disease. Updated: June 6, 2019. Available at: https://rarediseases.org/rare-diseases/fabry-disease/	6/2019	8/2025
4	Biegstraaten, M et al. Recommendations for initiation and cessation of enzyme replacement therapy in patients with Fabry disease: the European Fabry Working Group consensus document. Orphanet J Rare Dis. 2015;10(36).	2015	7/2024

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE CHOICES:	Subject to all terms and conditions noted in above application.
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 2/25/2026

New: 9/2023

Policy History

Revised	Reviewed
9/2025, 2/2026	9/2024

Revision Date	Changes Made
9/2025	Updated diagnosis criteria of Fabry disease Updated symptoms Added must have experienced serious side effects or drug failure to miglustat except in certain circumstances
2/2026	Updated step through Galafold to be applicable to formularies 3, 4, and CHP

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MEDICAL POLICY

Medical Policy Title	**Erectile Dysfunction**
Policy Number	**7.01.30**
Current Effective Date	**June 1, 2026**
Next Review Date	**October 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Diagnosis

I. Diagnosing of ED with **ANY** of the following procedures is considered **medically appropriate**:
   A. Nocturnal penile tumescence (NPT) test, only when the clinical evaluation is unable to distinguish psychogenic from organic impotence;
   B. Duplex scan in conjunction with intracorporeal papaverine;
   C. Pharmacological response test (PRT) using vasoactive medications such as papaverine HCL, prostaglandin E1;
   D. Dynamic infusion cavernosonogram and cavernosometry, for patients who meet the criteria for penile revascularization;
   E. Pudendal arteriography/angiography, for patients who meet the criteria for penile revascularization;
   F. Penile biothesiometry (considered an integral part of evaluation and management during an office visit).

II. Diagnosing ED with **ANY** of the following procedures is considered **not medically necessary**:
   A. Dorsal nerve conduction latencies;
   B. Penile plethysmography;
   C. Cavernosal nerve mapping;
   D. Evoked potential measurements;
   E. Corpora cavernosal electromyography.

Treatment

III. Treatment modalities for individuals with known erectile dysfunction (ED) are considered **medically appropriate** when **ALL** of the following criteria have been met:
   A. Symptoms have lasted more than six (6) months (See Policy Guidelines for treatment prior to six (6) months); **AND**
   B. **One** of the following treatment modalities:

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1. Oral Drug Therapy (i.e., sildenafil citrate (Viagra), vardenafil (Levitra, Staxyn), avanafil (Stendra), and tadalafil (Cialis);
2. Intracavernous Injection Therapy (e.g., Caverject, Edex);
3. Transurethral Delivery System (i.e., Medicated Urethral System for Erection [MUSE]);
4. Vacuum Constriction Devices (i.e., ErecAid);
5. Penile Prosthetic Implants (i.e., semi-rigid, malleable and inflatable): Only medically appropriate in patients who fail or refuse other forms of therapy. Penile prosthesis implantation should not be performed in men with psychogenic ED, unless a psychiatrist or psychologist participates in the preoperative evaluation and concurs with the need for prosthesis implantation;
6. Arterial Revascularization: Only medically appropriate in men with normal corporeal venous function who have arteriogenic ED secondary to pelvic or perineal trauma.

IV. Electroejaculation is considered **medically appropriate** for the following indications:

A. For men with spinal cord injury who desire to become biological fathers;

B. The inability to ejaculate is a consequence of retroperitoneal lymph node dissection (REPLND);

C. Insulin-dependent diabetes;

D. Multiple Sclerosis (MS);

E. Spina bifida or other neural tube deficit, complications due to bladder or rectal surgery, or idiopathic anejaculation (neurogenic, psychogenic or a combination of both).

V. Treatment of ED using **ANY** of the following modalities is considered **not medically necessary**:

A. Topical medications containing vasodilators;

B. Arterial (penile) revascularization (except for the indication listed above in Policy Statement I);

C. Venous ligation in the treatment of venous leak impotency (venous ligation attempts to close off the natural drainage of the penis to maintain blood in the penis during an erection);

D. Crural ligation for primary venous leakage ED;

E. Temporary or permanent lumbar ganglionic block or sympathectomy for ED secondary to cavernous adrenergic hypertone.

VI. Treatment of ED or Peyronie's Disease using **ANY** of the following modalities is considered **investigational**, including but not limited to:

A. Extracorporeal Shock Wave Therapy (ESWT);

B. Penile contracture devices (e.g., RestoreX).

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Treatment may be initiated prior to six (6) months, in the case of an acute event such as penile trauma or radical pelvic surgery (e.g., prostatectomy or cystectomy), or in the case of drug-induced ED caused by treatment of a co-morbid condition.

II. The least invasive procedure should be the first line of treatment. If a member fails oral therapy, a durable medical equipment (DME) modality should generally be the next step in treatment.

III. Vacuum constriction devices are considered to be durable medical equipment.

IV. The following treatment modalities are dependent upon a member's subscriber contract with a prescription drug benefit: oral drug therapy, intracavernous injection therapy, and transurethral delivery system. (Refer to Pharmacy Management for information regarding coverage of oral drug therapy).

V. With the exception of oral drug therapy, a statement of medical necessity from the urologist is required documenting results of clinical evaluation and any diagnostic test results.

VI. Oral drugs such as Sildenafil citrate (Viagra), vardenafil (Levitra, Staxyn), avanafil (Stendra), and tadalafil (Cialis) inhibit (block) the effect of an enzyme, phosphodiesterase-5 (PDE5), causing an increase in penile blood flow necessary for an erection.

   A. PDE5 inhibitors should not be used in combination with other treatment modalities for ED.

   B. PDE5 inhibitors are contraindicated if the patient is actively taking nitrates in any form.

   C. PDE5 inhibitors should be used with caution in patients who take alpha-blockers.

   D. Vardenafil should be used with caution if a patient, or a patient's family member, has a rare heart condition known as "prolongation of the QT interval."

VII. Patients using vasoactive drug injection therapy should be informed that a prolonged erection can occur and that they should present for treatment if the erection lasts longer than four (4) hours such as papaverine, phentamine, and/or prostaglandin E1 (alprostadil).

DESCRIPTION

ED, or impotence, is defined as the inability, over time, to consistently achieve or maintain an erection of sufficient rigidity for sexual penetration. ED involves the inability to achieve or maintain an erection and have sexual activity 80% of the time it is attempted.

ED may be psychogenic in origin; or caused by penile trauma, spinal cord injuries, abnormalities of the penis (e.g., penile fibrosis or Peyronie's disease), veno-occlusive dysfunction; or result from a radical pelvic surgery (e.g., radical prostatectomy or cystectomy). ED may also be a secondary

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symptom of a systemic disease or its treatment (e.g., diabetes mellitus, hypertension, blood lipid abnormalities, coronary artery disease or peripheral vascular disease). Brief, sporadic episodes of erectile failure are common occurrences and are often related to psychological stress.

The evaluation of a patient with ED usually consists of a structured interview and a thorough physical examination. Adjunctive testing, such as vascular assessment, neurological assessment, and monitoring of nocturnal erections, may be indicated in select patients.

Peyronie's Disease (PD) is a localized connective tissue disorder of unknown cause and is characterized by the formation of inelastic fibrous plaques within the tunica albuginea or erectile tissue of the penis. For many patients, PD results in sexual problems due to the difficulty in attaining and/or maintaining erections.

ED Treatment Modalities

- Vacuum constriction devices (e.g., ErecAid) use a hand pump and cylindrical component to create a vacuum around the penis, drawing blood into the penis, which results in an erection.
- Medicated Urethral System for Erection (MUSE) is a method in which alprostadil (prostaglandin E1) is given transurethrally to treat ED.
- Intracavernous Injection Therapy (e.g., Caverject, Edex) are vasodilating agents such as papaverine, phentamine, and/or prostaglandin E1 (alprostadil) are injected into the corpora of the penis to produce an erection.
- Arterial revascularization refers to taking a blood vessel from another part of the body and using it to surgically bypass a blockage in the natural blood vessel of the penis.
- Electroejaculation (EE) has had a large degree of success in enabling men with spinal cord injuries to become biological fathers. Up to 95% of men with spinal cord injury are unable to ejaculate normally. Vibratory and electrical stimulation, along with an appropriate method of semen collection followed by intrauterine insemination, has resulted in successful conception in a large number of cases.
- Extracorporeal Shock Wave Therapy (ESWT) uses energy from the acoustic waves in an attempt to increase the expression of local growth factors, improving endothelial function, angiogenesis and potentially regenerating nerve fibers.
- Penile Contracture Device (e.g., RestoreX) is used for the treatment of Peyronie's disease and is also now available to correct penile curvature or indentation/hourglass deformity, restore penile length loss secondary to medical conditions or due to prior surgery/trauma, and to limit loss of erectile function post-prostatectomy.

SUPPORTIVE LITERATURE

Sildenafil citrate (Viagra), vardenafil (Levitra, Staxyn), avanafil (Stendra), and tadalafil (Cialis) are phosphodiesterase type 5 inhibitors and are the only oral therapy approved by the FDA for the treatment of ED.

Eroxon (MED3000) is a topical gel for the treatment of ED, it was approved for over-the-counter use without a prescription based on its low risk profile and rapid onset. It is considered a medical device rather than a drug due to its mechanical mode of action by stimulating the nerve endings to trigger natural erection pathways.

Phase III clinical trials of alprostadil topical cream for the treatment of mild to severe ED have recently concluded. Topical alprostadil cream appears to have improved ED in a broad range of patients and was safe and well-tolerated in the trials; however, it has not received U.S. Food and Drug Administration (FDA) approval for this use.

There is rarely any indication for the routine use of nocturnal penile tumescence (NPT) or rigidity testing. These tests have been difficult to standardize, and their actual benefit in determining therapy is unclear. NPT and rigidity testing may be useful in a patient who reports a complete absence of erections or when a primary psychogenic etiology is suspected. Ultrasound, angiography, and intracavernosal papaverine injections are widely used for the diagnosis of vasculogenic impotence, such as when a patient has sustained a groin trauma. Biothesiometry is the accepted technique for the neurological assessment of impotence. More extensive neurology tests, including nerve conduction latencies, evoked potential measurements, and corpora cavernosal electromyography, are of limited clinical value and are usually not medically necessary for diagnostic purposes.

Low intensity extracorporeal shock wave therapy has been utilized by urologists since the 1980s for the non-invasive fragmentation of kidney stones in the form of extracorporeal shockwave lithotripsy (ESWL). Within the realm of sexual medicine there has been tremendous interest for LiSWT in the treatment of ED with a handful of preclinical studies followed by several clinical trials.

Abou Zahr et al (2022) conducted a systematic review and meta-analysis evaluating the effectiveness of intra-cavernosal injection (ICI) of botulinum toxin (BoNT-A) as a treatment for erectile dysfunction (ED). The authors reviewed literature from 1990 to 2021, ultimately including seven studies (five clinical and two pre-clinical). The meta-analysis focused on three key outcomes: Erection Hardness Score (EHS), Peak Systolic Velocity (PSV) in the cavernosal artery, and the Sexual Health Inventory for Men (SHIM) score. Results showed statistically significant improvements in EHS and PSV with BoNT-A compared to placebo, suggesting potential benefits in erectile function. However, no significant improvement was found in SHIM scores. The authors caution that these findings should be interpreted carefully due to limitations such as small sample sizes, heterogeneity among studies, and potential biases. They conclude that while BoNT-A shows promise, its use should remain within clinical research settings until further evidence supports broader application.

Vinay et al (2021) conducted a randomized, double-blinded, sham -controlled study, the aim of the trail was to assess the effects of electromagnetic low-intensity (LI-ESWT) on the erectile dysfunction of vascular phosphodiesterase type 5 inhibitor (PDE5I) refractory ED patients. There were 76 participants with vascular PDE5I refractory ED, 40 were treated with LI-ESWT (one session/ week for 4 weeks, 5000 shocks/session, 0.09 mJ/mm^2 energy density), and 26 were treated with a sham probe. Three-month follow-up, median change in IIEF-EF score for active and sham groups was 3.5 (IQR 0–10) and −0.5 (IQR −11 to 1). Six months after treatment, 52.5% of patients (21/40) in the active group and 27.8% of patients (10/36) in the sham group presented an EHS>2. At the same

evaluation, 40.0% (16/40) and 13.9% (5/36) of patients had positive answers to GAQ-1, in the treated and sham groups. While this therapy is promising longer follow-up is needed that compares different ED etiologies and protocol characteristics.

Toussi et al (2021) conducted a randomized single-center controlled study, they studied at 82 men post prostatectomy. with 6-month data available in 25 controls and 30 penile traction therapy cases. More penile traction therapy men reported satisfaction or improvement in penile length than controls. Adverse events were transient and mild; 87% would choose to repeat therapy, and 93% would recommend it to others. Although the use of the penile contracture device showed improvements in objective and subjective penile length post prostatectomy and measures of erectile dysfunction, intercourse satisfaction, external validation is warranted. Currently there is limited clinical trials, peer reviewed or supporting literature that supports the use of contracture devices for the treatment of Peyronie's Disease to aide with ED.

Joseph et al (2020) investigated the clinical outcomes of the RestoreX penile traction therapy device in men with Peyronie's disease. This open-label and follow-up phase study demonstrated that the device significantly improved penile curvature, length, and erectile function. Participants used the device for short daily sessions (typically 30–90 minutes), and those who adhered to the protocol experienced statistically significant reductions in curvature (up to 30°), gains in penile length (up to 1.5 cm), and improvements in sexual function scores. The study also noted that the device was well-tolerated, with minimal adverse effects, supporting its role as a non-invasive, first-line or adjunctive treatment for Peyronie's disease.

PROFESSIONAL GUIDELINE(S)

The American Urological Association (AUA) 2018 guidelines for Erectile Dysfunction state:

- For men with ED, low intensity extracorporeal shock wave therapy (ESWT) should be considered investigational. (Conditional Recommendation; Evidence Level: Grade C)
- For men with ED, intracavernosal stem cell therapy should be considered investigational. (Conditional Recommendation; Evidence Level: Grade C.)
- For men with ED, platelet rich plasma (PRP) therapy should be considered experimental. (Expert Opinion)
- For young men with ED and focal pelvic/penile arterial occlusion and without documented generalized vascular disease or veno-occlusive dysfunction, penile arterial reconstruction may be considered. (Conditional Recommendation; Evidence Level: Grade C)
- For men with ED, penile venous surgery is not recommended. (Moderate Recommendation; Evidence Level: Grade C)

National Comprehensive Cancer Network (NCCN) guidelines for Prostate Cancer V.2.2025

- "Recovery of erectile function is directly related to age at radical prostatectomy, preoperative erectile function, and the degree of preservation of the cavernous nerves. Replacement of

resected nerves with nerve grafts has not been shown to be beneficial. Early restoration of erections may improve late recovery."

REGULATORY STATUS

In 2008, New York State mandated that Medicaid, Family Health Plus, Healthy New York, and standardized HMO and HMO/POS direct payment policies exclude coverage of drugs, procedures, and supplies for the treatment of ED when provided to, or prescribed for use by, a person who is required to register as a sex offender under state law. In addition, in 2005, a federal law was enacted that excludes coverage of drugs to treat erectile dysfunction for all Family Health Plus enrollees.

Sildenafil citrate (Viagra), vardenafil (Levitra, Staxyn), avanafil (Stendra), and tadalafil (Cialis) are phosphodiesterase type 5 inhibitors and are the only oral therapy approved by the FDA for the treatment of ED.

Eroxon (MED3000) is an over-the-counter topical gel for the treatment of ED that received FDA approval in 2023.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
37788	Penile revascularization, artery, with or without vein graft
37790 (NMN)	Penile venous occlusive procedure
54220	Irrigation of corpora cavernosa for priapism
54230	Injection procedure for corpora cavernosography
54231	Dynamic cavernosometry, including intracavernosal injection of vasoactive drugs (e.g., papaverine, phentolamine)
54235	Injection of corpora cavernosa with pharmacologic agent(s) (e.g., papaverine, phentolamine)
54240 (NMN)	Penile plethysmography
54250	Nocturnal penile tumescence and/or rigidity test
54400	Insertion of penile prosthesis; non-inflatable (semi-rigid)
54401	Insertion of penile prosthesis; inflatable (self-contained)

Code	Description
54405	Insertion of multi-component, inflatable penile prosthesis, including placement of pump, cylinders, and reservoir
54406	Removal of all components of a multi-component, inflatable penile prosthesis without replacement of prosthesis
54408	Repair of component(s) of a multi-component, inflatable penile prosthesis
54410	Removal and replacement of all component(s) of a multi-component, inflatable penile prosthesis at the same operative session
54411	Removal and replacement of all components of a multi-component, inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
54415	Removal of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis, without replacement of prosthesis
54416	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis at the same operative session
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue
55870	Electroejaculation
93980	Duplex scan of arterial inflow and venous outflow of penile vessels; complete study
93981	Duplex scan of arterial inflow and venous outflow of penile vessels; follow-up or limited study
0864T (E/I)	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy

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HCPCS Codes

Code	Description
C1813	Prosthesis, penile, inflatable
C2622	Prosthesis, penile, non-inflatable
J0270	Injection, alprostadil, per 1.25 mcg (Code may be used for Medicare when drug administered under direct supervision of a physician, not for use when drug is self-administered)

Code	Description
J0275	Alprostadil urethral suppository (Code may be used for Medicare when a drug administered under direct supervision of a physician, not for use when drug is self-administered)
J2440	Injection, papaverine HCL, up to 60 mg
J2760	Injection, phentolamine mesylate, up to 5 mg
L7900	Male vacuum erection system
L7902	Tension ring, for vacuum erection device, any type, replacement only, each
E0201 (E/I) Effective 04/01/25 S4988 (E/I) Termed 03/31/25	Penile contracture device, manual, greater than 3 lbs. traction force Penile contracture device, manual, greater than 3 lbs. traction force

ICD10 Codes

Code	Description
E01.8	Other iodine-deficiency related thyroid disorders and allied conditions
E02	Subclinical iodine-deficiency hypothyroidism
E03.2-E03.9	Other hypothyroidism, other (code range)
E05.00-E05.91	Thyrotoxicosis [hyperthyroidism] (code range)
E10.40-E10.59; E10.69	Type 1 diabetes mellitus with complications (code range)
E11.40-E11.59; E11.69	Type 2 diabetes mellitus with complications (code range)
E13.40-E13.59; E13.69	Other specified diabetes mellitus with complications (code range)
E22.1-E23.7	Disorders of pituitary gland (code range)

Code	Description
E24.1	Nelson's syndrome
E27.0-E27.9	Other disorders of adrenal gland (code range)
E35	Disorders of endocrine glands in diseases classified elsewhere
E89.0	Postprocedural hypothyroidism
E89.3	Postprocedural hypopituitarism
E89.6	Postprocedural adrenocortical (-medullary) hypofunction
F52.0	Hypoactive sexual desire disorder
F52.21	Male erectile disorder
F52.32	Male orgasmic disorder
F52.8	Other sexual dysfunction not due to a substance or known physiological condition
N52.01 - N52.9	Male erectile dysfunction (code range)
R37	Sexual dysfunction, unspecified

REFERENCES

Abou Zahr R, et al. Intra-cavernosal injection of botulinum toxin in the treatment of erectile dysfunction: a systematic review and meta-analysis. Urology. 2022 Dec;170:5-13.

American Urological Association [Internet]. Erectile Dysfunction: AUA Guideline (2018). [accessed 2025 Jul 30]. Available from: http://www.auanet.org/guidelines/guidelines/erectile-dysfunction-(ed)-guideline

Clavijo RI, Kohn TP, Kohn JR, Ramasamy R. Effects of Low-Intensity Extracorporeal Shockwave Therapy on Erectile Dysfunction: A Systematic Review and Meta-Analysis. J Sex Med. 2017 Jan;14(1):27-35.

Joseph J, et al. Outcomes of RestoreX penile traction therapy in men with peyronie's disease: results from open label and follow-up phases. J Sex Med. 2020 Dec;17(12):2462-2471.

Kim S, et al. Novel emerging therapies for erectile dysfunction. World J Mens Health. 2021 Jan;39(1):48-64.

Liu JL, et al. Restorative therapies for erectile dysfunction: Position statement from the Sexual Medicine Society of North America (SMSNA). Sex Med. 2021 Jun;9(3):100343.

Lu Z, Lin G, Reed-Maldonado A, Wang C, Lee YC, Lue TF. Low-intensity extracorporeal shock wave

treatment improves erectile function: A systematic review and meta-analysis. Eur Urol. 2017 Feb;71(2):223-233.

Matz EL, et al. Stem cell therapy for erectile dysfunction. Sex Med Rev. 2019;7(2):321-328.

National Comprehensive Cancer Network [Internet]. Clinical Practice Guidelines in Oncology. Prostate Cancer. V.2.2025. [accessed 2025 Jul 31] Available from: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf

New York State Insurance Department Regulation 62, Part 52, 36th Amendment (11NYCRR 52).

Ortac M, et al. The impact of extracorporeal shock wave therapy for the treatment of young patients with vasculogenic mild erectile dysfunction: A prospective randomized single-blind, sham controlled study. Andrology. 2021 Sep;9(5):1571-1578.

Schoofs E, et al. Current guideline recommendations and analysis of evidence quality on low-intensity shockwave therapy for erectile dysfunction. Int J Impot Res. 2019;31:209–217.

Sighinolfi MC, et al. Low-intensity extracorporeal shockwave therapy for the management of postprostatectomy erectile dysfunction: a systematic review of the literature. Eur Urol Open Sci. 2022 Jul 30;43:45-53.

Sramkova T, et al. Erectile dysfunction treatment using focused linear low-intensity extracorporeal shockwaves: Single-blind, sham-controlled, randomized clinical trial. Urol Int. 2020;104(5-6):417-424.

Toussi A, et al. Efficacy of a novel penile traction device in improving penile length and erectile function post prostatectomy: results from a single-center randomized, controlled trial. J Urol. 2021 Aug;206(2):416-426.

Vinay J, et al. Penile low intensity shock wave treatment for PDE5I refractory erectile dysfunction: a randomized double-blind sham-controlled clinical trial. World J Urol. 2021 Jun;39(6):2217-2222.

Zganjar A, et al. Efficacy of RestoreX after prostatectomy: open-label phase of a randomized controlled trial. BJU Int. 2023 Aug;132(2):217-226.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Vacuum Erection Devices (VED) (LCD L34824) [accessed 2025 Jul 30]

Vacuum Erection Devices (VED) - Policy Article (A52712) [accessed 2025 Jul 30]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a

specific service, medical policy criteria apply to the benefit.

- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 02/06 (regulatory requirement) **Revised**: 01/09, 09/09, 01/10, 01/12, 01/13, 05/15, 11/15, 11/18, 11/23, 5/25, 5/26 **Reviewed**: 01/07, 12/07, 01/11, 11/13, 11/14, 11/16, 11/17, 11/19, 11/20, 11/21,11/22, 11/24, 11/25	
Date	**Summary of Changes**
6/1/2026	• Transitioned Erectile Dysfunction: Evaluation & Treatment policy, 1370/20.000432 to Lifetime HealthCare Companies policy.
4/1/2025	• Added new code E0201 to Exclusions.
11/1/2023	• Updated exclusion of Cavernosometry or cavernosography (54230, 54231) to remove coverage for 54230 in patients less than 50 years old with history of pelvic/perineal trauma.

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Policy/Procedure Name: Evkeeza (evinacumab-dgnb) **Control Number: 1350/20.000409**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Management of high cholesterol levels, particularly elevated low-density lipoprotein cholesterol (LDL-C), is recommended to reduce risk of cardiovascular adverse events. The most recent recommendations from the 2018 American College of Cardiology/American Heart Association (ACC/AHA) Guideline on the Management of Blood Cholesterol are based on evidence from primary sources of randomized controlled trials (RCTs). This guideline emphasizes LDL-C lowering drugs in high-risk patients produces marked reductions in atherosclerotic cardiovascular disease (ASCVD). Among lipid lowering drugs, statins are the cornerstone of therapy (statin intensities described in the guideline) as an adjunct to diet and other lifestyle modifications for cholesterol management and cardiovascular risk reduction. Other lipid lowering drugs include Zetia (ezetimibe), bile acid sequestrants and proprotein convertase subtilisin kexin-type 9 (PCSK9) inhibitors.

Familial hypercholesterolemia (FH) is an inherited genetic condition (chromosome 19) that results in very high LDL-C levels, usually starting at a younger age. FH leads to a twenty-fold increase in the risk of premature ASCVD. Diagnosis of this condition is important as early aggressive treatment may lower a patient's risk of heart disease or stroke. There are two forms of FH: heterozygous familial hypercholesterolemia (HeFH) and homozygous familial hypercholesterolemia (HoFH). Both forms of FH increase a patient's risk of ASCVD, however, the latter is a more severe and rare condition. It is estimated to affect as many as 1 in 300,000 people all over the world, whereas HeFH is more common affecting 1 in 250 people. Patients with HeFH have LDL-C levels > 190mg/dL, with coronary heart disease (CHD) onset between the ages of 30 to 60. Consequently, patients with HoFH have LDL-C levels typically > 400mg/dL, with CHD onset at childhood. Most patients with HeFH respond to drug therapy, whereas HoFH patients generally have poor response. HoFH patients may have serious cholesterol deposits in the arteries or aortic valve of the heart which may cause heart attacks in patients as early as < 10 years old.

In addition to elevated LDL-C levels, patients with FH may experience physical findings such as xanthomas, which are fatty deposits under the skin (often on the Achilles tendon or joints of the hand) and xanthelasmas, which are fatty deposits under the skin on the eyelids or corneal arcus, which is a grayish ring on the periphery of the cornea.

As mentioned, FH is inherited and passed down through families. Each child of a person with FH has a 50% chance of inheriting the disorder. Presently, most people with FH have genetic variants which may affect LDL-R, apolipoprotein B (APOB) or PCSK9, among others. Depending on how many mutations a person inherits determines whether they have HeFH or HoFH. If one abnormal mutation is passed down to a child, typically from one parent, the patient will have HeFH. When the mutation for HeFH is passed on from both parents to their children, this will result in HoFH (more rare and severe). HoFH is most often caused by a loss-of-function variant in the LDL-R, which leads to low or absent hepatic clearance of LDL from the circulation. Those with null homozygotes have higher LDL cholesterol levels due to very minimal to no LDL-R expression. Patients with two non-null alleles or one non-null allele/null allele, may have a partial reduction in LDL-R activity. Mechanistically, agents such as statins, ezetimibe and PCSK9 inhibitors rely heavily on upregulating LDL-receptor expression, which may have little efficacy on patients with null/null HoFH who may have no LDL receptor activity.

The standard of care for treatment of FH may consist of a combination of one or more medications in addition to dietary and lifestyle modifications (exercise and smoking cessation) for adequate management of LDL-C. Treatment options may include high-dose statins (used in most individuals), ezetimibe, bile acid sequestrants and PCSK9 inhibitors. Patients diagnosed with HoFH are more resistant to treatment and will have substantially high LDL-C levels despite combination treatment with these agents. As mentioned above, patients with HoFH may have reduced LDL receptor activity, which can lead to efficacy concerns when using conventional treatments (statins, ezetimibe and PCSK9 inhibitors).

Therefore, advanced treatment options are available for patients once they have exhausted other available treatments or those who

still remain with substantially high LDL-C levels. The effects of these treatments work independently of the LDL receptor, eliminating the concerns with LDL receptor expression and the use of statins, ezetimibe and PCSK9 inhibitors. These treatments include lipoprotein apheresis, which is a procedure done every week to every other week to remove LDL-C from the bloodstream.

Angiopoietin-like 3 (ANGPTL3) is molecule produced by the liver which inhibits lipoprotein lipase and endothelial lipase. Lipase plays a key role in lipid metabolism. Loss of function variants with ANGPTL3 have been associated with low levels of LDL-C and triglycerides and with a 41% lower risk of coronary artery disease (CAD). Pharmacological inhibition of ANGPTL3 with Evkeeza (evinacumab-dgnb), a fully human monoclonal antibody has shown to reduce LDL-C by 49% from baseline as well as lower levels of APOB, non-HDL and total cholesterol. The ELIPSE-HoFH has further shown evinacumab to be generally well tolerated, with reported incidence of nasopharyngitis and influenza-like illness. The safety and effectiveness of Evkeeza has have not been established in patients with other causes of hypercholesterolemia, including those with HeFH.

The 2022 ACC Expert Consensus Decision Pathway on the role of non-statin therapies for LDL-C lowering in the management of atherosclerotic cardiovascular disease includes Evkeeza as an optional intervention to consider in HoFH patients that fail to respond adequately to maximally-tolerated statin therapy.

Summary	
Effective Date of Policy:	9/10/2025
Indications	Homozygous familial hypercholesterolemia
ICD10 Diagnosis Codes	Select codes include: E78.01
Availability	Single dose vials for intravenous injection 345mg/2.3mL (150mg/mL) and 1,200mg/8mL (150mg/mL) solution J1305
Duration	Initial: Six months Continuation: 12 months

Required Criteria for Initial Approval	
All of the following conditions for the requested indication must be met in order to approve therapy:	
Indication	**Criteria**
Homozygous Familial Hypercholesterolemia (FDA approval) ICD10: E78.01	1. Evkeeza is prescribed by or in consultation with a cardiologist, lipid specialist, or endocrinologist **AND** 2. Member is ≥5 years of age or older with a diagnosis of homozygous familial hypercholesterolemia (HoFH) **AND** a. Genetic testing must demonstrate evidence of two mutant alleles at the low-density lipoprotein receptor (*LDLR*) apolipoprotein B (*APOB*), proprotein convertase subtilisin kexin type 9 (*PCSK9*) or low-density lipoprotein receptor adaptor protein 1 (*LDLRAP1*) gene **OR** b. Member has a history of untreated LDL-C plasma concentration of > 400 mg/dL or treated LDL-C ≥ 300 with one of the following: i. Xanthoma before the age of 10 years **OR** ii. At least one parent having clinically diagnosed familial hypercholesterolemia **AND** 3. One of the following must be met (a or b): a. For individuals 10 years of age and older, member must have failed to reach target LDL-C while receiving treatment with maximally tolerated high potency statin (goal is atorvastatin 40-80 mg daily or rosuvastatin 20-40 mg daily), in combination with ezetimibe, and a PCSK9 inhibitor (Repatha, Praluent) for at least 8 weeks. A trial with a PCSK9 inhibitor is not required if the member is known to have two LDL-receptor negative alleles (null homozygous). **OR** b. For individuals 5-9 years of age, member must have failed to reach target LDL-C while receiving treatment with at least one lipid lowering therapy (e.g., statins, ezetimibe, lipoprotein apheresis) for at least 8 weeks

	4. LDL-C must be > 70 mg/dL for patients with clinical atherosclerotic cardiovascular disease (ASCVD) OR LDL-C must be > 100 mg/dL for patients without documented clinical ASCVD o Clinical ASCVD defined as having a history of acute coronary syndrome, myocardial infarction (MI), stable or unstable angina, coronary/other arterial revascularization, stroke, TIA, peripheral arterial disease, or other documented atherosclerotic disease (such as coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, or Carotid plaque with ≥ 50% stenosis) 5. Prescriber must attest that a discussion with the patient has taken place regarding a heart healthy diet, the importance of exercise, and smoking cessation (if applicable) 6. Documentation of baseline LDL-C level must be provided-measurement must occur within 60 days prior to treatment

Exclusion Criteria

- Evkeeza will not be approved for other causes of hypercholesterolemia, including those with heterozygous familiar hypercholesterolemia (HeFH)
- Evkeeza will not be approved in combination with Juxtapid unless the patient demonstrated failure to achieve target LDL-C while on a minimum therapy duration of 8 weeks of combination Juxtapid, high-intensity or maximally tolerated statin therapy and a PCSK9 inhibitor

Continuation Criteria

- After the initial six-month approval, further approval will require evidence of an adequate reduction in LDL-C level compared to baseline. Continuation approvals will be granted for 12 months.

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.
- Evkeeza will be covered under the medical benefit
- The recommended dosage is 15 mg/kg administered by intravenous (IV) infusion every 4 weeks.
- Members should be involved with care plan towards optimal lifestyle, including, but not limited to:
  - Eating a heart-healthy diet
  - Regular exercise
  - Weight loss plan if BMI ≥ 30
  - Smoking cessation plan
- Based on the findings in animal reproduction studies, Evkeeza may cause fetal harm when administered to pregnant patients.
- If patient is unable to tolerate statin therapy, documentation in progress notes must include:
  - A contraindication to statin therapy according to FDA labeling OR
  - History of statin-related rhabdomyolysis
    - Must have symptoms consistent with rhabdomyolysis (i.e., muscle pain, swelling, and weakness, dark urine) AND
    - Must have creatine kinase (CK) level > 10 times upper limit of normal, myoglobinuria, or acute renal failure (increase in serum creatinine > 0.5 mg/dL) AND
    - Patient was receiving a statin at the time of the event and symptoms resolved upon discontinuation of the statin OR
  - History of statin intolerance. Documentation must include the following:
    - Inability to tolerate at least 2 different statins
      - At least 1 statin must be hydrophilic (such as pravastatin, fluvastatin, or rosuvastatin) starting at the lowest starting average daily dose AND

- Intolerance associated with confirmed, intolerable statin-related adverse effects (i.e., muscle related symptoms) or significant biomarker abnormalities (i.e., ALT/AST > 3 times the upper limit of normal accompanied by increase in total bilirubin > 2 times the upper limit of normal) AND
- Non-statin causes of muscle symptoms or biomarker abnormalities have been ruled out (for example, hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders such as polymyalgia rheumatic, steroid myopathy, vitamin D deficiency, or primary muscle disease)

References

		Accessed
1	Grundy SM, Stone NJ, Bailey AL, et al. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines [published correction appears in Circulation. 2019 Jun 18;139(25):e1182-e1186]. Circulation. 2019;139(25):e1082-e1143. Doi:10.1161/CIR.0000000000000625	1/2023
2	Family Heart Foundation. What is familial hypercholesterolemia. Available at https://familyheart.org/familial-hypercholesterolemia. Accessed January 3, 2025.	1/2025
3	Family Heart Foundation. How to treat familial hypercholesterolemia. Available at: https://familyheart.org/fh-treatments. Accessed January 3, 2025.	1/2025
4	Family Heart Foundation. Heterozygous vs homozygous FH. Available at: https://familyheart.org/heterozygous-vs-homozygous-fh. Accessed January 3, 2025.	1/2025
5	Soutar AK, et al. Mechanisms of Disease: genetic causes of familial hypercholesterolemia. Nature Clinical Practice Cardiovascular Medicine. 2007; 4:214-225.	1/2023
6	Writing Committee, Lloyd-Jones DM, Morris PB, Ballantyne CM, Birtcher KK, Covington AM, DePalma SM, Minissian MB, Orringer CE, Smith SC Jr, Waring AA, Wilkins JT. 2022 ACC Expert Consensus Decision Pathway on the Role of Nonstatin Therapies for LDL-Cholesterol Lowering in the Management of Atherosclerotic Cardiovascular Disease Risk: A Report of the American College of Cardiology Solution Set Oversight Committee. J Am Coll Cardiol. 2022 Oct 4;80(14):1366-1418. doi: 10.1016/j.jacc.2022.07.006. Epub 2022 Aug 25. PMID: 36031461.	1/2023
7	Evkeeza (evinacumab-dgnb) [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; 2023	1/2025
8	German, C. Homozygous Familial Hypercholesterolemia: Diagnosis and Emerging Therapies. American College of Cardiology. https://www.acc.org/Latest-in-Cardiology/Articles/2022/02/18/18/04/Homozygous-Familial-Hypercholesterolemia. Published Feb 18, 2022. Accessed December 15, 2023.	12/2023
9	Cuchel M, Raal FJ, Hegele RA, et al. 2023 update on European Atherosclerosis Society consensus statement on homozygous familial hypercholesterolemia: new treatment guidelines and clinical guidance. Eur Heart J. 2023; 44(25):2277-2291. Doi: 10.1093/eurheartj/ehad197.	1/2025

Policy/Procedure Name: Evkeeza (evinacumab-dgnb) **Control Number: 1350/20.000409**

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 9/10/2025

Policy History

Date	Notes
04/2021	New Policy
04/2022	Reviewed with no changes
04/2023	Revised - Added limitation of Evkeeza from package insert to background, added most recent guideline recommendation for using Evkeeza in HoFH.
04/2024	Revised: • Evkeeza can now be used in ages 5 years and older. • Updated diagnostic criteria in line with ACC publication.
04/2025	Revised – added ezetimibe as a prerequisite medication trial in combination with statin and PCSK9. Added lipid specialist and endocrinologist as appropriate prescribers. Separated the prerequisite trial of medication by age group requiring only one lipid lowering therapy for individuals ages 5-9. Changed continuation approval duration from six months to twelve months.
9/2025	Updated pre-requisite drug requirement Added language in considerations for statin intolerance

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MEDICAL POLICY

Medical Policy Title	**Evoked Potentials**
Policy Number	**2.01.27**
Current Effective Date	**September 1, 2026**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Visual-evoked potentials are considered **medically appropriate** for **ANY** of the following indications:

- A. To diagnose and monitor multiple sclerosis;
- B. To localize the cause of a visual field defect that is not explained by lesions seen on CT, or MRI, metabolic disorder, or infectious disease;
- C. To diagnose or evaluate deficits or damage to the visual system of infants or unresponsive/nonverbal patients.

II. Somatosensory-evoked potentials are considered **medically appropriate** for **ANY** of the following indications:

- A. To assess any decline that may be considered emergent to surgery in unconscious spinal cord injury patients who show specific structural damage to the somatosensory system and who are candidates for emergency spinal cord surgery;
- B. To diagnose and monitor multiple sclerosis;
- C. To evaluate patients with suspected brain death;
- D. To diagnose unexplained myelopathy;
- E. To localize the cause of a neurologic deficit seen on exam and not explained by lesions on CT or MRI.

III. Auditory-evoked potentials are considered **medically appropriate** for **ANY** of the following indications:

- A. To evaluate brainstem function in acquired metabolic disorders;
- B. To assess recovery of brainstem function after a lesion compressing the brainstem has been surgically removed;
- C. To localize the cause of a neurologic deficit seen on exam, not explained by lesions seen on computed tomography (CT) scan or magnetic resonance imaging (MRI);

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D. To diagnose and monitor demyelinating and degenerative diseases affecting the brain stem (e.g., multiple sclerosis, central pontine myelinolysis, olivopontocerebellar degeneration, and others);

E. To diagnose lesions in the auditory system;

F. To evaluate the irreversibility of coma or brain death, along with an electroencephalogram (EEG);

G. For children under age five (5), to determine the type and degree of hearing problems or to determine the developed status of nerves.

IV. Intra-operative neurophysiologic monitoring is **medically appropriate** during high-risk thyroid or parathyroid surgery, or during spinal, intracranial, or vascular procedures.

V. All other indications for intra-operative neurophysiologic monitoring are considered **not medically necessary.**

VI. Vestibular evoked myogenic potentials (cVEMPs and oVEMPs) are considered **investigational.**

VII. Intra-operative monitoring of visual-evoked potentials is considered **investigational.**

VIII. Visual-evoked potential testing for the diagnosis and evaluation of glaucoma is considered **investigational.**

IX. The use of transcranial magnetic stimulation to elicit motor-evoked potentials is considered **investigational.**

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Evoked potentials (EP) are responses (electrical signals) produced by the nervous system in response to a stimulus. These computerized tests help diagnose nerve disorders, locate the site of nerve damage, and evaluate the individual's condition after treatment or during surgery. There are several types of EP tests. Each uses mild stimulus to cause the nerves to react and send a message to the brain. Electrodes placed on the skin surface record how the brain and spinal cord respond to stimulus. The responses are analyzed by a computer and printed as a waveform pattern. The wave pattern may reveal certain problems and show where any damage is located along the nerve pathway(s) being tested. EPs can be further broken down into the following categories, according to the type of stimulation used:

Somatosensory-Evoked Potentials

Somatosensory-evoked potentials (SSEPs) are electrical waves that are generated by the response of sensory neurons to stimulation. Peripheral nerves, such as the median, ulnar or tibial nerves, are typically stimulated, but in some situations the spinal cord may be stimulated directly. Recording is done either cortically or at the level of the spinal cord above the surgical procedure.

Auditory-Evoked Potentials

Auditory-evoked potentials, also called auditory brainstem response (ABR), are electrophysiologic measures of auditory function that utilizes responses produced by the auditory nerve and brainstem and helps differentiate sensory from neural hearing loss. The response is the waveform averaged over many auditory clicks.

Brainstem auditory-evoked potentials (BAEPs) are generated in response to auditory clicks and can define the functional status of the auditory nerve. Surgical resection of a cerebellopontine angle tumor, such as an acoustic neuroma, places the auditory nerves at risk, and BAEPs have been extensively used to monitor auditory function during these procedures. The clinical utility of BAEP over standard auditory testing is due to BAEP's characteristics: (1) BAEP's resistance to alteration by systemic metabolic abnormalities, medications or pronounced changes in the state of consciousness of the patient; and (2) the close association of BAEP waveform abnormalities to underlying structural pathology. BAEP has been proven effective for differentiating conductive from sensory hearing loss, for detecting tumors and other disease states affecting central auditory pathways (e.g., acoustic neuromas, subclinical lesions in MS), and for non-invasively detecting hearing loss in patients who cannot cooperate with subjective auditory testing (e.g., infants, comatose patients). BAEP is the test of choice to assess hearing in infants and young children. It is most useful for following asphyxia, hyperbilirubinemia, intracranial hemorrhage, or meningoencephalitis or for assessing an infant who has trisomy. BAEP also is useful in the assessment of MS or other demyelinating condition, coma, or hysteria. Audiometric analysis using multiple sound frequencies is usually preferred over BAEP for testing hearing in cooperative patients who are able to report when sounds are heard.

Vestibular Evoked Myogenic Potentials

Vestibular-evoked myogenic potentials (VEMPs) testing is described as an alternative method of assessing otolith organs and their function, with a goal of diagnosing suspected vestibular disorders. VEMPs are performed by repeatedly stimulating the ears using loud sounds such as clicks and tone bursts or bone vibration. These sounds/vibrations create a pressure stimulus. VEMPs are recorded using slightly modified standard evoked potential equipment. The cervical VEMP (cVEMP) pathway begins in the saccule, that travels through the inferior vestibular nerve, vestibular nucleus, medial vestibulospinal tract, the accessory nucleus, the eleventh nerve, and then to a contracted ipsilateral sternocleidomastoid muscle where it is recorded via surface electrode. An abnormality in any part of the pathway is thought to affect the response.

Ocular VEMPs (oVEMPs) stimulate the otolithic membrane, traveling to the vestibule to trigger the utricle and the vestibular ocular reflex causing contraction of the extraocular muscle and is measured by surface electrodes placed under the contralateral eye during an upward gaze. VEMPS have been investigated for the diagnosis of vestibular neuritis, benign paroxysmal positional vertigo, vestibular

schwannoma, Meniere disease, vestibular migraine, superior semicircular canal dehiscence (SCDS), and other vestibular disorders.

Visual-Evoked Potentials

Visual-evoked potentials (VEPs) are used to track visual signals from the retina to the occipital cortex. VEP monitoring has been used for surgery on lesions near optic chiasm. However, intra-operatively recorded VEPs are very difficult to interpret, due to their sensitivity to anesthesia, temperature, and blood pressure.

Motor-Evoked Potentials

Motor-evoked potentials (MEPs) are elicited by either electrical or magnetic stimulation of the motor cortex or the spinal cord. Transcranial electrical stimulation involves stimulation of the motor cortex via electrodes placed on the scalp, or, if the brain is exposed by a craniotomy, placed directly on the brain surface. Magnetic stimulation delivers a pulsed magnetic field over the scalp in the region of the primary motor cortex. Magnetic stimulation is regarded as unsuitable for intra-operative monitoring because it is more sensitive to anesthesia.

Intra-Operative Neurophysiologic Monitoring

Intra-operative neurophysiologic monitoring (IONM) describes a variety of procedures used to monitor the integrity of neural pathways during high-risk neurosurgical, orthopedic, and vascular surgeries. It involves the detection of electrical signals produced by the nervous system in response to sensory or electrical stimuli, to provide information about the functional integrity of neuronal structures. Different methodologies include, but may not be limited to, SSEPs, MEPs using transcranial electrical stimulation, BAEPs, electromyography (EMG) of cranial nerves, electroencephalography, and electrocorticography. IONM has been utilized in attempts to minimize neurological morbidity from operative manipulations. The goal of such monitoring is to identify changes in brain, spinal cord, and peripheral nerve function prior to irreversible damage. Intraoperative monitoring also has been effective in localizing anatomical structures, including peripheral nerves and sensorimotor cortex, which helps guide the surgeon during dissection. SSEP has been the standard of intraoperative monitoring, with excellent ability to assess dorsal column and lateral sensory tract function; it may also be able to detect changes in function of anterior motor tracts by stimulating mixed sensorimotor peripheral nerves. However, significant motor deficits have been seen in individuals undergoing spinal surgery, despite normal SSEPs. MEPs were developed to better monitor the motor neurophysiological pathways.

In individuals with pre-operative spinal cord compromise, MEPs may be present when SSEPs are absent or ill-defined. This is because MEPs and SSEPs are conducted in different spinal cord pathways and have different blood supplies. Consequently, being able to perform MEP monitoring makes spinal cord monitoring possible in cases where SSEP signals are unobtainable. In the operating room, transcranial electrical stimulation is preferable to transcranial magnetic stimulation, because the electrical stimulus is more reproducible.

SUPPORTIVE LITERATURE

There is sufficient data published in the medical literature to conclude that measurement of evoked potentials (EPs) and intra-operative monitoring of EPs, in appropriate situations, improves health outcome. Improved health outcomes have been achieved outside the investigational setting.

Visual-Evoked Potentials

Clinical studies have demonstrated a statistically significant association between abnormal VEPs and an increased risk of developing clinically definite multiple sclerosis (CDMS). In these studies, individuals with suspected multiple sclerosis (MS) were 2.5 to 9 times as likely to develop CDMS as patients with normal VEPs. VEP sensitivities ranged from 25% to 83% (Gronseth 2000). VEPs improved the ability to predict which MS suspects will develop CDMS by as much as 29%. Measurement of visual-evoked responses (VERs) is the primary means of objectively testing vision in infants and young children. VER measurements are useful in infants and young children suspected of having disorders of the visual system, where the child is too young to report differences in color vision or to undergo assessment of visual fields and visual acuity. Lesions affecting the visual pathways can be localized by noting the presence of decreased amplitudes or increased latencies of VERs, and by determining whether VER abnormalities involve one or both eyes.

Several small studies (Pillai 2013; Mousa 2014; Jha 2017; Waisbourd 2017) have investigated the use of VEP technology to differentiate between normal, healthy eyes and eyes with early-to-advanced visual field loss resulting from glaucoma. The authors indicated that VEP signals may discriminate between normal eyes and glaucomatous eyes. However, larger studies are needed to confirm these findings. Additionally, VEP has not been shown to be superior to standard visual field testing in the diagnosis of glaucoma or management of clinical outcomes.

Published studies mostly assess how cVEMP and oVEMP change with various disease states as opposed to assessing the diagnostic accuracy or determination of appropriate populations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Intra-Operative Neurophysiologic Monitoring

For individuals who receive IONM while undergoing thyroid or parathyroid surgery due to high risk of injury to the recurrent laryngeal nerve (RLN), the evidence includes a large, randomized, controlled trial (RCT) and systematic reviews. Relevant outcomes are morbid events, functional outcomes, and quality of life. The strongest evidence on neurophysiologic monitoring derives from an RCT of 1,000 patients undergoing thyroid surgery (Barczynski 2009). This RCT found a significant reduction in RLN injury in patients at high risk for injury. "High risk" in this trial was defined as surgery for cancer, thyrotoxicosis, retrosternal or giant goiter, or thyroiditis. The high-risk category may also include patients with prior thyroid or parathyroid surgery or total thyroidectomy. A low volume of surgeries might also contribute to a higher risk for RLN injury. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

Cozzi et al (2023) reported on a systematic review of 164 studies examining intraoperative neurophysiologic monitoring during thyroid surgery. The overall rates of temporary and permanent recurrent laryngeal nerve injury were 3.15% and 0.422%, respectively, across all procedures. In

cases where intraoperative neurophysiologic monitoring was utilized, these rates were 3.29% and 0.409% for permanent injury. In contrast, the rates were 3.16% and 0.463%, respectively. The pooled rates of temporary recurrent laryngeal nerve injury were 2.48% for intermittent intraoperative neurophysiologic monitoring and 2.913% for continuous monitoring, while the pooled rates for definitive injury rates, the pooled rates were 0.395% and 0.40%, respectively. The authors noted that pooled rates had overlapping 95% confidence intervals (CI), concluding that intraoperative neurophysiologic monitoring does not significantly impact the rates of temporary or definitive recurrent laryngeal nerve injury following thyroidectomy.

Vestibular Evoked Myogenic Potential Testing

A cohort study by Verrecchia et al (2019) evaluated oVEMP testing in individuals experiencing dizziness. The study included ten patients diagnosed with superior canal dehiscence syndrome and 135 individuals with dizziness that were not already diagnosed as superior canal dehiscence syndrome (SCDS). The study included four oVEMP parameters (amplitude, latency, amplitude asymmetry ratio, and interaural latency difference). oVEMP was able to identify all subjects affected by SCDS, in a large cohort of unselected dizzy patients. Of the parameters, the amplitude to air-conducted stimulation had the greatest diagnostic accuracy (area under the curve score, 0.96). A cutoff point of 16.7 μV resulted in a sensitivity of 100% and specificity of 89%. The available evidence has indicated that the use of VEMP tests to evaluate suspected vestibular disorders is at a very early stage of development. Standardization of procedures and studies on the diagnostic accuracy of these procedures in the appropriate populations are needed.

PROFESSIONAL GUIDELINE(S)

The 2017 Practice Guidelines from American Academy of Neurology (AAN) (reaffirmed in 2024) assessed the diagnostic value of vestibular evoked myogenic potential testing in individuals with vestibular symptoms. The conditions of interest included superior canal dehiscence syndrome, vestibular neuritis or migraine, Meniere disease, and benign paroxysmal positional vertigo (BPPV). The evidence for testing in BPPV was drawn from two class III studies, neither of which presented sufficient diagnostic value of vestibular evoked myogenic potential testing for the treatment to be recommended (level C evidence).

In 2020, the Scoliosis Research Society published an information statement on neurophysiologic monitoring during spinal deformity surgery. The Society concluded that neurophysiologic monitoring facilitates early detection of complications and may help prevent postoperative neurologic injury. It is regarded as optimal care when the spinal cord is at risk which warrants a strong recommendation unless contraindications are present period the standard method for intraoperative monitoring should include transcranial motor evoked potentials and somatosensory evoked potentials with or without additional electromyographic monitoring.

In 2022, the American Head and Neck Society Endocrine Surgery Section and the International Neural Monitoring Study Group published a clinical review on intraoperative nerve monitoring during pediatric thyroid surgery. The review indicated that intraoperative neurophysiological monitoring can be considered for all pediatric thyroid surgeries. Procedures for which monitoring may be particularly

beneficial include total thyroidectomy, hemithyroidectomy in cases where the contralateral vocal cord is paralyzed, and reoperative surgeries.

In 2023, the American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM) recommended that intraoperative sensory-evoked potentials have demonstrated usefulness for monitoring of spinal cord, brainstem, and brain sensory tracts. The AANEM stated that intraoperative somatosensory-evoked potential monitoring is indicated for select spine surgeries in which there is a risk of additional nerve root or spinal cord injury. Indications for somatosensory-evoked potential monitoring may include, but are not limited to, complex, extensive, or lengthy procedures.

REGULATORY STATUS

Not Applicable

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
92517 (E/I)	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report, cervical (cVEMP)
92518 (E/I)	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report, ocular (oVEMP)
92519 (E/I)	Vestibular evoked myogenic potential (VEMP) testing, with interpretation and report, cervical (cVEMP) and ocular (oVEMP)
92650	Auditory evoked potentials; screening of auditory potential with broadband stimuli, automated analysis
92651	Auditory evoked potentials; for hearing status determination, broadband stimuli, with interpretation and report
92652	Auditory evoked potentials; for threshold estimation at multiple frequencies, with interpretation and report
92653	Auditory evoked potentials; neurodiagnostic, with interpretation and report
95925-95927, 95938	Somatosensory-evoked potentials (code range)
95928-95929, 95939	Central motor evoked potential study (transcranial motor stimulation) (code range)

Code	Description
95930	Visual-evoked potential (VEP) checkerboard or flash testing, central nervous system except glaucoma, with interpretation and report
95940	Continuous intraoperative neurophysiology monitoring in the operating room, one on one monitoring requiring personal attendance, each 15 minutes (List separately in addition to code for primary procedure)
95941	Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby) or for monitoring of more than one case while in the operating room, per hour (List separately in addition to code for primary procedure)
0333T (E/I)	Visual evoked potential, screening of visual acuity, automated, with report
0464T (E/I)	Visual evoked potential, testing for glaucoma, with interpretation and report

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HCPCS Codes

Code	Description
G0453	Continuous intraoperative neurophysiology monitoring, from outside the operating room (remote or nearby) per patient (attention directed exclusively to one patient) each 15 minutes (List separately in addition to code for primary procedure)

ICD10 Codes

Code	Description
C71.6	Malignant neoplasm of cerebellum
C79.31	Secondary malignant neoplasm of brain
D33.0-D33.2	Benign neoplasm of brain (code range)
D33.3	Benign neoplasm of cranial nerves
D43.0-D43.2	Neoplasm of uncertain behavior of brain (code range)
D43.4	Neoplasm of uncertain behavior of spinal cord
D49.6	Neoplasm of unspecified behavior of brain
H40.001-H40.9 (E/I)	Glaucoma (code range)
H53.411-H53.419	Scotoma involving central area (code range)
H53.421-H53.429	Scotoma of blind spot area (code range)
H53.431-H53.439	Sector or arcuate defects (code range)

Code	Description
H53.451-H53.459	Other localized visual field defect (code range)
H53.461-H53.469	Homonymous bilateral field defects (code range)
H53.47	Heteronymous bilateral field defects
H53.481-H53.489	Generalized contraction of visual field (code range)
I63.031-I63.039	Cerebral infarction due to thrombosis of carotid artery (code range)
I63.131-I63.139	Cerebral infarction due to embolism of carotid artery (code range)
I63.231-I63.239	Cerebral infarction due to unspecified occlusion or stenosis of carotid arteries (code range)
I65.21-I65.29	Occlusion and stenosis of carotid artery (code range)
I71.00-I71.03	Dissection of aorta (code range)
M40.00-M40.05	Postural kyphosis (code range)
M40.202-M40.209	Unspecified kyphosis (code range)
M40.292-M40.299	Other kyphosis (code range)
M40.30-M40.37	Flatback syndrome (code range)
M40.40-M40.57	Lordosis (code range)
M41.00-M41.27	Idiopathic scoliosis (code range)
M41.30-M41.35	Thoracogenic scoliosis (code range)
M41.80-M41.87	Other forms of scoliosis (code range)
M41.9	Scoliosis, unspecified
M43.6	Torticollis
M48.00-M48.08	Spinal stenosis (code range)

Code	Description
M50.10-M50.13	Cervical disc disorder with radiculopathy (code range)
M50.20-M50.23	Other cervical displacement (code range)
M53.0	Cervicocranial syndrome
M53.1	Cervicobrachial syndrome
M53.80-M53.88	Other specified dorsopathies (code range)
M54.11	Radiculopathy, occipito-atlanto-axial region
M54.13	Radiculopathy, cervicothoracic region
M54.81	Occipital neuralgia
M96.3	Postlaminectomy kyphosis
M96.4	Postsurgical lordosis
M99.20-M99.29	Subluxation stenosis of neural canal (code range)
M99.30-M99.39	Osseous stenosis of neural canal (code range)
M99.40-M99.49	Connective tissue stenosis of neural canal (code range)
M99.50-M99.59	Intervertebral disc stenosis of neural canal (code range)
M99.60-M99.69	Osseous and subluxation stenosis of intervertebral foramina (code range)
M99.70-M99.79	Connective tissue and disc stenosis of intervertebral foramina (code range)

REFERENCES

American Academy of Neurology. [Internet]. Cervical and ocular vestibular evoked myogenic potential testing: practice guidelines. 2017 [updated 2024 Feb 10; accessed 2026 Mar 30]. Available from: https://www.aan.com/Guidelines/home/GuidelineDetail/877

American Academy of Otolaryngology—Head and Neck Surgery. [Internet] Position statement: vestibular myogenic potential (VEMP) testing. [Updated 2021 Apr 21; accessed 2026 Mar 30]. Available from: https://www.entnet.org/resource/position-statement-vestibular-myogenic-potential-vemp-testing/

Barczyński M, et al. Randomized clinical trial of visualization versus neuromonitoring of recurrent laryngeal nerves during thyroidectomy. Br J Surg. 2009 Mar;96(3):240-6.

Cirocchi R, et al. Intraoperative neuromonitoring versus visual nerve identification for prevention of recurrent laryngeal nerve injury in adults undergoing thyroid surgery. Cochrane Database Syst Rev. 2019 Jan 19;1(1):CD012483.

Cohen H, et al. Relationship between clinical measures of hearing and clinical measures of vestibular function. Am J Otolaryngol. 2024 Jan-Feb;45(1):104052.

Cozzi AT, et al. Intraoperative neuromonitoring does not reduce the risk of temporary and definitive recurrent laryngeal nerve damage during thyroid surgery: a systematic review and meta-analysis of endoscopic findings from 73,325 nerves at risk. J Pers Med. 2023 Sep 23;13(10):1429.

Cui W, et al. Assessment of vestibular-evoked myogenic potentials in Parkinson's disease: a systematic review and meta-analysis. Brain Sci. 2022 Jul 21;12(7):956.

Di Martino A, et al. Should evoked potential monitoring be used in degenerative cervical spine surgery? A systematic review. J Orthop Traumatol. 2019 Apr 2;20(1):19.

Diercks GR, et al. Pediatric intraoperative nerve monitoring during thyroid surgery: A review from the American Head and Neck Society Endocrine Surgery Section and the International Neural Monitoring Study Group. Head Neck. 2022 Jun;44(6):1468-1480.

Evans AB. [Internet] Clinical utility of evoked potentials. [Updated 2019 Oct 25; accessed 2026 Mar 30]. Available from: https://emedicine.medscape.com/article/1137451-overview

Fife TD, et al. Practice guideline: Cervical and ocular vestibular evoked myogenic potential testing: report of the guideline development, dissemination, and implementation subcommittee of the American Academy of Neurology. Neurology. 2017 Nov 28;89(22):2288-2296.

Gronseth GS, et al. Practice parameter: the usefulness of evoked potentials in identifying clinically silent lesions in patients with suspected multiple sclerosis (an evidence-based review): report of the quality standards subcommittee of the American Academy of Neurology. Neurology. 2000 May 9;54(9):1720-5.

Jha MK, et al. Visual Evoked Potentials in Primary Open Angle Glaucoma. J Neurodegener Dis. 2017;2017:9540609. Epub 2017 Jul 20.

Mousa MF, et al. Evaluation of hemifield sector analysis protocol in multifocal visual evoked potential objective perimetry for the diagnosis and early detection of glaucomatous field defects. Korean J Ophthalmol. 2014 Feb;28(1):49-65. Epub 2014 Jan 21.

Muengtaweepongsa S. [Internet] General principles of somatosensory evoked potentials. Overview. [updated 2024 Oct 16; accessed 2026 Mar 30]. Available from: https://emedicine.medscape.com/article/1139906-overview?&icd=login_success_email_match_fpf

Pillai C, et al. Sensitivity and specificity of short-duration transient visual evoked potentials (SD-tVEP) in discriminating normal from glaucomatous eyes. Invest Ophthalmol Vis Sci. 2013 Apr 23;54(4):2847-52.

Verrecchia L, et al. Diagnostic accuracy of ocular vestibular evoked myogenic potentials for superior canal dehiscence syndrome in a large cohort of dizzy patients. Ear Hear. 2019 Mar/Apr;40(2):287-294.

Waisbourd M, et al. Short-duration transient visual evoked potentials and color reflectivity discretization analysis in glaucoma patients and suspects. Int J Ophthalmol. 2017 Feb 18;10(2):254-261.

SEARCH TERMS

SEEPs

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Evoked Response Tests (160.10) [accessed 2026 Mar 30]

LCD - Visual Electrophysiology Testing (L36831) [accessed 2026 Mar 30]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 5/26

Revised:

Reviewed:

Date	Summary of Changes
9/1/2026	• New

MEDICAL POLICY

Medical Policy Title	**Experimental or Investigational Services**
Policy Number	**11.01.03**
Current Effective Date	**October 1, 2026**
Next Review Date	**March 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Services, devices, delivery systems, drugs or biological products are considered **experimental/investigational** when there is insufficient peer-reviewed scientific evidence to support **ALL** of the following, for the requested indication:

   A. It is recognized by the Health Plan, in accordance with its standard policies and procedures, as standard medical care;

   B. It has final approval by applicable governmental agencies (e.g., U.S. Food and Drug Administration);

   C. Its safety and effectiveness have been proven;

   D. It improves the net health outcome;

   E. The health outcome improvements can be achieved outside the clinical investigational setting; **and**

   F. It is at least as beneficial as any established service or technology alternatives.

RELATED POLICIES

Corporate Medical Policy

11.01.10 Clinical Trials

Non-Covered Technologies, 1370/20.000444

Technology Assessment & Policy Development, 1370/20.000407.

Out of Network Care, 1370/20.000145.

Coverage with Evidence Development for Medicare Advantage, 1370/20.000517

Pharmacy Policy

Off Label Uses of FDA Approved Drugs, 1350/20.000048

POLICY GUIDELINE(S)

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

I. Governmental approval of a service will be considered in determining whether a service is experimental or investigational. The fact that a service has received governmental approval does not necessarily mean that it is of proven benefit or appropriate or effective treatment for a particular diagnosis or for a particular condition.

II. The experimental/investigational services exclusion shall not limit in any way the benefits available for prescription drugs that are otherwise covered under the member's subscriber contract and that have been approved by the FDA for the treatment of certain types of cancers, when those drugs are prescribed for the treatment of a type of cancer for which they have not been approved by the FDA, so long as the drugs so prescribed meet the requirements of Section 4303(q) of the New York Insurance Law.

III. Experimental/investigational procedures and/or services are excluded from coverage under Health Plan contracts unless mandated by state or federal law.

DESCRIPTION

Experimental or investigational services are those treatments, procedures (including organ transplantation), drugs, biological products, or medical devices which, in the judgment of the Health Plan, are experimental/investigational in nature.

SUPPORTIVE LITERATURE

Not Applicable

PROFESSIONAL GUIDELINE(S)

Not Applicable

REGULATORY STATUS

Food

The United States Food and Drug Administration (FDA) regulates food, and food ingredients including dietary supplements, bottled water, food additives, and infant formulas to ensure they are safe and effective for human use. Refer to the FDA Food website. Available from: https://www.fda.gov/food [accessed 2026 Feb 20]

Food producers recall their products from the marketplace when the products are mislabeled or when the food may present a health hazard to consumers because the food is contaminated or has caused a foodborne illness outbreak. The FDA maintains a list of recalls, outbreaks, safety alerts and emergencies. Available from: Recalls of Foods & Dietary Supplements | FDA [accessed 2026 Feb 20]

Medical Devices

The United States Food and Drug Administration (FDA) regulates medical devices. All medical devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available

from: https://www.fda.gov/medical-devices [accessed 2026 Feb 20]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2026 Feb 20]

Labs

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service. Laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA).

Laboratories that offer laboratory-developed tests must be licensed by CLIA for high-complexity testing. More information is available at: Clinical Laboratory Improvement Amendments (CLIA) | FDA [accessed 2026 Feb 20]

Drugs

The United States Food and Drug Administration (FDA) is responsible for ensuring the safety, efficacy, and quality of drugs sold in the United States. This includes both prescription and over-the-counter medications. Refer to the FDA Drug website. Available from: https://www.fda.gov/drugs [accessed 2026 Feb 20]

The FDA maintains information for consumers and health professionals on new drug warnings and other safety information, drug label changes, and shortages of medically necessary drug products. Available from: Drug Safety and Availability | FDA [accessed 2026 Feb 20]

Vaccines, Blood and Biologics

The United States Food and Drug Administration (FDA) regulates vaccines, blood and blood products, and biologics via the Center for Biologics Evaluation and Research (CBER) which ensures the safety, efficacy, and quality of these products. Refer to the FDA vaccines/blood/biologics website. Available from: https://www.fda.gov/vaccines-blood-biologics [accessed 2025 Dec 29]

The FDA maintains information for consumers and health professionals on vaccine, blood and biologics warnings and other safety information. Available from: Recalls (Biologics) | FDA [accessed 2026 Feb 20]

New York State Insurance Law, Section 4303 (q).

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

New York State Insurance Law, Section 4303 (q) [Internet]. [updated 2025 Dec 19; accessed 2026 Feb 20]. Available from: https://newyork.public.law/laws/n.y._insurance_law_section_4303

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Experimental or investigational services are not addressed in separate National or Regional Medicare coverage determinations or policies. Refer to policies specific to a procedure/technology for indications of when services are considered experimental/investigational.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 10/93 **Revised**: 02/99, 10/99, 10/03, 09/04, 04/05, 04/06, 10/06, 10/07, 09/09, 09/11, 03/14, 07/14, 09/15, 9/24, 5/26 **Reviewed**: 08/94,08/95,06/96,06/97,01/03,02/06,09/08,09/10,09/12,09/13,09/14,09/16, 09/17,09/18,09/19, 9/20, 9/21, 9/22, 9/23, 9/25, 11/26	
Date	**Summary of Changes**
10/1/2026	• Annual review. Policy statements were revised for clarity. The policy intent is unchanged.
6/1/2026	• Transitioned Experimental, Investigational & Non-Standard Treatments/Clinical Trials policy 1370/20.000152 to Lifetime HealthCare Companies policy.
9/1/2024	• Added new policy Coverage with Evidence Development for Medicare Advantage, 1370/20.000517 in the Related Policies and Medicare Advantage sections

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

MEDICAL POLICY

Medical Policy Title	**Expanded Molecular Testing for Infectious Disease Pathogens in the Outpatient Setting**
Policy Number	**2.02.62**
Current Effective Date	**February 15, 2027**
Next Review Date	**October 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Expanded molecular testing for infectious disease pathogen identification is **medically necessary** when **ALL** the following criteria are met:

- A. Individual is in the outpatient setting (See Policy Guidelines);
- B. Initial focused diagnostic evaluation has not identified a causative pathogen (e.g., sputum culture, urine culture);
- C. The results of the testing are expected to directly influence clinical management (e.g., antibiotic/antiviral selection) and avoid unnecessary treatment or additional testing;
- D. The number of pathogens tested does not exceed those reasonably necessary to evaluate the member's clinical presentation;
- E. Individual has signs and symptoms of acute infection and **any** of the following indication-specific testing categories are met:
  1. Expanded Respiratory Pathogen testing when **either** of the following criteria are met:
     - a. Individual is being evaluated in the outpatient setting and is considered at risk for hospitalization due to illness severity;
     - b. Individual is considered high risk (i.e., Age ≥ 65, immunocompromised, with significant comorbidities) **or**;
  2. Expanded Genitourinary/Urinary Tract Infection (UTI) testing when **any** of the following criteria are met:
     - a. Individual is being evaluated in the outpatient setting and is considered at risk for hospitalization due to illness severity;
     - b. Individual is considered high risk (i.e., Age ≥ 65, immunocompromised, with significant comorbidities);
     - c. Complicated UTI (e.g. chronic indwelling catheter or ileal conduit);
     - d. Recurrent infections that have failed empiric therapy **or**;

3. Expanded Sexually Transmitted Infection (STI) testing when **any** of the following criteria are met:
    a. Individual is being evaluated in the outpatient setting and is considered at risk for hospitalization due to illness severity;
    b. Documentation supports the individual is considered high risk (i.e., high risk of exposure, age ≥ 65, immunocompromised, significant comorbidities);
    c. There is clinical concern due to a high-risk or symptomatic presentation requiring broad evaluation **or**;
4. Expanded Gastrointestinal Pathogen testing when **all** the following criteria are met:
    a. Individual is being evaluated in the outpatient setting and is considered at risk for hospitalization due to illness severity;
    b. Individual is considered high risk (i.e., Age ≥ 65, immunocompromised, with significant comorbidities, travel outside of the country);
    c. Individual with acute or persistent diarrhea and risk factors or signs of severe disease (e.g., bloody diarrhea, dysentery, dehydration, severe abdominal pain).

II. Expanded molecular testing is **not medically necessary** for **ANY** of the following:
    A. Routine screening;
    B. Duplicate/repeat panel within the same illness episode or before the appropriate re-test interval;
    C. Initial evaluation when standard testing/culture is appropriate (e.g., uncomplicated cystitis);
    D. Individual is asymptomatic and without risk factors;
    E. Symptoms are mild and self-limited;
    F. Documentation does not support clinical utility (e.g. when a single-pathogen test or smaller targeted testing can provide the information necessary for clinical management);
    G. Convenience or rapid turnaround time alone.

RELATED POLICIES

Corporate Medical Policy

11.01.15 Medically Necessary Services

Administrative Policy

AP-55 Sexually Transmitted Infection (STI) Testing

POLICY GUIDELINE(S)

I. Expanded molecular testing refers to multiplex molecular assays that evaluate numerous pathogens associated with a clinical syndrome (e.g., respiratory, gastrointestinal, urinary tract, bloodstream, or sexually transmitted infections) from a single patient specimen.

II. Targeted single- or low-target assays (e.g., influenza/RSV/SARS-CoV-2, Chlamydia trachomatis/Neisseria gonorrhoeae NAAT), standard urine culture, or guideline-directed serology are expected within urgent care or in-office settings, as the use of expanded molecular tests should be reserved for settings where rapid identification of polymicrobial infections is critical (i.e., ventilator-associated pneumonia or blood stream infections).

III. If individual and expanded molecular tests are requested on the same date of service, the clinical rationale must be documented to establish that each test is separate and distinct from any other procedure performed on that date.

DESCRIPTION

Targeted diagnostic testing is laboratory testing performed to detect, identify, confirm, or rule out a specific suspected infectious pathogen or a limited number of pathogens based on the patient's clinical presentation, medical history, exposure risk, or other diagnostic information. Expanded molecular testing for infectious disease pathogens involves the use of multiplex molecular diagnostic assays to simultaneously identify multiple microorganisms associated with a clinical syndrome from a single specimen. These tests may include detection of bacterial, viral, fungal, parasitic, and antimicrobial resistance targets and are intended to provide comprehensive pathogen identification beyond traditional targeted diagnostic testing.

Targeted diagnostic testing is most commonly used to confirm or rule out a specific suspected disease, condition, or pathogen when clinical findings point to a likely diagnosis. Common applications include respiratory tract infections, gastrointestinal infections, urinary tract infections, central nervous system infections, bloodstream infections, and sexually transmitted infections and may utilize molecular, culture-based, antigen, serologic, or other laboratory methodologies and is directed toward a focused diagnostic hypothesis.

Advantages of using targeted diagnostic testing:

- Aligns testing with the patient's symptoms and clinical findings.
- Reduces unnecessary broad testing.
- Helps confirm or exclude a suspected disease or infection.
- Identifies the specific condition or pathogen responsible for illness.
- Supports targeted therapy and may reduce inappropriate antimicrobial use.
- Focused testing is less likely to identify incidental findings, asymptomatic colonization, or organisms of uncertain clinical significance.
- Results may be easier to interpret in the clinical context.

Limitations of using targeted diagnostic testing:

- Evaluates only the specific pathogen, condition, or analyte selected for testing.
- May fail to identify the actual cause of illness if the suspected diagnosis is incorrect.
- If initial testing is negative, additional testing may be needed to evaluate alternative diagnoses.
- This can increase diagnostic delays and healthcare utilization.
- When the etiology is uncertain, sequential targeted testing may take longer than broad testing approaches that evaluate multiple pathogens simultaneously.
- Targeted testing only identifies organisms included in the test.

Expanded molecular testing is most commonly used to evaluate infectious disease syndromes in which multiple pathogens may produce similar clinical manifestations. Common applications include respiratory tract infections, gastrointestinal infections, central nervous system infections, bloodstream infections, and sexually transmitted infections where molecular techniques are used to simultaneously detect multiple pathogens from a single specimen, facilitating rapid and comprehensive pathogen identification.

Advantages of using expanded molecular testing:

- Multiple targets can be detected from a single specimen.
- Increases the likelihood of identifying the causative organism when symptoms may be caused by a variety of pathogens.
- Can detect coinfections involving more than one pathogen.
- May facilitate appropriate patient isolation and infection control measures.
- Particularly valuable when symptoms are nonspecific and multiple pathogens could be responsible.

Limitations of expanded molecular testing:

- Higher cost than singleplex assays.
- Detection of an organism does not necessarily indicate active infection.
- Panels may identify colonization or asymptomatic carriage.
- Broad testing may detect organisms of uncertain clinical significance.

Diagnostic stewardship is the coordinated approach to the selection, timing, performance, and interpretation of diagnostic tests to improve patient outcomes, promote appropriate clinical management, reduce unnecessary testing, support antimicrobial stewardship, and optimize the efficient use of healthcare resources. Inappropriate testing can lead to misdiagnosis, detection of colonization rather than active infection, increased healthcare costs and unnecessary antimicrobial use. By promoting appropriate test selection and interpretation, diagnostic stewardship helps ensure that laboratory results support meaningful clinical decision-making. Testing should be based on the patient's clinical presentation, risk factors, and suspected diagnosis, with consideration given to the

benefits and limitations of both targeted diagnostic testing and expanded molecular testing. Broad molecular panels may not be necessary when a focused diagnostic approach is sufficient to answer the clinical question.

SUPPORTIVE LITERATURE

Expanded molecular panels, commonly referred to as syndromic or multiplex assays, are capable of simultaneously detecting viral, bacterial, and parasitic pathogens from a single specimen. These assays offer high analytic sensitivity and rapid turnaround times. However, the primary consideration for their use is not diagnostic performance alone, but whether the additional pathogen information meaningfully influences clinical decision-making and improves patient outcomes. Across respiratory, urinary, sexually transmitted, and gastrointestinal applications, a consistent pattern is demonstrated: expanded molecular panels offer the greatest benefit in patients who are acutely ill, high-risk, or clinically complicated, and when targeted testing has proven inconclusive. In contrast, broad and routine use in mild or uncomplicated outpatient presentations generates findings of uncertain significance and can risk antibiotic overtreatment (Nairz and Weiss 2025; Reddy 2026).

Respiratory Pathogen Panels

Professional society recommendations tend to steer clinicians away from routine use of broad respiratory panel testing when the results will not influence management. Through the Choosing Wisely initiative, the American Society for Clinical Pathology recommends against routinely ordering broad respiratory pathogen panels because specific viral identification rarely alters the treatment for most immunocompetent patients in whom most non-influenza viral infections will resolve on their own and only influenza has a targeted treatment (Greenberg 2020). The American Thoracic Society clinical practice guideline on nucleic acid–based testing for non-influenza viral pathogens in suspected community-acquired pneumonia arrived at similar conclusions, and its evidence review highlights a limited and inconsistent effect on antibiotic use (Evans 2021).

Clinical studies have demonstrated mixed results regarding the impact of multiplex respiratory testing on outcomes. A randomized trial of 432 emergency-department patients with acute lower respiratory tract illness found that the patients who received multiplex PCR testing had a greater likelihood of reduced antibiotic prescribing among patients compared with immunofluorescence testing (Echavarría 2018). In contrast, a multicenter randomized trial of 107 hospitalized patients with lower respiratory tract infection found that reporting multiplex PCR results within 48 hours produced no significant reduction in antibiotic duration and no effect on length of stay compared with the control (Oosterheert 2021).

Observational outpatient data supports a targeted approach. Among 295 adult outpatients undergoing FilmArray respiratory panel testing, a positive influenza result was associated with fewer antibiotic prescriptions, but detection of a non-influenza virus produced no difference in reduction compared to a negative test. This prompted the authors to conclude that influenza-specific testing alone may be sufficient and more cost-effective than multiplex testing for most outpatients (Green 2016). Nairz and Weiss 2025, published a narrative review of point-of-care testing in primary care similarly concluded that multiplex panels are most useful in severely immunocompromised patients

and that routine multiplex use in community-acquired respiratory infections is not recommended unless they can be shown to be a benefit for patient-important outcomes.

As a whole, these findings support restricting expanded respiratory panels to patients with moderate-to-severe illness or elevated risk of deterioration and to high-risk hosts (age ≥ 65, immunocompromised, or with significant comorbidities), where pathogen identification is more likely to alter antiviral or antibiotic decisions and infection-control measures (Greenberg 2020; Nairz and Weiss, 2025).

Genitourinary (GU)/ Urinary Tract Infection (UTI) Panels

Guidelines and reviews emphasize that the increased sensitivity of molecular testing has not produced a proven benefit for uncomplicated infection and may promote overtreatment. The microbiology utilization guide from the Infectious Diseases Society of America and the American Society for Microbiology (IDSA/ASM) explicitly states that expanded urine culture and molecular methods often obtain additional low-count organisms of uncertain clinical significance. It therefore does not recommend routine use across all patient populations and reserves modified workups for chronic or recurrent UTI following discussion with the laboratory (Miller 2024). Likewise, the American Urological Association, Canadian Urological Association and Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (AUA/CUA/SUFU) recurrent UTI guideline specifies PCR and next-generation sequencing as investigational, pointing out that these techniques identify bacteria in a large portion of asymptomatic controls and warns outright that their use for lower urinary tract symptoms may stimulate antibiotic overtreatment (Anger 2022).

Primary studies mirror these concerns. In a prospective within-subject study of women ≥ 60 years presenting with acute cystitis symptoms, multiplex PCR was positive significantly more often than standard culture (81.6% vs 41.4%), with inconsistent findings in 43.7% of patients. Even so, there was no significant overall difference in how quickly the correct antibiotic therapy was started, and the only real advantage was limited to detecting non–E. coli organisms such as Enterococcus faecalis (Bauer 2025). Reddy 2026 similarly determined that, despite faster turnaround and broader organism detection, the effect of molecular urine diagnostics on clinical outcomes remains uncertain, with particular concern that detection of coexisting urinary-microbiome organisms may lead to overdiagnosis. This evidence supports the exclusion of expanded UTI panels for uncomplicated cystitis and asymptomatic patients, while allowing them in high-risk hosts, complicated UTI (e.g., chronic indwelling catheter or ileal conduit), and recurrent infections that have failed empiric therapy (Miller 2024; Bauerl 2025).

Sexually Transmitted Infection (STI) Panels

Multiplex sexually transmitted infection (STI) assays provide excellent analytic performance and can accurately detect multiple pathogens simultaneously. Karellis 2022 published a systematic review spanning 24 studies and 26,126 individuals, most platforms demonstrated sensitivity and specificity exceeding 95%, which supports their application in screening, confirmatory testing, and antimicrobial stewardship among suitable populations. Such testing makes the most sense when coinfection is likely or when multiple pathogens need to be ruled out, since coinfection rates climb to 25% or more in high-risk groups (Dichtl 2023).

The chief drawback is that broad panels often identify organisms of uncertain pathogenic significance. A retrospective evaluation by Dichtl 2023 of multiplex STI testing found that the most common secondary discovery were Mycoplasma hominis and Ureaplasma spp.—organisms that the necessity of treatment has been debated as that may simply be benign—prompting the investigators to recommend that only true pathogens be routinely reported for clinical action. A 2026 real-world analysis arrived at the same view, noting that the organisms detected most often (U. parvum, U. urealyticum, M. hominis) frequently occur in asymptomatic people, and concluding that a diagnostic approach centered on clinically significant pathogens can improve appropriate treatment while curbing unnecessary antimicrobial use (Özgen-Top 2026). For these reasons, expanded STI panels are best reserved for high-risk hosts and for symptomatic or high-risk presentations that call for broad evaluation, with all results interpreted in clinical context.

Gastrointestinal Pathogen Panels

Among the major applications of expanded molecular testing, gastrointestinal pathogen panels have demonstrated some of the most consistent evidence for clinical utility. These panels substantially increase pathogen detection rates and have been associated with reductions in downstream diagnostic testing, healthcare utilization, and inappropriate antibiotic exposure, particularly among patients with more significant illness. A large retrospective U.S. outpatient study by Moon 2023, comprised of 36,787 patients found that large multiplex panels (≥ 12 targets) identified a pathogen in 73.1% of tested patients compared with 45.4% using traditional workup, along with faster turnaround, fewer stool tests, a lower likelihood of in-hospital antibiotics, reduced 30-day GI-related follow-up cost, and a lower 30-day GI-related hospitalization risk (1.7% vs 2.7%). In a single-center comparative analysis of more than 15,000 patients, GI panel testing—relative to conventional stool testing—was associated with less endoscopy, less abdominal imaging, and fewer antibiotic prescriptions during the follow-up window (Axelrad 2019). A prospective study pairing multiplex GI testing with an antimicrobial stewardship program showed a significant reduction in inappropriate antibiotic use and better detection of organisms that are difficult to isolate by routine culture (Keske 2018). Despite these benefits, gastrointestinal panels may also detect colonizing organisms or pathogens associated with self-limited disease, creating the potential for unnecessary treatment. The greatest clinical value is observed in patients with severe symptoms, prolonged illness, immunocompromising conditions, significant comorbidities, or other features suggesting a higher likelihood that test results will meaningfully influence clinical management.

PROFESSIONAL SOCIETY GUIDELINE(S)

In 2024 the Infectious Disease Society of America (IDSA) and the American Society for Microbiology (ASM) published the Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2024 Update. The overall theme suggests the provider should choose the most appropriate testing based on the clinical scenario.

Respiratory Infections:

- Nucleic Acid Amplification Tests (NAAT's) have largely replaced rapid antigen tests and cultures for respiratory virus detection.

- Multiplex syndromic respiratory panels, when used judiciously may provide earlier opportunity for therapeutic optimization than traditional cultures.
- Comprehensive/pneumonia panels used on lower respiratory specimens (including semiquantitative bacterial targets and resistance markers) may optimize therapy earlier than culture but should be used selectively.
- For fastidious pathogens (e.g., Bordetella pertussis), consult the laboratory's test directory before collection; for bacterial culture, first-morning expectorated sputum is preferred, with blood cultures useful in high-risk CAP and those at risk for MRSA or Pseudomonas.

Gastrointestinal infections:

- Fecal testing for causes of infectious gastroenteritis using culture or culture independent methods is indicated for patients with moderate to severe, bloody, febrile, dysenteric, nosocomial, or persistent diarrheal illnesses or immunocompromised patients.
- Culture-independent multiplex molecular panels are reported to be more sensitive than culture (which has a longer TAT and often misses the agent), result in higher rates of detection, and often cost more than culture methods.

Genitourinary infections:

- In the absence of signs and symptoms consistent with urinary tract infections a urine culture is typically not recommended.
- Reflexing to culture based on a positive pyuria screen may be considered. If a reflexive algorithm is implemented, it should be a locally approved policy guided by clinicians and laboratorians.
- Standard testing is urine culture (Gram stain optional, low sensitivity) on midstream or straight-catheter urine, with mycobacterial culture (first-void urine) and specific NAATs for viruses (adenovirus, BK polyomavirus) as indicated.

Sexually transmitted infections:

- For genital/sexually transmitted infections, HIV testing is recommended for all persons with unknown status seeking STI evaluation; many STIs are reportable.
- Managing appropriate and directed therapy is an important strategy in antimicrobial stewardship and resistance development in STI's.
- Some NAAT technologies require a specific manufacturer collection/transport device for STI's, or results could be compromised and specimens rejected. Use devices recommended by the laboratory.

REGULATORY STATUS

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service. Laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA).

Laboratories that offer laboratory-developed tests must be licensed by CLIA for high-complexity testing. More information is available at: Clinical Laboratory Improvement Amendments (CLIA) | FDA [accessed 2026 Sept 18]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
81513	Infectious disease, bacterial vaginosis, quantitative real-time amplification of RNA markers for Atopobium vaginae, Gardnerella vaginalis, and Lactobacillus species, utilizing vaginal-fluid specimens, algorithm reported as a positive or negative result for bacterial vaginosis
81514	Infectious disease, bacterial vaginosis and vaginitis, quantitative real-time amplification of DNA markers for Gardnerella vaginalis, Atopobium vaginae, Megasphaera type 1, Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), and Lactobacillus species (L. crispatus and L. jensenii), utilizing vaginal-fluid specimens, algorithm reported as a positive or negative for high likelihood of bacterial vaginosis, includes separate detection of Trichomonas vaginalis and/or Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata, Candida krusei, when reported
81515	Infectious disease, bacterial vaginosis and vaginitis, real-time PCR amplification of DNA markers for Atopobium vaginae, Atopobium species, Megasphaera type 1, and Bacterial Vaginosis Associated Bacteria-2 (BVAB-2), utilizing vaginal-fluid specimens, algorithm reported as positive or negative for high likelihood of bacterial vaginosis, includes separate detection of Trichomonas vaginalis and Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis), Candida glabrata/Candida krusei, when reported
87505	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets
87506	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 6-11 targets

Code	Description
87507	Infectious agent detection by nucleic acid (DNA or RNA); gastrointestinal pathogen (eg, Clostridium difficile, E. coli, Salmonella, Shigella, norovirus, Giardia), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets
87631	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 3-5 targets
87632	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 6-11 targets
87633	Infectious agent detection by nucleic acid (DNA or RNA); respiratory virus (eg, adenovirus, influenza virus, coronavirus, metapneumovirus, parainfluenza virus, respiratory syncytial virus, rhinovirus), includes multiplex reverse transcription, when performed, and multiplex amplified probe technique, multiple types or subtypes, 12-25 targets
87800	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; direct probe(s) technique
87801	Infectious agent detection by nucleic acid (DNA or RNA), multiple organisms; amplified probe(s) technique
0068U	Candida species panel (C. albicans, C. glabrata, C. parapsilosis, C. kruseii, C tropicalis, and C. auris), amplified probe technique with qualitative report of the presence or absence of each species
0112U	Infectious agent detection and identification, targeted sequence analysis (16S and 18S rRNA genes) with drug-resistance gene
0115U	Respiratory infectious agent detection by nucleic acid (DNA and RNA), 18 viral types and subtypes and 2 bacterial targets, amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
0202U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected

Code	Description
0223U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 22 targets including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), qualitative RT-PCR, nasopharyngeal swab, each pathogen reported as detected or not detected
0225U	Infectious disease (bacterial or viral respiratory tract infection) pathogen-specific DNA and RNA, 21 targets, including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), amplified probe technique, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
0321U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms and identification of 16 associated antibiotic-resistance genes, multiplex amplified probe technique
0371U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogen, semiquantitative identification, DNA from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qPCR), urine
0373U	Infectious agent detection by nucleic acid (DNA and RNA), respiratory tract infection, 17 bacteria, 8 fungus, 13 virus, and 16 antibiotic-resistance genes, multiplex amplified probe technique, upper or lower respiratory specimen
0374U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 21 bacterial and fungal organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, urine
0416U	Infectious agent detection by nucleic acid (DNA), genitourinary pathogens, identification of 20 bacterial and fungal organisms, including identification of 20 associated antibiotic-resistance genes, if performed, multiplex amplified probe technique, urine
0504U	Infectious disease (urinary tract infection), identification of 17 pathologic organisms, urine, real-time PCR, reported as positive or negative for each organism

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
Not Applicable	

REFERENCES

Anger JT, et al. Updates to recurrent uncomplicated urinary tract infections in women: AUA/CUA/SUFU Guideline. Journal of Urology [Internet]. 2022 Sep 1;208(3):536–41[accessed 2026 Sept 28]. Available from: https://doi.org/10.1097/JU.0000000000002860

Axelrad JE, et al. Impact of gastrointestinal panel implementation on health care utilization and outcomes. J Clin Microbiol. 2019 Feb 27;57(3):e01775-18.

Bauer HH, et al. Multiplex polymerase chain reaction vs standard urine culture in women presenting with symptoms of acute cystitis. Int Urogynecol J. 2025 Dec;36(12):2517-2526.

Dichtl K, et al. A retrospective evaluation of the Euroarray STI-11 multiplex system for the detection of eight STI causing agents. Sci Rep 13, 11382 (2023). [accessed 2026 Sept 28]. Available from: https://doi.org/10.1038/s41598-023-38121-w

Echavarría M, et al. Clinical impact of rapid molecular detection of respiratory pathogens in patients with acute respiratory infection. J Clin Virol. 2018;108:90–95.

Green DA, et al. Clinical utility of on-demand multiplex respiratory pathogen testing among adult outpatients. J Clin Microbiol. 2016 Dec;54(12):2950-2955.

Greenberg A, et al. Overuse of respiratory viral panels: a teachable moment. JAMA Intern Med. 2020;180(10):1373–1374.

Karellis A, et al. Multiplexed rapid technologies for sexually transmitted infections: a systematic review. Lancet Microbe. 2022 Apr;3(4):e303-e315.

Keske Ş, et al. Rapid molecular detection of gastrointestinal pathogens and its role in antimicrobial stewardship. J Clin Microbiol. 2018 Apr 25;56(5):e00148-18.

Miller JM, et al. Guide to utilization of the microbiology laboratory for diagnosis of infectious diseases: 2024 update by the Infectious Diseases Society of America (IDSA) and the American Society for Microbiology (ASM). Clin Infect Dis. 2024 Mar 5:ciae104.

Moon RC, et al. Relationship between diagnostic method and pathogen detection, healthcare resource use, and cost in U.S. adult outpatients treated for acute infectious gastroenteritis. J Clin Microbiol. 2023 Feb 22;61(2):e0162822.

Nairz M, Weiss G. How to identify respiratory pathogens in primary health care - a review on the benefits, prospects and pitfalls in using point of care tests. Infection 53, 2321–2340 (2025)[accessed 2026 Sept 28]. Available from: https://doi.org/10.1007/s15010-025-02600-1

Özgen-Top, Ö, et al. Real-world impact of multiplex PCR testing on antimicrobial management in

patients evaluated for sexually transmitted infections. Eur J Clin Microbiol Infect Dis (2026)[accessed 2026 Sept 28]. Available from: https://doi.org/10.1007/s10096-026-05659-2

Reddy M, et al. Molecular based diagnostic testing for urinary tract infections: the results remain unclear. World J Urol 44, 681 (2026)[accessed 2026 Sept 28]. Available from: https://doi.org/10.1007/s00345-026-06798-z

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Respiratory Pathogen Panel Testing (LCD L39027)[accessed 2026 Sept 29]

Multiplex Gastrointestinal Pathogen Panel (GPP) Tests for Acute Gastroenteritis (AGE) (LCD L9226) [accessed 2026 Sept 29]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
02/15/27	• Original effective date

MEDICAL POLICY

Medical Policy Title	**Extracorporeal Photochemotherapy/Photopheresis**
Policy Number	**8.01.01**
Current Effective Date	**November 1, 2026**
Next Review Date	**October 2027**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Extracorporeal photochemotherapy (ECP), or photopheresis is considered **medically appropriate** for **ANY** of the following indications:

   A. Palliative treatment of the skin manifestations of cutaneous T-cell lymphoma (CTCL) [also called mycosis fungoides (MF)] Sézary syndrome (SS) that have not responded to other therapy;

   B. Acute and chronic extensive graft-versus-host disease (GVHD) that is refractory to conventional therapy;

   C. Cardiac allograft rejection that is recurrent or refractory to immunosuppressive treatment.

II. The use of ECP (photopheresis) is considered **investigational** for **ALL** other indications, including, but not limited to, the treatment of:

   A. Acute or chronic GVHD in previously untreated patients or those responding to conventional therapy;

   B. Lyme disease;

   C. Scleroderma (a.k.a. progressive systemic sclerosis (PSS), systemic sclerosis (SS), dermatosclerosis, or CREST syndrome);

   D. Autoimmune diseases (e.g., pemphigus vulgaris, pemphigus foliaceus, psoriatic arthritis, rheumatoid arthritis, systemic lupus erythematosus, severe atopic dermatitis);

   E. Crohn's disease;

   F. Allograft rejections of solid organs other than the heart;

   G. Diabetes Mellitus.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

ECP, or photopheresis, is an immune-modulating therapy technique used in the treatment of certain skin disorders. It involves an oral intake of 8-methoxypsoralen (8-MOP) and cytopheresis, or addition of 8-MOP to the cells after removal, followed by ultraviolet actinotherapy (UVA) irradiation and reinfusion of leukocytes into the patient.

SUPPORTIVE LITERATURE

Connelly-Smith et al (2023) states the overall response rate of CTCL to ECP is approximately 60% with complete response rates of 14% to 26%. Response to ECP correlates with short duration of disease, early use of ECP in the treatment paradigm, lower blood Sézary cell burden and significant early response of skin lesions (i.e., > 50% regression within 6 months).

Sener et al (2025) noted that primary CTCLs are characterized by high relapse rates to initially highly effective therapies. Combination therapies have proven beneficial, especially if they incorporate ECP. This study investigated the synergistic effects of dimethyl fumarate (DMF) and ECP in treating CTCL, particularly SS. In vitro experiments using CTCL cell lines (HH, HuT 78, SeAx) and patient-derived SS cells demonstrated that the combination therapy significantly enhanced cell death compared to either treatment alone. Mechanistically, the combination led to increased inhibition of NF-κB signaling, elevated reactive oxygen species (ROS) production, and reduced thioredoxin reductase activity and glutathione levels—indicating oxidative stress-mediated cytotoxicity. A cell death inhibitor screen revealed that the DMF/ECP combination induced multiple cell death pathways, including apoptosis and necroptosis. Clinically, four patients with advanced CTCL were treated with this combination therapy, achieving a 100% overall response rate. Notably, the time to next treatment in skin and blood compartments extended up to 57 months, suggesting durable remission. These findings support the DMF/ECP combination as a potent and long-lasting therapeutic strategy for CTCL, warranting further clinical investigation in larger cohorts. There are several limitations to this study which suggest that, while the DMF/ECP combination is promising, larger, controlled clinical trials are needed to validate its efficacy and safety across diverse patient populations.

Evidence supporting the use of ECP for the treatment of GVHD relates to both acute GVHD (aGVHD) and chronic GVHD (cGVHD) in pediatric and adult populations. The published literature lacks randomized trials. Evidence comprises retrospective reviews and non-randomized comparisons. The data consistently show improvement in GVHD that is unresponsive to standard therapy. Additionally, there is a lack of other treatment options for these patients, and this option has the added benefit of minimal side effects from ECP, as well as the possibility of reduction and often cessation of treatment with corticosteroids and other immunosuppressive agents, if there is a response to ECP. For patients with untreated disease or those who are showing improvement on standard therapy, there is no data to support the use of ECP.

Scleroderma is the most studied of the autoimmune diseases utilizing photopheresis, but the efficacy of photopheresis for these diseases, as yet, has not been demonstrated in well-designed clinical trials.

Photopheresis alone, or in combination with immunosuppressive therapy is also being investigated in the treatment of solid organ transplant rejection. While ECP has been utilized for prevention of cardiac allograft rejection and acute rejection, the strongest evidence in cardiac transplant patients revolves around its use for recurrent and refractory allograft rejection. While the evidence consists of non-randomized studies, the outcomes from these studies provide consistent evidence of the beneficial effect of ECP for cardiac transplant patients with rejection refractory to standard therapy. There is insufficient evidence to support the use of ECP for graft rejection in other solid organs, such as lung, liver, and kidney. Though preliminary results are promising, additional studies with longer follow-up are needed, to evaluate the ultimate effect of photopheresis on patient survival.

Benazzo et al (2024) conducted a prospective randomized controlled trial that evaluated the efficacy of ECP as a prophylactic treatment to prevent rejection after lung transplantation. The study included 62 patients with COPD who underwent lung transplantation, split evenly between a treatment group receiving ECP alongside standard triple-drug immunosuppression and a control group receiving only the standard regimen. The primary composite endpoint, incidence of high-grade acute cellular rejection (ACR), cytomegalovirus (CMV) infection, or chronic lung allograft dysfunction (CLAD) within 24 months, was significantly lower in the ECP group (19.4%) compared to the control group (61.3%) ($p<0.001$). Freedom from high-grade ACR was notably higher in the ECP group ($p=0.045$), and cumulative A scores were significantly reduced at both three months (0.18 ± 0.44 vs. 0.56 ± 0.94; $p<0.05$) and 12 months (0.25 ± 0.48 vs. 1.0 ± 1.45; $p=0.002$). Additionally, the ECP group experienced fewer infections (five cases vs. 22 cases) and significantly fewer hospital days (67 vs. 309; $p=0.002$). At three years post-transplant, freedom from CLAD was also significantly greater in the ECP group ($p=0.015$). These findings suggest that adding ECP to standard immunosuppressive therapy can substantially reduce the risk of both acute and chronic rejection, improve infection outcomes, and enhance long-term transplant success. However, there are several limitations to this study including single-center design, small sample size, heterogeneous patient selection, lack of blinding, limited mechanistic insight, short follow up and need for multicenter validation.

PROFESSIONAL GUIDELINE(S)

National Comprehensive Cancer Network guidelines on primary cutaneous lymphomas (v.3.2025) list the use of ECP as a category 2A treatment alone or in combination with other agents as first-line systemic therapy for advanced (stages III-IV) disease, as well as for patients with earlier stage mycosis fungoides with Sézary syndrome involvement. The guidelines add that ECP may be more appropriate as systemic therapy in patients with or at risk of blood involvement (B1 or B2).

The terms B1 and B2 refer to levels of blood involvement as part of the TNMB staging system:

- B1 (Low blood involvement): Indicates a moderate presence of malignant T-cells in the blood. This level may occur at any disease stage except for stage IIIA. It is associated with inferior survival, even in early-stage Mycosis Fungoides.
- B2 (High blood involvement): Represents advanced disease with a high burden of malignant T-cells in the blood. It is typically seen in Sézary Syndrome and is linked to significantly worse prognosis, including a 4.6-fold increased risk of disease progression.

In 2024, the European Society for Blood and Marrow Transplantation published updated prophylaxis and management guidelines for acute and chronic GVHD. The guidelines state that while there is no standard second-line treatment for both acute and chronic GVHD, ECP is listed as therapy for use for second-line treatment. The guideline does comment that not enough data exists to compare the efficacy of different second-line treatments.

The National Cancer Institute lists ECP (alone or in combination with total-skin electron-beam radiation) as a phototherapeutic option for patients with stage III or IV Sezary syndrome or erythrodermic mycosis fungoides.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) has approved, via premarket application, two photopheresis systems manufactured by Therakos, Inc. (West Chester, PA). Both systems are approved for use in ultraviolet A (UVA) irradiation treatment, in the presence of the photoactive drug 8-methoxypsoralen (8-MOP), of extracorporeally circulating leukocyte-enriched blood, in the palliative treatment of skin manifestations of cutaneous T-cell lymphoma (CTCL), in persons who have not been responsive to other forms of treatment. The two systems are: the UVAR XTS Photopheresis System, FDA-approved in 1987, and CELLEX, FDA-approved in 2009. Treatment of GVHD is considered an off-label use of the device. Therefore, the use for treatment of autoimmune disease is considered off-label use.

The United States Food and Drug Administration (FDA) regulates photopheresis systems as medical devices. All photopheresis systems including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Sept 15].

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 Sept 15].

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
36522	Photopheresis, extracorporeal

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HCPCS Codes

Code	Description
No Applicable	

ICD10 Codes

Code	Description
C84.00-C84.09	Mycosis fungoides (code range)
C84.10-C84.19	Sézary syndrome (code range)
D89.810-D89.813	Graft-versus-host disease (code range)
T86.00-T86.09	Complication of bone marrow transplant (code range)
T86.20-T86.39	Complications of heart transplant or heart-lung transplant (code range)

REFERENCES

Benazzo A, et al. Extracorporeal photopheresis for the prevention of rejection after lung transplantation: a prospective randomised controlled trial. Eur Respir J. 2025 Feb 6;65(2):2400733.

Benazzo A, et al. Outcome of extracorporeal photopheresis as an add-on therapy for antibody-mediated rejection in lung transplant recipients. Transfus Med Hemother. 2020 Jun. 47 (3):205-13

Connelly-Smith L, et al. Guidelines on the use of therapeutic apheresis in clinical practice-evidence-based approach from the writing committee for the American society for apheresis: the ninth special issue. J Clin Apher. 2023 Apr;38(2):77-278.

Hildebrandt GC, et al. Diagnosis and treatment of pulmonary chronic GVHD: report from the consensus conference in clinical practice in chronic GVHD. Bone Marrow Transplant. 2011 Oct;46(10):1283-95.

National Cancer Institute [Internet]. Mycosis fungoides and other cutaneous T-cell lymphomas treatment (PDQ)-Health Professional Version. 2025 Feb 19. [accessed 2025 Sept 17]. Available from: https://www.cancer.gov/types/lymphoma/hp/mycosis-fungoides-treatment-pdq

National Comprehensive Cancer Network (NCCN) [Internet]. NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous Lymphomas. 2025 June 10. [accessed 2025 Sept 15]. Available from: https://www.nccn.org/guidelines/nccn-guidelines.

National Institute for Health and Clinical Excellence (NICE) [Internet. Interventional procedure guidance 288. Extracorporeal photopheresis for Crohn's disease. 2009 Feb 25. [accessed 2025 Sept 15]. Available from: https://www.nice.org.uk/guidance/ipg288

Penack O, et al. Prophylaxis and management of graft-versus-host disease after stem-cell transplantation for haematological malignancies: updated consensus recommendations of the European Society for Blood and Marrow Transplantation. Lancet Haematol. Feb 2024; 11(2): e147-e159.

Sener OC, et al. Dimethyl fumarate and extracorporeal photopheresis combination-therapy synergize in inducing specific cell death and long-term remission in cutaneous T cell lymphoma. Leukemia. 2025 Feb;39(2):438-450.

Vieyra-Garcia PA, Wolf P. Extracorporeal photopheresis: A case of immunotherapy ahead of its time. Transfus Med Hemother. 2020 Jun;47(3):226-235.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Extracorporeal Photopheresis (110.4) [accessed 2025 Aug 29]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 7/26

Revised:

Reviewed:

Date	Summary of Changes
11/1/2026	• New

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Fasenra (benralizumab) is an interleukin (IL)-5 receptor alpha-directed cytolytic antagonist monoclonal antibody. This inhibition reduces the production and survival of eosinophils thus decreasing eosinophilic airway inflammation. Fasenra is indicated for add-on maintenance treatment of patients with severe asthma aged ≥ 6 years who have an eosinophilic phenotype. Fasenra should not be used in other eosinophilic conditions or for relief of acute bronchospasm or status asthmaticus.

The Global Initiative for Asthma Global Strategy for Asthma Management and Prevention (2024) proposes a stepwise approach to asthma treatment. Fasenra is listed as an option for add-on therapy in patients with severe eosinophilic asthma. Severe asthma is defined as asthma that is uncontrolled despite adherence to optimized high-dose ICS/LABA therapy or that worsens when high-dose treatment is decreased.

Poor asthma symptom control itself substantially increases the risk of exacerbations. Other contributing risk factors include history of ≥ 1 exacerbation in the previous year, poor adherence, incorrect inhaler technique, chronic sinusitis and smoking.

In September 2024, the Food and Drug Administration (FDA) approved Fasenra to be used for the treatment of adult patients with Eosinophilic granulomatosis with polyangiitis (EGPA, also known as Churg-Strauss Syndrome). The approval was based on the results from the MANDARA Phase 3 trial which compared the efficacy and safety of Fasenra to the only other approved EGPA treatment Nucala (mepolizumab). In the trial, nearly 60% of Fasenra-treated patients achieved remission which was comparable to Nucala treated patients. The study data revealed that 41% of Fasenra-treated patients fully tapered off oral corticosteroids.

Summary

Effective Date of Policy:	6/10/2026
Indications	• Add-on maintenance treatment of patients aged six years and older with severe asthma, and with eosinophilic phenotype • Treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA) • Treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) without an identifiable non-hematologic secondary cause
Availability	Prefilled syringe: 10 mg/0.5 mL (00310-1745-01) and 30 mg/mL (00310-1730-30) Autoinjector solution for injection: 30 mg/mL (00310-1830-30)
HCPCS Code	J0517
Duration	Initial: Six months Continuation: Two years

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve all:

Indication	Inclusion	Recommended Dosing Regimen
Severe eosinophilic asthma (FDA approval) ICD10: J82	1. The prior authorization is requested by or in consultation with a specialist (pulmonologist, allergist, or immunologist) 2. The enrollee must be six years or older 3. The enrollee must be a non-smoker defined as someone who has not smoked in the preceding 6 months. 4. The enrollee has documented evidence of severe persistent asthma. 5. Patient must have well-documented use of high-dose inhaled corticosteroids (ICS) (see Tables 1-3 in policy guidelines section) for at least 3 months, be compliant with existing therapy, and have followed GINA guidelines for asthma treatment including an	Adults and children 12 years and older: 30 mg every four weeks for the first three doses followed by once every eight weeks thereafter Note: Maximum dose of 30 mg once every eight weeks after loading doses Pediatric patients six to 11 years of

<table>
<tr>
<td></td>
<td>adequate trial of a high-dose inhaled steroid in combination with a long-acting beta agonist
a. Compliance will be assessed based on pharmacy refill history. If the patient does not have pharmacy benefits through this health plan, a recent pharmacy profile will be requested. Progress notes documenting usage of sample medication may also be requested.
b. If there is a contraindication to use of a long-acting beta agonist, then an alternative controller drug may be used in combination with a high-dose inhaled steroid such as a leukotriene inhibitor or long-acting muscarinic antagonist.
c. Patient must have documentation of inadequate control despite optimal therapy (above) for a period of at least 3 months AND
6. Must be used in combination with existing asthma therapy (as defined above)
a. Monotherapy will not be authorized as these agents are only FDA approved as an add-on maintenance treatment AND
7. Patient must have a peripheral blood eosinophil count of at least 150 cells per microliter within the preceding 6 weeks
8. Patient must have experienced 2 or more asthma exacerbations within the preceding 12 months that required medical intervention (defined as non-routine doctor visits, urgent care visits, emergency room visits, hospital admissions, or documented need for acute systemic steroids) despite existing therapy as outlined in criterion #5</td>
<td>age
Recommended dose is based on body weight
<table><tr><td>Body Weight</td><td>Dosage</td></tr><tr><td>Less than 35 kg</td><td>10 mg every four weeks for first three doses, then every eight weeks thereafter</td></tr><tr><td>35 kg or more</td><td>30 mg every four weeks for first three doses, then every eight weeks thereafter</td></tr></table></td>
</tr>
<tr>
<td>Treatment of eosinophilic granulomatosis with polyangiitis (EGPA)/Churg-Strauss Syndrome
(FDA approval)
ICD10: M30.1</td>
<td>1. The enrollee must be 18 years or older
2. The prior authorization is requested by or in consultation with a specialist (pulmonologist, rheumatologist, cardiologist or other specialist based on the organ/tissue involvement)
3. Patient must have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)
a. There must be a history or presence of asthma AND
b. There must be a history or presence of blood eosinophil level of at least 10% or an absolute eosinophil count of more than 1000 cells per microliter (See links to eosinophil calculators in policy guidelines section below) AND
c. There must be history of two or more of the following clinical findings:
i. Histopathological evidence of eosinophilic vasculitis via biopsy, motor deficit or nerve conduction abnormality, pulmonary infiltrates, sino-nasal abnormality, cardiomyopathy, glomerulonephritis, alveolar hemorrhage, palpable purpura, or positive test for antineutrophil cytoplasmic antibody (ANCA)
4. Provider must attest that the patient has 'Active, Non-Severe disease.' This criterion is based upon the most recent clinical guidelines published by the ACR/Vasculitis Foundation (2021).</td>
<td>Adults:
30 mg every four weeks</td>
</tr>
</table>

	Current guidelines do not support use for 'Active, Severe disease.' a. Non-severe disease is defined as vasculitis without life- or organ-threatening manifestations. Examples of symptoms in patients with non-severe disease include rhinosinusitis, asthma, mild systemic symptoms, uncomplicated cutaneous disease, mild inflammatory arthritis i. Remission induction: Fasenra + corticosteroids is recommended over other traditional treatments (such as corticosteroids +/- methotrexate, azathioprine, or mycophenolate mofetil) ii. Relapsed disease: For patients receiving maintenance therapy with only low dose corticosteroids or methotrexate, azathioprine, or mycophenolate mofetil, Fasenra 'add-on' to these treatments is recommended over other interventions b. Severe EGPA is defined as vasculitis with life-or organ-threatening manifestations (within 3 months), such as alveolar hemorrhage, glomerulonephritis, central nervous system vasculitis, mononeuritis multiplex, cardiac involvement, mesenteric ischemia, or limb/digit ischemia i. Remission induction: Cyclophosphamide or rituximab is recommended over Fasenra ii. Remission maintenance: Methotrexate, azathioprine, or mycophenolate mofetil are recommended over Fasenra 5. Fasenra will not be approved for granulomatosis with polyangiitis (also known as GPA or Wegener's granulomatosis) or microscopic polyangiitis 6. Initial approval will be for 6 months.	
Hypereosinophilic Syndrome (FDA Approval) ICD10: D72.11	1. Patient must be at least 12 years old AND 2. Must have a diagnosis of Hypereosinophilic Syndrome (HES) for ≥ 6 months, without an identifiable non-hematologic secondary cause. a. Please note, this excludes patients with non-hematologic secondary HES (such as drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy, FIP1L1-PDGFRα kinase-positive HES, and eosinophilia of unknown clinical significance (unexplained HE, but without apparent complications/clinical manifestations related to organ/tissue infiltration)) AND 3. Patient must be followed by an Allergist/Immunologist, or an appropriate specialist based on the involved organ/tissue (ex. Pulmonologist for lung involvement) AND 4. Must have a blood eosinophil count of ≥ 1000 cells/microL within the last 6 weeks AND	Adults: 30 mg every 4 weeks

	5. Must have experienced ≥ 2 HES flares within the past 12 months (HES flare defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring escalation in therapy (ex. increased doses or addition of other drugs). a. Note: Background HES therapy includes, but is not limited to, chronic or episodic oral corticosteroids (ex. prednisone), immunosuppressive (ex. interferon alfa, methotrexate, cyclosporine, azathioprine), and/or cytotoxic therapy (ex. hydroxyurea, imatinib, cyclophosphamide) AND 6. Initial approval will be for 6 months.	

Exclusion Criteria

CDPHP will not administer benefits for replacement doses of Fasenra due to the improper storage or reconstitution of this drug. It is the responsibility of the requesting practitioner to ensure that all medical staff are following the unique guidelines for the stability, storage, and reconstitution of Fasenra as indicated in the product insert for this drug.

The efficacy of Fasenra is considered unproven and will not be approved for:

- Chronic Obstructive Pulmonary Disease (COPD)
- Acute bronchospasm
- Status asthmaticus
- Hypereosinophillic syndrome
- Used concurrently with other biologics (Cinqair, Nucala, Dupixent, Tezspire, Xolair, Adbry)
- Used as monotherapy

Continuation Criteria

Severe Asthma

- Subsequent recertifications after the initial 6-month approval will require an objective assessment of response from the provider (reductions in hospitalizations, ER visits, and rescue medication use) as well as compliance history with the inhaled corticosteroid and controller medication.
- Recertification will not be granted if the patient starts or re-starts smoking.
- Approval will be contingent on the continued use of standard of care for asthma (inhaled corticosteroids and additional controlled medications such as long-acting beta-agonist inhalers). Fasenra is not FDA approved for monotherapy.
- CDPHP expects that the use of Fasenra therapy will be part of a comprehensive asthma treatment regimen that includes, but is not limited to, intensive counseling on the importance of medication compliance and avoidance of allergic asthma triggers.

Eosinophilic Granulomatosis with Polyangiitis (EGPA)/Churg-Strauss Syndrome

- Recertification will be for 2 years and require documentation of attainment and maintenance of remission.
- Remission defined as absence of clinical signs/symptoms attributed to EGPA while maintained on an oral corticosteroid dose no greater than 7.5 mg per day prednisone or equivalent.
- Given the heterogenous nature of this disease that may have multi-organ involvement, consideration may be given on recertification when there is additional subjective evidence or statement of medical necessity from provider showing clear improvement in symptoms attributed to the use of Nucala OR Fasenra which warrants continued use (such as reduced rate of relapse, corticosteroid dose reduction, and reduced eosinophil level).

Hypereosinophilic Syndrome

- Recertification will be for 2 years and require documentation of a decrease in the frequency/severity of HES flares compared to baseline.
- Given the heterogeneous nature of the disease and variability in affected organs, consideration may be given on recertification when there is additional subjective evidence or statement of medical necessity from provider showing clear improvement in

symptoms attributed to the use of Nucala which warrants continued use of the drug (such as an improvement of symptoms, a reduction of background HES therapy, and/or a significant reduction in eosinophil count).

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.
- Fasenra approved for coverage as a medical benefit will be treated as buy and bill.
- A prescription drug benefit is required for covered under the pharmacy benefit.

Table 1:

Estimated comparative daily doses for inhaled glucocorticoids in adolescents ≥12 years and adults

Drug	Low dose (total daily dose)	Medium dose (total daily dose)	High dose (total daily dose)*
Beclomethasone HFA (Qvar RediHaler product available in United States) Administer as 2 divided doses	80 to 160 mcg	>160 to 320 mcg	>320 to 640 mcg
40 mcg per actuation	2 or 4 inhalations	¶	¶
80 mcg per actuation	2 inhalations	4 inhalations	6 or 8 inhalations
Beclomethasone HFAΔ (Qvar product available in Canada, Europe, and elsewhere) Administer as 2 divided doses	100 to 200 mcg	>200 to 400 mcg	>400 to 800 mcg
50 mcg per actuation	2 to 4 inhalations	¶	¶
100 mcg per actuation	2 inhalations	4 inhalations	6 or 8 inhalations
Budesonide DPI (Pulmicort Flexhaler product available in United States) Administer as 2 divided doses	180 to 360 mcg	>360 to 720 mcg	>720 to 1440 mcg
90 mcg per actuation	2 or 4 inhalations	¶	¶
180 mcg per actuation	2 inhalations	4 inhalations	6 or 8 inhalations
Budesonide DPIΔ (Pulmicort Turbuhaler or Turbohaler product available in Canada, Europe, and elsewhere) Administer low doses (ie, ≤400 mcg/day) once daily; administer higher doses (ie, >400 mcg/day) as 2 to 4 divided doses	200 to 400 mcg	>400 to 800 mcg	>800 to 2400 mcg
100 mcg per actuation	2 to 4 inhalations	¶	¶
200 mcg per actuation	1 to 2 inhalations	3 to 4 inhalations	¶
400 mcg per actuation	1 inhalation	2 inhalations	3 to 6 inhalations
Ciclesonide HFA (Alvesco product available in United States, Europe, and elsewhere) United States: Administer as 2 divided doses Australia, Europe, and elsewhere: Administer lower doses (ie, 160 to 320 mcg/day) once daily; administer 640 mcg dose as 2 divided doses	160 mcg	320 mcg	640 mcg
80 mcg per actuation	2 inhalations	4 inhalations	¶
160 mcg per actuation	◇	2 inhalations	4 inhalations
Ciclesonide HFAΔ (Alvesco product available in Canada) Administer lower doses (eg, 100 to 400 mcg) once daily; administer 800 mcg dose as 2 divided doses	100 to 200 mcg	>200 to 400 mcg	>400 to 800 mcg
100 mcg per actuation	1 to 2 inhalations	3 to 4 inhalations	¶
200 mcg per acutation	1 inhalation	2 inhalations	3 to 4 inhalations

Fluticasone propionate HFA (Flovent HFA product available in United States) Administer as 2 divided doses	176 to 220 mcg	>220 to 440 mcg	>440 to 1760 mcg
44 mcg per actuation	4 inhalations	¶	¶
110 mcg per actuation	2 inhalations	4 inhalations	¶
220 mcg per actuation	◇	2 inhalations	4 to 8 inhalations
Fluticasone propionate HFAΔ (Flovent HFA product available in Canada; Flixotide Evohaler product available in Europe and elsewhere) Administer as 2 divided doses	100 to 250 mcg	>250 to 500 mcg	>500 to 2000 mcg
50 mcg per actuation	2 to 4 inhalations	¶	¶
125 mcg per actuation	2 inhalations	4 inhalations	¶
250 mcg per actuation	◇	2 inhalations	4 to 8 inhalations
Fluticasone propionate DPI (Flovent Diskus product available in United States and Canada; Flixotide Accuhaler product available in Europe and elsewhere) Administer as 2 divided doses	100 to 250 mcg	>250 to 500 mcg	>500 to 2000 mcg
50 mcg per actuation	2 to 4 inhalations	¶	¶
100 mcg per actuation	2 inhalations	4 inhalations	¶
250 mcg per actuation	◇	2 inhalations	4 to 8 inhalations
500 mcg per actuation (strength not available in United States)	◇	◇	2 or 4 inhalations
Fluticasone propionate DPI (Armonair Digihaler product available in United States; Aermony Respiclick product available in Canada) Administer as 2 divided doses	110 mcg	226 mcg	464 mcg
55 mcg per actuation	2 inhalations	¶	¶
113 mcg per actuation	◇	2 inhalations	¶
232 mcg per actuation	◇	◇	2 inhalations
Fluticasone furoate DPI (Arnuity Ellipta product available in United States, Canada, Australia, and elsewhere, but not available in Europe or UK) Administer once daily **NOTE:** Inhaled fluticasone furoate has a greater anti-inflammatory potency per microgram than fluticasone propionate inhalers. Thus, fluticasone furoate is administered at a lower daily dose and used only once daily.	50 mcg (by use of pediatric DPI, which is off-label in adolescents and adults)	100 mcg	200 mcg
50 mcg per actuation	1 inhalation	¶	¶
100 mcg per actuation	◇	1 inhalation	2 inhalations
200 mcg per actuation	◇	◇	1 inhalation
Mometasone DPI (Asmanex Twisthaler product available in United States) May administer lower doses (ie, 220 to 440 mcg/day) once daily; administer 880 mcg dose as 2 divided doses	220 mcg	>220 to 440 mcg	>440 to 880 mcg
110 mcg per actuation	2 inhalations	¶	¶
220 mcg per actuation	1 inhalation	2 inhalations	4 inhalations

Mometasone DPI (Asmanex Twisthaler product available in United States) May administer lower doses (ie, 220 to 440 mcg/day) once daily; administer 880 mcg dose as 2 divided doses	220 mcg	>220 to 440 mcg	>440 to 880 mcg
110 mcg per actuation	2 inhalations	¶	¶
220 mcg per actuation	1 inhalation	2 inhalations	4 inhalations
Mometasone HFA (Asmanex HFA product available in United States) Administer as 2 divided doses	200 mcg	>200 to 400 mcg	>400 to 800 mcg
100 mcg per actuation	2 inhalations	4 inhalations	¶
200 mcg per actuation	◇	2 inhalations	4 inhalations
Mometasone DPIΔ (Asmanex Twisthaler product available in Canada, Europe, and elsewhere) May administer lower doses (ie, 200 to 400 mcg/day) once daily; administer 800 mcg dose as 2 divided doses	200 mcg	>200 to 400 mcg	>400 to 800 mcg
200 mcg per actuation	1 inhalation	2 inhalations	¶
400 mcg per actuation	◇	1 inhalation	2 inhalations

- **The most important determinant of appropriate dosing is the clinician's judgment of the patient's response to therapy.** The clinician must monitor the patient's response on several clinical parameters and adjust the dose accordingly. The stepwise approach to therapy emphasizes that once control of asthma is achieved, the dose of medication should be carefully titrated to the minimum dose required to maintain control, thus reducing the potential for adverse effects.
- Suggested total daily doses for low, medium, and high dose inhaled glucocorticoid regimens are based on daily doses recommended by Global Initiative for Asthma (GINA), National Asthma Education and Prevention Program (NAEPP), and/or product labeling[1-5]. This is not a table of equivalence.
- Depending on the specific product, total daily doses are administered once or divided and given twice daily. Refer to local product information or a clinical drug reference (eg Lexicomp).
- Some doses are outside the approved product information recommendations.

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant metered dose inhaler.

* Evidence for additional improvement with dose increases >1000 mcg/day is limited.

¶ Select alternate preparation with higher mcg/actuation to improve convenience.

Δ Products shaded in light gray color are not available in the United States but are available widely elsewhere.

◇ Select preparation with fewer mcg/actuation.

Table 2:

Usual doses of combined inhaled glucocorticoids and bronchodilators

Medication	Low dose	Medium dose	High dose
ICS-SABA combination			
Budesonide-albuterol HFA (Brand name: Airsupra)*			
NOTE: Not used for maintenance therapy.			
Acute symptom relief: Budesonide-albuterol (80 mcg/90 mcg) 2 inhalations as needed (usual maximum: 12 inhalations/day).			
ICS-LABA combinations			
Beclomethasone [beclometasone]-formoterol DPI or HFA (Not available in United States or Canada, but available elsewhere [sample brand names: Formodual, Fostair, Foster])¶Δ			
100 mcg/6 mcg	1 inhalation twice a day	2 inhalations twice a day	
200 mcg/6 mcg			2 inhalations twice a day
Budesonide-formoterol HFA (Brand name: Symbicort)¶			
80 mcg/4.5 mcg	2 inhalations twice a day		
160 mcg/4.5 mcg		2 inhalations twice a day	
Fluticasone furoate-vilanterol DPI (Brand name: Breo Ellipta)Δ			
NOTE: Inhaled fluticasone furoate has a greater anti-inflammatory potency per microgram than fluticasone propionate inhalers. Thus, fluticasone furoate is administered at a lower daily dose and used only **once** daily.			
50 mcg/25 mcg◇	1 inhalation once daily		
100 mcg/25 mcg		1 inhalation once daily	
200 mcg/25 mcg			1 inhalation once daily
Fluticasone propionate-formoterol MDI (Not available in United States or Canada, but available elsewhere [sample brand name: Flutiform])			
50 mcg/5 mcg	2 inhalations twice daily		
125 mcg/5 mcg		2 inhalations twice daily	
250 mcg/10 mcg			2 inhalations twice daily
Fluticasone propionate-salmeterol DPI (Brand names: Advair Diskus, Wixela Inhub)Δ			
100 mcg/50 mcg	1 inhalation twice a day		
250 mcg/50 mcg		1 inhalation twice a day	
500 mcg/50 mcg			1 inhalation twice a day
Fluticasone propionate-salmeterol HFA (Brand name: Advair HFA)			
45 mcg/21 mcg	2 inhalations twice a day		
115 mcg/21 mcg		2 inhalations twice a day	
230 mcg/21 mcg			2 inhalations twice a day
Fluticasone propionate-salmeterol DPI (Brand names: AirDuo RespiClick, AirDuo Digihaler)Δ§			
55 mcg/14 mcg	1 inhalation twice a day		
113 mcg/14 mcg	1 inhalation twice a day	1 inhalation twice a day	
232 mcg/14 mcg			1 inhalation twice a day
Mometasone-formoterol HFA (Brand name: Dulera)			
100 mcg/5 mcg		2 inhalations twice a day	
200 mcg/5 mcg			2 inhalations twice a day
Mometasone-indacaterol DPI (Brand name: Atectura Breezhaler; available in Canada)Δ			
80 mcg/150 mcg	1 inhalation (capsule) once a day		
160 mcg/150 mcg		1 inhalation (capsule) once a day	
320 mcg/150 mcg			1 inhalation (capsule) once a day
ICS-LAMA-LABA combinations¥			
Fluticasone furoate-umeclidinium-vilanterol DPI (Brand name: Trelegy Ellipta)Δ			
100 mcg/62.5 mcg/25 mcg		1 inhalation once daily	
200 mcg/62.5 mcg/25 mcg			1 inhalation once daily
Mometasone-glycopyrrolate (glycopyrronium)-indacaterol DPI (Brand name: Enerzair Breezhaler; available in Canada)*Δ			
160 mcg/50 mcg/150 mcg			1 inhalation (capsule) once a day

Do not exceed the maximum number of inhalations/puffs per day listed in the table due to the risk of toxicity from an excess dose of long-acting beta-agonist (ie, salmeterol, formoterol, or vilanterol). Brand names and dose per puff or per inhalation of commercially available fixed dose combinations are according to United States prescribing information, unless otherwise noted. Consult local product information before use.

ICS: inhaled glucocorticoid (inhaled corticosteroid); SABA: short-acting beta-agonist; LABA: long-acting beta-agonist; LAMA: long-acting muscarinic antagonist; HFA: metered dose inhaler with hydrofluoroalkane propellant; DPI: dry powder inhaler; SMI: soft mist inhaler.

* Not approved for use in patients <18 years old.

¶ When using ICS-formoterol as reliever, use one to two inhalations as needed. Maximum daily dose of maintenance and rescue is 12 inhalations.

Δ DPI contains lactose which may have small amounts of milk protein.

◇ Fluticasone furoate-vilanterol 50 mcg/25 mcg DPI is approved for use in patients 5 to 11 years old; use in adolescents and adults is off-label.

§ In AirDuo inhalers, the daily dose of salmeterol is approximately one-fourth of the dose in Advair, and the daily dose of fluticasone is approximately one-half that of the comparable low-, medium-, and high-dose strengths of Advair.

¥ Alternatively, tiotropium SMI (Brand name: Spiriva Respimat) can be used with an ICS or ICS-LABA inhaler. The dose in asthma is two inhalations (1.25 mcg/inhalation) once daily.

Reference: Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. https://ginasthma.org/wp-content/uploads/2023/05/GINA-2023-Full-Report-2023-WMS.pdf. Updated 2023 (Accessed on June 13, 2023).

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Table 3:

Estimated comparative daily doses for inhaled glucocorticoids in children

Drug	Low daily dose		Medium daily dose		High daily dose	
	Child 0 to 4	Child 5 to 11	Child 0 to 4	Child 5 to 11	Child 0 to 4	Child 5 to 11
Beclomethasone HFA 40 or 80 mcg/puff	NA	40 mcg/puff - 1 to 2 puffs twice per day	NA	40 mcg/puff - 2 to 4 puffs twice per day 80 mcg/puff - 1 to 2 puffs twice per day	NA	80 mcg/puff - 3 to 4 puffs twice per day
Budesonide DPI* (breath activated) 90 or 180 mcg/inhalation	NA	90 mcg/inhalation - 1 to 2 inhalations twice per day	NA	180 mcg/inhalation - 1 to 2 inhalations twice per day	NA	180 mcg/inhalation - 3 to 4 inhalations twice per day
Budesonide nebulization suspension¶ 0.25 mg/2 mL, 0.5 mg/2 mL, or 1 mg/2 mL	0.25 to 0.5 mg once daily or as 2 divided doses	0.5 mg once daily or as 2 divided doses	0.75 to 1 mg once daily or as 2 or 3 divided doses	1 mg once daily or as 2 divided doses	1.25 to 2 mg once daily or as 2 divided doses	2 mg once daily or as 2 divided doses
Ciclesonide HFAΔ 80 or 160 mcg/puff	NA	80 mcg/puff - 1 to 2 puffs once daily	NA	80 mcg/puff - 3 to 4 puffs once daily	NA	80 mcg/puff - 5 to 6 puffs once daily or as 2 divided doses 160 mcg/puff - 3 puffs once daily or as 2 divided doses
Fluticasone HFA◇ 44, 110, or 220 mcg/puff	44 mcg/puff - 2 puffs twice per day◇	44 mcg/puff - 1 to 2 puffs twice per day	44 mcg/puff - 2 to 4 puffs twice per day 110 mcg/puff - 1 puff in AM and 2 puffs in PM	44 mcg/puff - 2 to 4 puffs twice per day 110 mcg/puff - 1 puff in AM and 2 puffs in PM	110 mcg/puff - 2 puffs twice per day 220 mcg/puff - 1 puff twice per day	110 mcg/puff - 2 puffs twice per day 220 mcg/puff - 1 puff twice per day
Fluticasone DPI (breath activated)§ 50, 100, or 250 mcg/inhalation	NA	50 mcg/inhalation - 1 to 2 inhalations twice per day	NA	50 mcg/inhalation - 3 to 4 inhalations twice per day 100 mcg/inhalation - 1 inhalation in AM and 2 inhalations in PM to 2 inhalations twice per day	NA	100 mcg/inhalation - 2 inhalations in AM and 3 inhalations in PM 250 mcg/inhalation - 1 inhalation twice per day
Mometasone aerosol DPI (breath activated)* 110 or 220 mcg/inhalation	NA	110 mcg/inhalation - 1 inhalation once daily	NA	110 mcg/inhalation - 2 to 3 inhalations once daily	NA	110 mcg/inhalation - 4 inhalations once daily or 2 inhalations twice per day 220 mcg/inhalation - 2 inhalations once daily or 1 inhalation twice per day
Mometasone HFA MDI 50, 100, or 200 mcg/puff	NA	50 mcg/puff - 1 puff once or twice per day	NA	50 mcg/puff - 2 to 3 puffs twice per day 100 mcg/puff - 1 puff twice per day	NA	100 mcg/puff - 2 puffs twice per day 200 mcg/puff - 1 inhalation twice per day

Some doses may be outside approved package labeling, especially in the high-dose range. Doses shown and strengths (ie, mcg per puff or inhalation) are based upon product descriptions approved in the United States, which may differ from how strengths are described for products available in other countries. Consult local product information before use.

HFA: hydrofluoroalkane; NA: not approved and no data available for this age group; DPI: dry-powder inhaler; AM: in morning; PM: in evening; US FDA: US Food and Drug Administration; MDI: metered-dose inhaler.

* Contains milk protein.

¶ Budesonide suspension is compatible with albuterol, ipratropium, and levalbuterol nebulizer solutions in the same nebulizer. Use only jet nebulizers as ultrasonic nebulizers are ineffective for suspensions.

Δ Ciclesonide is not approved by the US FDA for use in children under 12. It is approved for use in children 6 years of age and older in Canada, some European countries, and elsewhere.

◇ For fluticasone HFA, the low dose for children <4 years is higher than for children 5 to 11 years of age due to lower dose delivered with facemask and data on efficacy in young children.

§ Contains lactose.

Data from:

1. National Heart, Blood, and Lung Institute Expert Panel Report 3 (EPR 3): Guidelines for the Diagnosis and Management of Asthma. NIH Publication no. 08-4051, 2007.
2. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. Updated 2012. Available at www.ginasthma.org.

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References

		Accessed
1	Fasenra [package insert]. Wilmington DE: AstraZeneca Pharmaceuticals LP; 2024 Sept.	11/2024
2	Venkatesan P. 2023 GINA report for asthma. Lancet Respir Med. 2023 Jul;11(7):589. doi: 10.1016/S2213-2600(23)00230-8. Epub 2023 Jun 8. PMID: 37302397.	11/2023
3	Bleecker ER, Fitzgerald JM, Chanez P, et al. Efficacy and safety of benralizumab for patients with severe asthma uncontrolled with high-dosage inhaled corticosteroids and long-acting β2-agonists (SIROCCO): a randomized, multicenter, placebo-controlled phase 3 trial. Lancet. 2016;388(10056):2115-2127.	11/2023
4	Castro M, Wenzel SE, Bleecker ER, et al. Benralizumab, an anti-interleukin 5 receptor α monoclonal antibody, versus placebo for uncontrolled eosinophilic asthma: a phase 2b randomized dose-ranging study. Lancet Respir Med. 2014;2(11):879-890.	11/2023
5	Wechsler ME, Nair P, Terrier B, et al. Benralizumab versus mepolizumab for eosinophilic granulomatosis with polyangiitis. N Eng J Med. 2024 Mar 7;390(10):911-921. Doi: 10.1056/NEJMoa2311155.	11/2024
6	Global Initiate for Asthma. Global strategy for asthma management and prevention. Updated 2024. Available at http://www.ginathma.org. Accessed November 2, 2024.	11/2024

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to the terms and conditions noted in above policy for those medications listed as a medical benefit when administered and provided by physician office, coverage will be provided as a medical benefit. All other medications for Medicare Advantage with Part D members listed are subject to coverage under the current Part D benefit and Medicare Advantage Part D Formulary.

SELECT/HARP PLAN:

Medical Benefit - Subject to all terms and conditions noted in above application.
Pharmacy Benefit - Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program.

CDPHP Pharmacy Services 6/10/2026

New: 02/2018

Policy History

Date	Notes
02/2019, 02/2020, 02/2023	Reviewed with no changes
02/2024	Additional formulation available as auto-injector. Removed criteria around not having a parasitic infection within the last six months. Changed the criteria related to smoking status from "The enrollee must not use tobacco products or have had a greater than 10 pack-year past history of smoking" to "must be non-smoker, defined as someone who has not smoked in the preceding 6 months".
9/2024	Revised – Updated to reflect use in pediatric patients aged six and older. Added NDCs for the three available products.
12/2024	Revised with new indication for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).
6/2025	Revised – aligned criteria with that of Nucala for shared indications, corrected/added back smoking status and extended continuation duration to two years.
9/2025	Revised - Updated EGPA criteria, including diagnostic criteria and attestation of non-severe disease
6/2026	Added new indication Hypereosinophilic Syndrome Updated EGPA continuation Updated eosinophilic asthma criteria language Added tables to considerations

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Background

Mucopolysaccharidosis type III (MPS III), also known as Sanfilippo syndrome, is a rare genetic condition that causes fatal brain damage. It is caused by the lack of an enzyme that normally breaks down and recycles a large, complex sugar molecule called heparan sulfate. This heparan sulphate accumulates and causes damage to the cells of the body, particularly in the central nervous system (brain and spinal cord).

There are four subtypes of MPS III: types A, B, C and D. Each type is caused by a change (variant or mutation) in a different gene (see below). All types of MPS III are associated with mental deterioration, but the severity and rate of progression depends on the type of MPS III. There is also variability in severity within the subtypes and even between affected siblings.

All four types of MPS III are caused by variants in different genes that contain the instructions for making enzymes that break down heparan sulfate.

TYPE……GENE……ENZYME
MPS IIIA……..*SGSH*……heparan N-sulfatase
MPS IIIB……..*NAGLU*……alpha-N-acetylglucosaminidase
MPS IIIC……..*HGSNAT*……..heparan-alpha-glucosaminide N-acetyltransferase
MPS IIID……..*GNS*……..N-acetylglucosamine 6-sulfatase

MPS III is inherited in an autosomal recessive manner. This means that both parents have one copy of the altered gene and one normal copy – they are known as carriers and do not show signs of the condition. A child with MPS III inherits two copies of the altered gene, one from each parent.

Children with MPS III usually appear healthy at birth, but developmental delay is usually evident by age 2-5 years. A mild speech delay is often one of the first presenting features. Mental and motor development peak by 3-6 years of age, after which intellectual decline usually occurs Severe behavioral disturbances, such as hyperactivity and irritability, are a very common feature of Sanfilippo syndrome, and one of the more difficult aspects of the disorder to manage. The nature of the behavioral symptoms can often lead to an initial diagnosis (misdiagnosis) of autism and/or attention deficit/hyperactivity disorder (ADHD).

Other symptoms can include coarse hair, excess hair growth (hirsutism), slightly coarse facial features, severe sleeping problems, mildly enlarged liver and/or spleen, speech delay, respiratory and ear infections, diarrhea, hernias, seizures and a wobbly and erratic walk. The heart may also be affected and children with MPS III also often have hearing loss and vision impairment.

Children with Sanfilippo syndrome usually start to lose their intellectual functions, especially speech, before their motor function declines. **Death can occur from before the age of 10 or not until the third or fourth decades of life, with the average being around 15 to 20 years of age**. Children with MPS IIIC have a longer life expectancy into the mid-twenties on average. There are other forms of MPS III which result in slower progression and a longer life expectancy.

The combined estimated prevalence of Sanfilippo syndrome (types A, B, C, and D) is between 1:50,000 and 1:250,000 depending on the population studied. Type A is the most common globally; however, the prevalence of subtypes can vary depending on the region, with type A being more prevalent in Northern Europe and Eastern Europe than in the Mediterranean countries. Type B is the most prevalent subtype in Southern Europe. Types C and D are much less common overall, with estimated global incidences of 1:1,500,000 and 1:1,000,000 respectively.

To diagnose MPS III, mucopolysaccharides are usually first measured in urine, followed by measurement of enzyme activity in blood or a small skin sample. Increased heparan sulfate in urine, and a decrease in the activity of any one of the four enzymes (shown in the table above) is usually consistent with a diagnosis of MPS III and will identify the MPS III type (A, B, C, or D). It is important to know the MPS III type as many of the treatments being developed are only for specific types.

Fayuvi (rebisufligene etisparvovec) is an in vivo adeno-associated virus serotype 9 (AAV9) gene therapy administered as a one-time IV infusion. It uses a self-complementary AAV9 vector to deliver a functional copy of N-sulfoglucosamine sulfohydrolase (SGSH) gene to cells. The transduced cells then produce and secrete functional sulfamidase (heparan N-sulfatase or SGSH enzyme), which can be taken up by surrounding neurons and other cells and transported to lysosomes. This is intended to reduce the abnormal accumulation of heparan sulfate, a glycosaminoglycan, and prevent further lysosomal storage–related cellular injury and neurodegeneration

A Phase I/II, open-label study evaluated a single IV dose of Fayuvi 3×10^{13} vg/kg in 5 patients with middle-to-advanced MPS IIIA and cognitive developmental quotient (DQ) < 60. The study was terminated due to lack of efficacy in patients with advanced MPS IIIA, with annual safety follow-up planned through 5 years after dosing.

The safety and effectiveness of Fayuvi was evaluated in an open-label, single-arm, multicenter clinical study in pediatric patients with MPS IIIA (**NCT02716246)**. The study measured mean changes in cognitive scores in patients between the ages of 2 and 5 years. Fayuvi-treated patients maintained or improved cognitive function compared to an untreated historical control cohort. The overall efficacy set (N=27), CSF heparan sulfate decreased within the first month following treatment with Fayuvi 3×10^{13} vg/kg. Median CSF-HS exposure decreased by 63.98% ($p<0.001$), and ≥ 50% reductions were achieved by 88.2% of younger patients and 81.5% of the overall efficacy set

There is an ongoing Phase 3, multicenter long-term follow-up study (**NCT04360265)** evaluating the long-term safety, tolerability, and efficacy of UX111 in patients previously treated in NCT02716246 or NCT04088734. No additional UX111 dose is administered. The study is expected to enroll in approximately 41 patients and follows safety and neurodevelopmental outcomes for up to 5 years.

Fayuvi will be distributed through a network of Qualified Treatment Centers.

Summary	
Effective Date of Policy:	10/7/2026
Indications	Treatment of neurologic manifestations of mucopolysaccharidosis type IIIA (MPS IIIA, Sanfilippo syndrome type A) in pediatric patients with preserved neurodevelopmental function
ICD10 Diagnosis Codes	E76.22
HCPCS	J3590 (non-specific)
Availability	suspension for intravenous infusion with a concentration of 1.0×10^{13} vg/m
Duration	6 months to allow completion of the one-time administration

Required Criteria for Approval

1. Must have a confirmed diagnosis of Mucopolysaccharidosis type IIIA (Sanfilippo syndrome type A), demonstrated by either:
    a. Genetic testing confirming biallelic pathogenic or likely pathogenic variants of the SGSH gene (homozygous or compound heterozygous) **OR**
    b. Deficiency of N-sulphoglucosamine sulphohydrolase enzyme
2. Fayuvi must be prescribed by or in consultation with a specialist experienced in the diagnosis and treatment of MPS IIIA, such as a metabolic/genetics specialist or neurologist.
3. Must be less than 18 years of age.
4. Must have preserved neurodevelopmental function as assessed by at least of one the following:
    a. Patients 2 years of age or younger must have documented preserved cognitive developmental skills assessed using the Bayley Scales of Infant and Toddler Development, Third Edition (Bayley-III), or the Mullen Scales of Early Learning, with confirmation from the treating specialist
    b. Patients older than 2 years of age must have a Cognitive Developmental Quotient (DQ) of 60 or greater, calculated using either the Bayley-III or the Mullen Scales of Early Learning.
5. The provider must attest to completing the following baseline laboratory assessments within 30 days prior to the planned Fayuvi infusion:
    a. Liver function tests, including alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyl transferase (GGT), and total bilirubin.
    b. Platelet count, prothrombin time (PT), and activated partial thromboplastin time (aPTT).
6. Must have documentation of a baseline anti-AAV9 total binding antibody titer of less than 1:100 prior to Fayuvi administration.
    a. The laboratory report must specify the assay type, collection date, and reported titer.
7. Must not have previously received Fayuvi or another gene/cell therapy for MPS IIIA. Fayuvi is administered as a one-time intravenous gene therapy and will not be authorized for retreatment.
8. Use of Fayuvi in MPS IIIA patients who failed to meet the preserved-neurodevelopmental-function criterion is considered not medically necessary based on previous clinical trials.

9. Use of Fayuvi is considered experimental and investigational when the above criteria are not met.
10. Fayuvi must be dosed and administered per the FDA approved prescribing information.
    a. Single-dose 3.0×10^{13} vector genomes per kilogram (vg/kg) body weight, administered as a single intravenous infusion
    b. Required corticosteroid regimen (prednisone or prednisolone 1 mg/kg/day beginning one day prior to infusion, continued for 8 weeks followed by gradual taper)
    c. Post-treatment monitoring of liver function and platelet counts as specified in the prescribing information
11. Initial authorization will be for 6 months to allow completion of the one-time administration.

Policy Guidelines

1. Utilization Management are contract dependent. Refer to specific contract/benefit language for exclusions.
    a. Coverage criteria may be dependent on the contract renewal date.
    b. Coverage of drugs listed in this policy are contract dependent.
    c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit
    d. Not all contracts/benefits cover all medical infusible drugs.
2. Clinical documentation must be submitted for each request (initial and recertification [if applicable]) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging and other objective or subjective measures of benefit. Requested dosing must remain consistent with FDA-approved dosing recommendations.
3. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
4. Unless otherwise indicated within drug specific criteria, the drugs listed in this policy are administered by a healthcare professional and therefore are covered under the medical benefit.
5. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
6. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.
7. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
8. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.
9. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS permits a Medicare Advantage Organization (MAO) to establish its own coverage determinations in accordance with 42 CFR § 422.101(b)(6). Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan. Step therapy requirements may be imposed in addition to LCD/NCD requirements.
10. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
11. The requested site of care may impact approval timeframe and is subject to review.
12. The following applies to all gene and cellular therapies unless otherwise specified within the drug-specific coverage criteria:
    a. Administration, Retreatment, and Treatment with Additional or Other Gene/Cellular Therapies
        i. One-Time Administration

1. Most gene and cellular therapies, whether autologous, allogeneic ("off-the-shelf"), or in vivo gene-transfer therapies, are designed and studied as one-time treatments.
2. Repeat dosing, reinfusion, or sequential therapy with other gene or cellular products has not been established as safe, effective, or clinically appropriate.

ii. Retreatment/Repeat Administration
1. Retreatment with the same gene or cellular therapy product is considered experimental and investigational because:
   a. Clinical trials evaluated these therapies as single-administration interventions
   b. Safety, efficacy, and durability of a second administration have not been established
   c. Risks of immune activation, insertional mutagenesis, or vector immunity may be increased with repeat dosing

iii. Treatment with an Additional or Other Gene/Cellular Therapy
1. Treatment with an additional or different gene or cellular therapy after prior exposure to any gene or cellular therapy is also considered experimental and investigational, unless supported by evidence demonstrating (a-c):
   a. Anticipated clinical benefit beyond available standard therapies
   b. Safety of sequential administration
   c. Justification for selecting a second gene/cellular intervention after a prior one
2. This includes, but is not limited to:
   a. Switching between CAR-T products (e.g., CD19 → CD19 or CD19 → BCMA)
   b. Switching between autologous and allogeneic cellular therapies
   c. Sequential use of CAR-T, TCR-T, NK-cell therapies, or other genetically engineered cell therapies
   d. Receiving a gene therapy after previous gene or cellular therapy exposure
   e. Receiving an in vivo gene therapy following any prior vector-based therapy

iv. Prior Gene/Cell Therapy Exposure
1. An individual is generally not eligible for additional gene or cellular therapy if they have previously received:
   a. Any autologous cellular therapy (e.g., CAR-T, TCR-T, TIL),
   b. Any allogeneic genetically modified cellular therapy,
   c. Any in vivo gene therapy (e.g., AAV, lentiviral vector)
   d. Any ex vivo gene-modified cell product
   e. Are being considered for any other gene or cellular therapy without documented evidence supporting safety and anticipated benefit.

References

		Updated	Accessed
	PackGene Biotech. FDA accepts BLA for Ultragenyx AAV9 gene therapy UX111 for Sanfilippo syndrome type A [Internet]. 2026 [cited 2026 Sep 10]. Available from: https://www.packgene.com/frontier/040226-fda-accepts-bla-for-ultragenyx-aav9-gene-therapy/	4/2026	9/2026
	Ultragenyx Pharmaceutical Inc. Ultragenyx announces positive longer-term data demonstrating treatment with UX111 gene therapy results in sustained, significant reductions in CSF-HS and continued meaningful improvements in clinical function across multiple developmental domains in children with Sanfilippo syndrome (MPS IIIA) [Internet]. 2026 Feb 3 [cited 2026 Sep 10]. Available from: https://ir.ultragenyx.com/news-releases/news-release-details/ultragenyx-announces-positive-longer-term-data-demonstrating	2/2026	9/2026
	IPD Analytics, MPS IIIA treatment pipeline / DNL126 clinical summary	9/2026	9/2026
	ClinicalTrials.gov. Gene transfer clinical trial of scAAV9.U1a.hSGSH for mucopolysaccharidosis (MPS) IIIA (NCT02716246) [Internet]. Bethesda (MD): National Library of Medicine; [cited 2026 Sep 10]. Available from: https://clinicaltrials.gov/study/NCT02716246	9/2026	9/2026
	Muschol N, Giugliani R, Jones SA, Muenzer J, Smith NJ, Whitley CB, et al. Sanfilippo syndrome: consensus guidelines for clinical care. Orphanet J Rare Dis. 2022;17(1):391. doi:10.1186/s13023-022-02484-6.	10/2022	9/2026
	ClinicalTrials.gov. Gene transfer study of ABO-102 in patients with middle and advanced phases of MPS IIIA disease (NCT04088734) [Internet]. Bethesda (MD): National Library of Medicine (US); 2019 [updated 2023 Jul 25; cited 2026 Sep 16]. Available from: https://clinicaltrials.gov/study/NCT04088734	7/2023	9/2026
	ClinicalTrials.gov. Follow-up study of AAV-mediated gene transfer (UX111; previously known as ABO-102) for MPS type IIIA (NCT04360265) [Internet]. Bethesda (MD): National Library of Medicine (US); 2020	7/2026	9/2026

	[updated 2026 Jul 17; cited 2026 Sep 16]. Available from: https://clinicaltrials.gov/study/NCT04360265		
	Ultragenyx Pharmaceutical Inc. FAYUVI (rebisufligene etisparvovec-hopf) suspension for intravenous infusion: prescribing information [Internet]. Available from: https://www.fda.gov/media/194920/download	9/2026	9/2026
	Ultragenyx Pharmaceutical Inc. Ultragenyx announces approval of FAYUVI gene therapy, the first-ever FDA-approved treatment for Sanfilippo syndrome type A (MPS IIIA) [Internet]. 2026 Sep 17 [cited 2026 Sep 23]. Available from: https://ir.ultragenyx.com/news-releases/news-release-details/ultragenyx-announces-approval-fayuvitm-gene-therapy-first-ever	9/2026	9/2026
	Ultragenyx Pharmaceutical Inc. FAYUVI (rebisufligene etisparvovec-hopf): qualified treatment centers [Internet]. 2026 Sep 17 [cited 2026 Sep 24]. Available from: https://www.fayuvi.com/wp-content/uploads/FAYUVI-QTC-list_9.17.26.pdf	9/2026	9/2026

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application

CDPHP Pharmacy Services 10/7/2026

New: 10/2026

Revised	Reviewed

Revision Date	Changes Made

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Policy/Procedure Name: Fc Receptor Blocker Drugs for Generalized Myasthenia Gravis **Control Number: 1350/20.000493**

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Background

Generalized myasthenia gravis is a chronic autoimmune, neuromuscular disease that causes muscle weakness and fatigue. The muscle weakness presenting in MG is due to an antibody-mediated immunologic attack directed at proteins in the postsynaptic membrane of the neuromuscular junction. Myasthenia gravis has been associated with antibodies against 3 postsynaptic proteins: acetylcholine receptor (AChR), muscle-specific kinase (MuSK), and low-density lipoprotein receptor-related protein 4 (LRP4). AChR antibody–positive patients represent the vast majority of gMG patients. There are two classifications of MG: ocular and generalized. In the ocular form the weakness is limited to the eyelids and extraocular muscles whereas in generalized the weakness involves the ocular, limb, and the respiratory tract. Many patients suffer from bulbar weakness (impairment of lower cranial nerves). This results in difficulty chewing, swallowing, talking, and even holding the head up. The degree of muscle weakness can fluctuate and vary in severity from person to person; however, it will generally improve with rest and worsen with physical activity. Other precipitating factors include pregnancy, infection, surgery, and stress. There is no cure for gMG, with symptoms progressing and often reaching their worst after a few years of disease onset.

Treatment options are aimed as managing the disease as no cure is known. Goals are restoring muscle strength and reducing disease activity as well as preventing myasthenic crisis. Therapeutic options are:

1. Symptomatic therapy with acetylcholinesterase inhibitors (e.g., oral pyridostigmine) to increase acetylcholine at the neuromuscular junction
2. Chronic immunosuppressive therapies to manage immune dysregulation (e.g., glucocorticoids, nonsteroidal immunosuppressants)
3. Rapid immunomodulatory therapies (e.g., intravenous [IV] immunoglobulin [IVIG], plasma exchange) for patients with severe disease or those experiencing myasthenic crisis
4. Thymectomy (i.e., surgical removal of the thymus gland); usually reserved for patients with a thymoma (10%–15% of MG patients) or for those < 60 years of age without a thymoma with AChR antibodies (the thymus plays a role in the pathogenesis of MG in seropositive patients)

Initial therapy is oral pyridostigmine for mild to moderate disease, whereas more severe disease is treated with IVIG (myasthenic crisis) followed by immunosuppressive therapy (corticosteroids, azathioprine, mycophenolate mofetil, cyclosporine, tacrolimus). It is noted that individuals will very likely utilize more than one of these medications in combination with each other. Those that are eligible for a thymectomy typically continue their medications and see an improvement approximately one year after surgery. Unfortunately, between 10 and 30 percent of those with MG do not respond to conventional immunosuppressive therapy and will require treatment with other therapies such as off-label Rituximab, IVIG, Plasma Exchange, or Soliris.

Rystiggo (rozanolixizumab) was approved by the FDA under the priority review designation for the treatment of generalized myasthenia gravis in adult patients who are an anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive. Approval was based on the results of the phase 3 MycarinG trial, where patients were randomized to either Rystiggo at roughly 7 mg/kg, 10 mg/kg or placebo. At day 43, patients in the Rystiggo groups had an improvement in MG-ADL score of -2.6 points in the 7 mg/kg group (-4.1,-1.2; p <0.001) and -2.6 points in the 10 mg/kg group (-4.0,-1.2; p<0.001) when compared to placebo. Rystiggo is the first treatment option approved by the FDA for the treatment of patients with anti-MuSK antibody positive gMG.

Imaavy (nipocalimab-aahu) was approved by the FDA for the treatment of generalized myasthenia gravis in adults and pediatric patients 12 years of age and older who are anti-AChR or anti-MuSK antibody positive. Approval was based on the results of phase 3 Vivacity-MG3 trial, where patients were randomized to either Imaavy or placebo. At weeks 22, 23, and 24, patients in the Imaavy group had a mean improvement in MG-ADL score of -1.5 points (-2.4, -0.5; p = 0.002) compared to placebo. Imaavy is the first treatment option approved by the FDA for the treatment of anti-AChR and anti-MuSK antibody positive gMG in pediatric patients 12 years of age and older.

Summary

Effective Date of Policy:	6/10/2026
Indications	Rystiggo: Treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or antimuscle-specific tyrosine kinase (MuSK) antibody positive Imavvy: Treatment of generalized myasthenia gravis (gMG) in adult and pediatric patients 12 years of age and

	older who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive
ICD10 Diagnosis Codes	G70.0
Availability	*Rystiggo – Injection: 280 mg/2 mL in a single-dose vial* *Imaavy – Injection: 300 mg/1.62 mL or 1,200 mg/6.5 mL in a single-dose vial*
HCPCS Code	Rystiggo: J9333 Imaavy: J9256
Duration	Initial: 6 months Recertification: 12 months

Required Criteria for Approval

All of the following conditions for the requested indication must be met in order to approve therapy:

Indication	Criteria for Approval
Rystiggo (rozanolixizumab-noli) **Medical benefit**	1. Enrollee is ≥ 18 years of age 2. Must be prescribed by or in consultation with a neurologist. If geographically available, it is also recommended for patients to have been evaluated by a neuromuscular specialist 3. Must have a diagnosis of generalized myasthenia gravis (gMG) **AND** 4. Must have Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IVa **AND** 5. Must be antibody positive for either (a or b): a. Anti-acetylcholine receptor (AChR) **OR** b. Muscle-specific kinase (MuSK) **AND** 6. Must documentation of a baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) score of at least 5 7. Must meet one of the following (a or b) a. Must have had serious side effects or drug failure to ONE of the following treatments for gMG (i or ii). i. Corticosteroids for at least 3 months of treatment **OR** ii. Non-steroidal immunosuppressive therapy (i.e., azathioprine, mycophenolate mofetil, cyclosporine) for at least 6 months of treatment **OR** b. Despite treatment with at least ONE immunosuppressant agent (i.e., corticosteroid, non-steroidal immunosuppressive therapy), the member required at least ONE treatment with plasma exchange, plasmapheresis, or intravenous immunoglobulin within the previous 12 months. 8. Must have had serious side effects or drug failure with Vyvgart Hytrulo prefilled syringe (PFS). This applies to New Starts only for all lines of business. 9. Rystiggo will not be approved in combination with Uplizna, Soliris/Bkemv/Epysqli, Ultomiris, Vyvgart, Vyvgart Hytrulo, Imaavy, Zilbrysq, intravenous immunoglobulin (other than when used as rescue therapy), or rituximab-containing products as Rystiggo has not been studied in combination with these therapies. 10. The recommended dosage of Rystiggo is weight based (see Table 1) and is administered as a subcutaneous infusion once weekly for 6 weeks. Administer subsequent treatment cycles based on clinical evaluation. The safety of initiating subsequent cycles sooner than 63 days from the start of the previous treatment cycle has not been established. 11. Initial approval will be for 6 months. Continued approval will require documentation of ≥ 2-point improvement in the MG-ADL scale from baseline **OR** provider attests that patient is experiencing clinical benefit from treatment (i.e., reduction of myasthenia gravis exacerbations, improvement in symptoms such as swallowing, mobility, breathing). Recertification will be required every 12 months. **Table 1: Recommended Dose Based on Body Weight** **Body Weight of Patient** / **Dose** / **Volume to be Infused** Less than 50 kg / 420 mg / 3 mL 50 kg to less than100 kg / 560 mg / 4 mL 100 kg and above / 840 mg / 6 mL

Imaavy (nipocalimab-aahu) **Medical benefit**	1. Must be 12 years of age or older **AND** 2. Must be prescribed by or in consultation with a neurologist. If geographically available, it is also recommended for patients to have been evaluated by a neuromuscular specialist **AND** 3. Must have a diagnosis of generalized myasthenia gravis (gMG) **AND** 4. Must have Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV **AND** 5. Must be antibody positive for either (a or b): a. Anti-acetylcholine receptor (AChR) **OR** b. Muscle-specific kinase (MuSK) **AND** 6. Must have documentation of a baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) score of at least 6 **AND** 7. Must meet one of the following (a or b): a. Must have had serious side effects or drug failure to ONE of the following treatments for gMG (1 or 2). i. Corticosteroids for at least 3 months of treatment **OR** ii. Non-steroidal immunosuppressive therapy (i.e., azathioprine, mycophenolate mofetil, cyclosporine) for at least 6 months of treatment **OR** b. Despite treatment with at least ONE immunosuppressant agent (i.e., corticosteroid, non-steroidal immunosuppressive therapy), the member required at least ONE treatment with plasma exchange, plasmapheresis, or intravenous immunoglobulin within the previous 12 months 8. For individuals 18 years of age and older with AChR antibody positive gMG, must have serious side effects or drug failure to Vyvgart/Vyvgart Hytrulo. 9. Imavvy will not be approved in combination with Uplizna, Soliris/Bkemv/Epysqli, Ultomiris, Vyvgart, Vyvgart Hytrulo, Rystiggo, Zilbrysq, intravenous immunoglobulin (other than when used as rescue therapy), or rituximab-containing products as Imavvy has not been studied in combination with these therapies. 10. The recommended initial dosage of Imaavy is 30 mg/kg administered once via intravenous infusion over at least 30 minutes. Two weeks after the initial dosage administer a maintenance dosage of 15 mg/kg via intravenous infusion over at least 15 minutes. Continue the maintenance dosage every two weeks thereafter. 11. Initial approval will be for 6 months. Continued approval will require documentation of > 2-point improvement in the MG-ADL scale from baseline OR provider attests that patient is experiencing clinical benefit from treatment (i.e., reduction of myasthenia gravis exacerbations, improvement in symptoms such as swallowing, mobility, breathing). Recertification will be required every 12 months.

Exclusion Criteria

Rystiggo	Therapy will not be authorized if any of the above Inclusion Criteria are not met OR any of the below noted Exclusion Criteria are met: • Enrollee has Myasthenia Gravis Foundation of America Class I or V • Enrollee has worsening muscle weakness secondary to concurrent infections or medications
Imaavy	Imavvy will not be approved in combination with Soliris/Bkemv/Epysqli, Ultomiris, Vyvgart, Vyvgart Hytrulo, Rystiggo, Zilbrysq, intravenous immunoglobulin (other than when used as rescue therapy), or rituximab-containing products as Imavvy has not been studied in combination with these therapies.

Continuation Criteria

Rystiggo	• Requests will be reviewed per criteria every six months • Continuation of therapy will be authorized if disease response occurs defined as at least a two-point improvement in the MG-ADL score from the members pre-treatment baseline
Imaavy	• Initial approval will be for 6 months. Recertification will be required every 12 months. • Continued approval will require documentation of ≥ 2-point improvement in the MG-ADL scale from baseline **OR** • Provider attests that patient is experiencing clinical benefit from treatment (i.e., reduction of myasthenia gravis exacerbations, improvement in symptoms such as swallowing, mobility, breathing).

Considerations

• Prior authorization is obtained through the CDPHP pharmacy department

References

		Updated	Accessed
1.	Narayanaswami P, et al. International Consensus Guidance for Management of Myasthenia Gravis. Neurology. 2021. 96; 3:114-122.	1/21	8/23

2.	IPD Analytics. New Drug Review: Rystiggo(rozanolixizumab). Published August 2023. Available by subscription only.	8/23	8/23
3.	Rystiggo (rozanolixizumab) Clinical Trial MycarinG (NCT03971422) Available at: https://classic.clinicaltrials.gov/ct2/show/NCT03971422		7/24
4.	Rystiggo Prescribing Information. UCB, Inc. Smyrna, GA 30080	3/25	7/25
5.	IPD Analytics. New Drug Review: Imaavy (nipocalimab-aahu). Published July 2025. Available by subscription only.	7/25	8/25
6.	Imaavy [package insert]. New Brunswick, NJ: Johnson & Johnson, Inc; 2025	4/25	8/25

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE CHOICES:	Subject to all terms and conditions noted in above application.
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 6/10/2026

New: 9/2025

Revised	Reviewed
9/25, 6/26	9/24

Revision Date	Changes Made
9/2025	Revised – Added Imaavy and renamed policy from "Rystiggo (rozanolixizumab-noli)" to "Fc Receptor Blocker Drugs for Generalized Myasthenia Gravis"
6/2026	Revised therapy trial and failure for Imaavy Revised Rystiggo diagnosis and MG-ADL scoring Updated durations of approval

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MEDICAL POLICY

Medical Policy Title	**Fecal Microbiota Transplantation**
Policy Number	**2.01.48**
Current Effective Date	**November 1, 2026**
Next Review Date	**September 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Fecal microbiota transplantation (FMT) is considered **medically appropriate** for the treatment of adults with recurrent Clostridioides difficile infection (CDI), when **BOTH** the following criteria have been met:

   A. The individual has a history of two (2) or more recurrences after the initial episode, despite standard antibiotic treatment (total of three [3] or more episodes);

   B. The appropriate donor stool screening has been completed.

II. Fecal microbiota transplantation (FMT) is considered **investigational** for all other indications, including but not limited to, the first line treatment for CDI or the treatment of inflammatory bowel disease.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. FMT should be performed with appropriately screened donor stool. Rigorous evaluation of all candidate stool donors is important to minimize the risk for transmitting infection and to maximize the likelihood of successful treatment outcome.

DESCRIPTION

Fecal microbiota transplantation (FMT), also called fecal bacteriotherapy or intestinal microbiota transplantation, involves the administration of intestinal microorganisms from a healthy, screened donor into a patient's gastrointestinal tract to restore normal colonic flora. FMT can be delivered via colonoscopy, oral capsules, nasogastric or nasoduodenal tube, or rectal enema. The goal is to replace disordered native microbiota (dysbiosis) with a stable donor microbial community.

The primary clinical application of FMT is recurrent Clostridioides difficile infection (CDI). C. difficile is a major cause of clinically significant diarrhea and colitis, most commonly following disruption of

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normal colonic flora by antibiotics and often becomes recurrent. When severe or fulminant, CDI can cause life-threatening complications including toxic megacolon and colonic perforation. Recurrent CDI, defined as reappearance of symptoms after resolution on appropriate therapy, typically within 8 weeks of treatment completion. Risk factors for recurrence include advancing age, concomitant antibiotic exposure, defective humoral immune response to C. difficile toxins, severe underlying disease, and proton pump inhibitor use. Standard first-line treatment for initial and recurrent CDI is antibiotic therapy.

The principal potential risk associated with FMT is transmission of contagious agents contained in the donor stool. There are risks of transmitting agents that do not cause a disease immediately after transplantation but may complicate the treatment of the patient in the future. The fecal transplant material (donor stool) must be appropriately screened for infectious diseases and pathogens.

SUPPORTIVE LITERATURE

Recurrent CDI

Based on published outcomes from case series/case reports and randomized controlled trials (RCT), FMT is a highly effective therapy for recurrent CDI when standard treatments have failed.

A Cochrane systematic review (Minkoff 2023) of 6 RCTs (320 participants) found moderate-certainty evidence that FMT leads to a large increase in resolution of recurrent CDI compared with alternative treatments such as antibiotics, with an approximately 77% cure rate.

First-Line FMT for CDI

The evidence for FMT as a first-line therapy for CDI is insufficient to determine that first-line FMT therapy results in an improvement in the net health outcome. The American Gastroenterological Association's clinical practice guidelines indicate that trials are needed to assess FMT therapies as primary prevention in patients at high risk of CDI and as first-line treatment after short course of anti-CDI therapy (Peery 2024).

Baunwall et al (2022) conducted the EarlyFMT trial, a small randomized, double-blind, placebo-trial to compare the efficacy and safety of FMT compared with placebo after vancomycin for first or second C difficile infection. Eligible patients were aged 18 years or older with first or second C difficile infection. Patients were randomly assigned (1:1) to FMT (n=21) or placebo (n=21) administered on day 1 and between day 3 and 7, after they had received 125 mg oral vancomycin four times daily for 10 days. The trial was stopped early after interim analysis showed significantly higher resolution in the FMT group (19/21) versus placebo (7/21; p=0.00031). The absolute risk reduction for recurrence following FMT compared with placebo was 57%. The authors indicated that the results should not be interpreted as evidence for FMT alone, but for its use in combination with antibiotics. The authors concluded that FMT after vancomycin is superior to standard-of-care vancomycin alone in achieving sustained cure of first or second C difficile infection.

Irritable Bowel Syndrome (IBS)

Ianiro et al (2019) conducted a systematic review with meta-analysis reviewed 5 randomized controlled trials (RCTs) and reported mixed outcomes for FMT in patients with IBS. When all studies

were pooled, no net benefit was found for active FMT.

Lahtinen et al (2020) reported the results of a double-blind RCT evaluating the efficacy of FMT in patients with IBS. The intervention group (n=23) received donor FMT via colonoscopy and the control group (n=26) received autologous FMT placebo via the same route. Approximately 35% of patients experienced adverse events, with no significant difference between groups.

Holvoet et al (2021) reported the results of a double-blind RCT evaluating the efficacy of FMT in patients with refractory IBS, defined as failure of ≥3 conventional therapies. The intervention group (n=43) received donor FMT via the nasojejunal route and the control group (n=19) received autologous FMT placebo via the same route. A daily symptom diary was used to assess IBS-related symptoms and improvement in IBS symptoms at 12 weeks was the primary outcome of the trial. After a single FMT, more patients in the treatment group versus placebo reported efficacy for more than 1 year (21% vs. 5%). A second FMT reduced symptoms in 67% of patients with an initial response to donor stool, but not in patients with a prior non-response.

Madsen et al (2021) reported the results of a double-blind RCT evaluating the efficacy of FMT capsules (n=26) versus placebo capsules (n=25) in patients with moderate-to-severe IBS (IBS-SSS score ≥175 points). Both groups administered capsules for 12 days and patients were allowed to continue any concomitant IBS medications, including laxatives or agents for constipation. Patients tracked their symptoms in a diary and were followed for 6 months. The primary outcome was not specified, but investigators evaluated abdominal pain, stool frequency, and stool form. Subgroup analyses by IBS subtype were not performed.

El-Salhy et al (2022) published 3-year follow-up results of a double-blind, placebo-controlled study that randomized 165 patients with IBS, published in 2020 by the same researcher. The current study included 125 patients (n=38 placebo group; n=42 received 30 grams (g) of donor feces; n=45 received 60 g of donor feces). Two years after FMT, response rates were 26.3%, 69.1%, and 77.8% in the placebo, 30 g, and 60 g groups, respectively. Three years after FMT, response rates were 27.0%, 64.9%, and 71.8%, respectively. The response rates were significantly higher in the 30-g and 60-g groups than in the placebo group. Patients in the 30-g and 60-g groups had significantly fewer IBS symptoms and fatigue, and a greater quality of life both at 2 and 3 years after FMT. No long-term adverse events were recorded.

Wang et al (2023) performed a meta-analysis of 9 RCTs (n=516) and found that a single FMT significantly decreased IBS-SSS scores at months 1, 3, 6, 24, and 36 compared with placebo, with improved clinical response rates and quality of life at months 3, 24, and 36. FMT did not increase adverse event risk. The authors conclude that a single FMT is effective and safe for patients with IBS, however, the authors noted that the relationship between the gut microbiome and FMT efficacy in IBS remains unclear.

Inflammatory Bowel Disease (IBD) – Crohn's Disease

Sokol et al (2020) conducted a pilot RCT investigating endoscopic delivery of FMT in patients with Crohn's disease (CD). This small, multicenter, single-blind, placebo-controlled RCT was conducted in France and randomized patients to FMT (n=8) and sham transplantation (n=9). The primary

endpoint was the colonization of donor microbiota at week 6, which was not reached by any patient. The rate of clinical flares in the 24 weeks following FMT was a secondary endpoint in the study. Only those patients who achieved clinical remission within the 3 weeks following the commencement of corticosteroids were randomized to treatment or placebo. The treatment group received FMT after colon cleansing with polyethylene glycol. The steroid-free clinical remission rate at 10 and 24 weeks was 44.4% (4/9) and 33.3% (3/9) in the sham transplantation group and 87.5% (7/8) and 50.0% (4/8; one patient loss of follow-up while in remission at week 12 and considered in flare at week 24) in the FMT group. Crohn's Disease Endoscopic Index of Severity decreased 6 weeks after FMT ($p = 0.03$) but not after sham transplantation ($p = 0.8$). Conversely, the CRP level increased 6 weeks after sham transplantation ($p = 0.008$) but not after FMT ($p = 0.5$). None of the adverse events observed in the trial was related to FMT. These results must be confirmed in larger studies.

Zhou et al (2023) conducted a systematic review and meta-analysis to examine the safety and effectiveness of FMT in patients with CD. Eleven cohort studies and one RCT involving 228 patients were included. In a meta-analysis, the pooled proportion of adult patients with active CD that achieved clinical remission 2 to 4 weeks after FMT was 57%. Results showed that FMT reduced Crohn's disease activity index scores 4 to 8 weeks after FMT. Subgroup analyses showed no difference between FMT methodologies, except for pre-FMT treatment with antibiotics ($P = 0.02$). Most adverse events were self-limiting and disappeared spontaneously within hours or days after FMT. The authors concluded that FMT could be a promising therapy in the short-term treatment of active CD; however, more placebo-controlled RCTs, with long-term-up follow-up, are necessary.

Kao et al (2024) conducted the first placebo-controlled multicenter RCT of FMT in active Crohn's disease (CD). Patients with mild-to-moderate CD were randomized 1:1 and received FMT (n=17) or placebo (n=12). The first treatment was administered by colonoscopy followed by weekly oral capsules for 7 weeks. Primary end point was clinical and endoscopic remission at week 8. Secondary outcomes included clinical and endoscopic response, adverse events, and health-related quality of life using generic and disease-specific instruments. At week 8, 0% (0/15) of patients in the FMT group versus 8.3% (1/11) in the placebo group reached the primary end point of combined clinical and endoscopic remission as per protocol analysis. There were no differences between the groups in clinical or endoscopic responses. One patient in each group had worsening of CD. Although both groups experienced statistically significant improvements in health-related quality of life, only the FMT group had a significant decrease in activity impairment. FMT was not effective at inducing clinical and endoscopic remission in CD using the FMT regimen in this study. Future studies should use an adequately powered multicenter trial and use a longer intervention period to improve clinical efficacy.

Inflammatory Bowel Disease (IBD) – Ulcerative Colitis

A Cochrane review (Imdad 2023) of 12 studies (N=550 participants) evaluated the efficacy and safety of FMT for the treatment of IBD. The follow-up duration across studies ranged from 6 to 12 weeks for the evaluation of induction and from 48 to 56 weeks for the evaluation of remission. Comparators included autologous FMT, placebo, standard medication, and no intervention. The results showed that FMT may increase rates of clinical remission induction in UC compared with controls (risk ratio, 1.79; 95% CI, 1.13 to 2.84; low certainty), but FMT did not significantly improve

the likelihood of induction of endoscopic remission. FMT did not significantly improve the maintenance of clinical or endoscopic remission of UC. There were no statistically significant differences in the rates of adverse events or serious adverse events. Evidence was very uncertain regarding serious adverse events, quality of life, and maintenance of remission.

Caenepeel et al (2025) conducted a multi-centric, double-blind, sham-controlled, randomized trial with repeated FMTs to induce clinical remission in patients with active UC through rigorous donor screening and by applying an anerobic workflow to create cell-density-standardized FMT preparations. Thereby, targeting the identification and characterization of potentially highly effective donors (also referred to as 'superdonors') for treatment of UC. Patients (n=66) were randomized to receive 4 infusions of allogenic donor or autologous FMT (allogenic FMT, n=30; and autologous FMT, n=36). At week 8, respectively, 3 and 5 patients reached the primary endpoint of steroid-free clinical remission (P= .72), indicating no treatment difference of at least 5% in favor of allogenic FMT. The trial did not meet its primary endpoint of increased steroid-free clinical remission and was halted at 66% of intended inclusions due to futility. The authors concluded that strict allogenic donor selection could not increase the efficacy of FMT in active UC. Nevertheless, key lessons for future research were learned.

Gefen et al (2025) indicated that FMT has been shown to restore gut microbiome composition with an acceptable safety profile. A systematic review and meta-analysis of randomized controlled trials was conducted to assess the efficacy of FMT in inducing UC remission. A total of 14 studies (n= 600 patients with a median age of 40.7 years) were assessed. FMT was used in 299 patients and associated with significantly higher odds of combined clinical and endoscopic remission ($p<0.0001$), clinical remission ($p=0.0002$), and endoscopic remission ($p=0.011$). Compared with baseline, FMT was more effective when biologics, steroids, or methotrexate were used as pre-FMT treatment. Oral delivery of FMT and pooled donors led to higher odds of remission. On meta-regression, pooled donors and methotrexate pre-treatment were associated with an increased likelihood of remission. Current evidence shows that oral delivery of FMT and multi-donor FMT may confer better results than transanal delivery and single-donor FMT. Standardization of the administration method, dosage, donors, and pre-FMT treatment is needed.

Other Indications

FMT has been shown to have some effect in alleviating symptoms in patients with other difficult-to-treat conditions (e.g., diabetes, obesity and metabolic syndrome, neurological disorders); however, most studies of these diseases consist of case series, case reports, and cohort studies. While outcome data are promising, there is insufficient evidence currently to implement FMT as a treatment regimen. Additional RCTs and longer-term studies are still needed to determine efficacy and safety profiles.

Pediatric Population

Ulcerative colitis (UC) and FMT in children was studied in the first pilot RCT, the Pediatric FEcal microbiota Transplant in ulcerative Colitis (PediFETCh) (Pai 2021). During a 36-month study period, patients aged 4 to 17 years with active UC for less than 1-year were randomized to FMT (n=13) or placebo (n=12) arms. Seven patients randomized to the placebo arm crossed over to the open-label

arm, and six patients completed the 30-week arm. The study did not reach the primary feasibility outcome of achieving recruitment targets (50 patients over 2 years), which suggests that recruitment remains the most significant challenge. There were several study limitations, however, the authors indicated that this pilot RCT offers evidence that FMT may have an important role in improving symptoms and inflammatory indices in the pediatric UC.

Tun et al (2022) performed a systematic review and meta-analysis of 14 observational studies (n=904 children) assessing FMT for CDI in patients ≤21 years. The pooled clinical success rate was 86% (p<0.001). There were 47 adverse events and 38 serious adverse events with no single predominant cause. No RCTs were available. The authors concluded FMT is effective and safe in pediatric patients with CDI but remains poorly regulated and standardized.

Gu et al (2024) conducted a double-blind RCT to determine the safety and efficacy of retrograde colonic enema (RCE)-based FMT in the treatment of intractable constipation in children. A total of 110 children were randomized to the FMT with RCE group or the placebo with RCE group. All participants received a daily RCE, followed by a 4-week FMT treatment (twice a week) and a 12-week follow-up period. Spontaneous bowel movements ≥ 3 per week were the main outcome. At the end of the follow-up period, 22 patients (40.0%) in the FMT with RCE group and 10 patients (18.2%) in the placebo with RCE group had ≥ 3 spontaneous bowel movements per week (P < 0.05). Both RCE and FMT enriched the intestinal bacterial diversity of patients with constipation. The adverse events were all mild self-limiting gastrointestinal symptoms. The authors concluded that FMT enhances the efficacy of RCE, and the use of RCE-based FMT is a safe and effective method in the treatment of intractable constipation in children.

PROFESSIONAL GUIDELINE(S)

Adult Population

American Gastroenterological Association (AGA) In 2024, the AGA published a clinical practice guideline on fecal microbiota–based therapies for select gastrointestinal diseases (Peery 2024). The AGA:

- Suggests the use of fecal microbiota-based therapies upon completion of standard of care antibiotics over no fecal microbiota–based therapies in immunocompetent adults with recurrent C difficile infection, and mildly or moderately immunocompromised adults with recurrent C difficile infection. (Conditional recommendation, low certainty evidence)
- Suggests against the use of fecal microbiota–based therapies upon completion of standard of care antibiotics over no fecal microbiota–based therapies for severely immunocompromised adults with recurrent C difficile infection. (Conditional recommendation, very low certainty of evidence)
- Suggests the use of conventional FMT over no FMT in adults hospitalized with severe or fulminant C difficile infection not responding to antimicrobial therapy. (Conditional recommendation, low certainty of evidence)

- Suggests against the use of conventional FMT except in the context of clinical trial in adults with ulcerative colitis, Crohn's disease, pouchitis, and irritable bowel syndrome. (Conditional recommendation, very low certainty of evidence)

The AGA defines severely immunocompromised patients as those receiving active cytotoxic therapy for solid tumors and hematologic malignancies, patients who have received chimeric antigen receptor T-cell therapy or hematopoietic cell transplant (only when neutropenic), any neutropenia, patients with severe primary immunodeficiency, and patients with advanced or untreated HIV infection (CD4 counts <200/mm^3, AIDS-defining illness without immune reconstitution, or symptomatic HIV). Mildly or moderately immunocompromised patients are those who are immunocompromised but do not meet the definition of severe.

The AGA intentionally refrains from limiting fecal microbiota–based therapies to patients with ≥2 recurrences, noting that some patients at increased risk of recurrence or morbid recurrence may benefit after the initial CDI episode or first recurrence.

In 2026, the AGA published clinical best practice advice for the management of CDI in adults and in patients with IBD. These documents were developed through expert review of the literature and do not provide formal guideline recommendations or evidence ratings.

- CDI in adults: Conventional FMT should be offered after treatment of a second recurrence (third CDI episode) (Fischer 2026). Microbiota restoration therapy may be considered after treatment of an initial infection or first recurrence in patients who are at high risk for further recurrence or in patients whose initial CDI episode was particularly morbid or difficult to treat.
- CDI in IBD: Microbiome-based therapies (e.g., fecal microbiota) should be offered to patients with IBD with at least one (1) recurrence of CDI to prevent future infection (Khanna 2026).

American College of Gastroenterology (ACG)

In 2021, the ACG published a guideline on the management of Clostridioides difficile infection (Kelly 2021). The ACG considers FMT to be the best treatment option for multiple recurrent CDI, including immunocompromised patients who are seronegative for cytomegalovirus (CMV) and Epstein-Barr virus (EBV). Key recommendations:

- FMT should be considered for patients with severe and fulminant CDI refractory to antibiotic therapy, particularly, when patients are deemed poor surgical candidates (strong recommendation, low quality of evidence).
- Patients experiencing their second or further recurrence of CDI be treated with FMT to prevent further recurrences (strong recommendation, moderate quality of evidence).
- FMT be delivered through colonoscopy (strong recommendation, moderate quality of evidence) or capsules (strong recommendation, moderate quality of evidence) for treatment of CDI; we suggest delivery by enema if other methods are unavailable (conditional recommendation, low quality of evidence).
- Repeat FMT for patients experiencing a recurrence of CDI within 8 weeks of an initial FMT (conditional recommendation, very low quality of evidence).

- FMT should be considered for recurrent CDI in patients with IBD (strong recommendation, very low quality of evidence).

In 2021, the ACG recommends against the use of fecal transplant for the treatment of global irritable bowel syndrome (IBS) symptoms. (strong recommendation; very low quality of evidence) (Lacy 2021)

In 2019, the ACG recommends against the use of fecal transplant in adults with ulcerative colitis (UC), noting FMT requires more study and clarification of treatment before use as therapy for UC. (Rubin 2019)

American Society of Colon and Rectal Surgeons (ASCRS)

The 2021 ASCRS guideline on the management of CDI recommends (Poylin 2021):

- Patients with recurrent or refractory CDI should typically be considered for fecal bacteriotherapy (e.g., intestinal microbiota transplantation) if conventional measures, including appropriate antibiotic treatment, have failed. (Grade of recommendation: Strong recommendation based on moderate-quality evidence, 1B)
- Patients with three (3) or more CDI episodes can be managed with a vancomycin tapered and pulsed course or fidaxomicin followed by a microbiome-based therapy such as fecal microbiota transplantation.
- In general, conventional antibiotic treatment should be used for at least two (2) recurrences (i.e., 3 CD episodes) before offering fecal microbiota transplantation.

Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA)

In 2021, the IDSA and SHEA published a focused update guideline echoing earlier recommendations for FMT (Johnson 2021). FMT is recommended only for patients with multiple recurrences of CDI who have failed appropriate antibiotic treatments and where appropriate screening of donor and donor fecal specimens have been performed, in accordance with these newer FDA recommendations.

The 2017 updated IDSA and SHEA clinical practice guidelines for the diagnosis and treatment of CDI in children and adults (McDonald 2018) recommendations include:

- Consider fecal microbiota transplantation for pediatric patients with multiple recurrences of CD following standard antibiotic treatments. (Weak recommendation, very low quality of evidence)
- Fecal microbiota transplantation is recommended for patients with multiple recurrences of CDI who have failed appropriate antibiotic treatments. (Strong recommendation, moderate quality of evidence)
- Potential candidates for FMT include patients with multiple recurrences of CDI who have failed to resolve their infection despite treatment attempts with antibiotic agents targeting CDI. Although there is no data to indicate how many antibiotic treatments should be attempted before referral for FMT, the opinion of the panel is that appropriate antibiotic treatments for at least 2 recurrences (i.e., 3 CDI episodes) should be tried.

Pediatric Population

In 2018, an international multidisciplinary panel of experts in pediatric oncology and infectious diseases performed systematic reviews of RCTs for the prevention or treatment of CDI in any population and considered the directness of the evidence to children with cancer and pediatric hematopoietic stem-cell transplantation (HSCT) patients (Diorio 2018). A strong recommendation to not use FMT was made in this population.

In 2019, a joint position paper on FMT for recurrent CDI (rCDI) and other conditions in children was issued from the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (Davidovics 2019). The group of experts acknowledge that controlled trials with FMT for rCDI have not been performed in children, and numerous clinical and regulatory considerations have to be considered when using this untraditional therapy. In general, the group concurs with current adult guidelines when considering FMT for the treatment of rCDI in children and propose FMT be considered in children with one of the following:

- For rCDI (recurrence of symptoms within 8 weeks of treatment for CDI), either:
  - At least 3 episodes of mild to moderate CDI and failure of a 6- to 8- week taper with vancomycin with or without an alternative antibiotic (eg, rifaximin, nitazoxanide), or
  - At least 2 episodes of severe CDI resulting in hospitalization and associated with significant morbidity.
- For moderate CDI not responding to standard therapy (including vancomycin) for at least 1 week. We recommend caution, however, in such cases, with repeated testing for etiologies other than CDI such as IBD.
- For severe CDI or fulminant C difficile colitis with no response to standard therapy after 48 hours.

American Academy of Pediatrics (AAP)

In 2023, the AAP published a clinical report on FMT to provide the general pediatrician with a broad overview to enable appropriate guidance to families seeking FMT as treatment of a child's condition. (Oliva-Hemker 2023). The AAP's summary states that, to date, controlled trials are not available and there are no prospective pediatric clinical trials using FMT to treat CDI. The long-term effects of FMT are unknown. Cohort studies support the use of FMT in pediatric patients with moderate to severe or recurrent CDI but is not recommended for the clinical treatment of any other medical condition.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) views FMT as both a biologic and as a drug with the applicable regulations in respect to procedures and monitoring. The FDA regulates vaccines, blood and blood products, and biologics via the Center for Biologics Evaluation and Research (CBER) which ensures the safety, efficacy, and quality of these products. Refer to the FDA vaccines/blood/biologics website. Available from: https://www.fda.gov/vaccines-blood-biologics [accessed 2026 Aug 1]

The FDA maintains information for consumers and health professionals on vaccine, blood and biologics warnings and other safety information. Available from: https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/recalls-biologics (Biologics) | FDA [accessed 2026 Aug 1]

The FDA issued safety alerts on the potential risk of serious or life-threatening infections with the use of FMT and safety protocols for screening protections of donor stool (e.g., multi drug-resistant organisms [MDROs], Escherichia coli, SARS-Co-V-2, COVID-19, and monkeypox virus (FDA 2023).

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
44705	Preparation of fecal microbiota for instillation, including assessment of donor specimen
0780T	Instillation of fecal microbiota suspension via rectal enema into lower gastrointestinal tract

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HCPCS Codes

Code	Description
G0455	Preparation with instillation of fecal microbiota by any method, including assessment of donor specimen

ICD10 Codes

Code	Description
A04.7 - A04.72	Enterocolitis due to Clostridium difficile (code range)

REFERENCES

Allegretti JR, et al. Inflammatory bowel disease outcomes following fecal microbiota transplantation for recurrent C. difficile infection. Inflamm Bowel Dis. 2021;27(9):1371-1378.

Baunwall SMD, et al. Faecal microbiota transplantation for first or second Clostridioides difficile infection (EarlyFMT): a randomised, double-blind, placebo-controlled trial. Lancet Gastroenterol

Hepatol. 2022 Dec;7(12):1083-1091.

Caenepeel C, et al. Rigorous donor selection for fecal microbiota transplantation in active ulcerative colitis: key lessons from a randomized controlled trial halted for futility. Clin Gastroenterol Hepatol. 2025 Mar;23(4):621-631.e7.

Davidovics ZH, et al. Fecal microbiota transplantation for recurrent Clostridium difficile infection and other conditions in children: a joint position paper from the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition. J Pediatric Gastroenterol Nutr. 2019 Jan;68(1):130-143.

Diorio C, et al. Guideline for the management of Clostridium difficile infection in children and adolescents with cancer and pediatric hematopoietic stem-cell transplantation recipients. J Clin Oncol. 2018 Nov;36(31):3162-3171.

Drekonja DM, et al. A randomized controlled trial of efficacy and safety of fecal microbiota transplant for preventing recurrent clostridioides difficile infection. Clin Infect Dis. 2025 Feb 5;80(1):52-60. Erratum in: Clin Infect Dis. 2025 Feb 5;80(1):242-243.

El-Salhy M, et al. Efficacy of fecal microbiota transplantation for patients with irritable bowel syndrome at 3 years after transplantation. Gastroenterol. 2022 Oct;163(4):982-994.e14.

El-Salhy M, et al. Efficacy of faecal microbiota transplantation for patients with irritable bowel syndrome in a randomised, double-blind, placebo-controlled study. Gut. 2020 May;69(5):859-867.

Fischer M, et al. aga clinical practice update on management of clostridioides difficile infection in adults: expert review. Clin Gastroenterol Hepatol. 2026 Jun 30:S1542-3565(26)00358-7. Epub ahead of print.

Gefen R, et al. Fecal microbiota transplantation for patients with ulcerative colitis: a systematic review and meta-analysis of randomized controlled trials. Tech Coloproctol. 2025 Apr 17;29(1):103.

Gu X, et al. Effects of retrograde colonic enema-based fecal microbiota transplantation in the treatment of childhood constipation: a randomized, double-blind, controlled trial. Am J Gastroenterol. 2024;119(11):2256-2264.

Holvoet T, et al. Fecal microbiota transplantation reduces symptoms in some patients with irritable bowel syndrome with predominant abdominal bloating: short- and long-term results from a placebo-controlled randomized trial. Gastroenterol. 2021 Jan;160(1):145-157.e8. Epub 2020 Jul 15.

Ianiro G, et al. Systematic review with meta-analysis: efficacy of faecal microbiota transplantation for the treatment of irritable bowel syndrome. Aliment Pharmacol Ther. 2019;49(9):1087-1098.

Imdad A, et al. Fecal transplantation for treatment of inflammatory bowel disease. Cochrane Database Syst Rev. 2023 Apr 25;4(4):CD012774.

Johnson S, et al., Clinical practice guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 focused update guidelines on management of Clostridioides difficile infection in adults. Clin Infectious Diseases. 2021;75(5):p.e.1029-e1044.

Kao D, et al. Preliminary results from a multicenter, randomized trial using fecal microbiota transplantation to induce remission in patients with mild-to-moderate Crohn's disease. Am J Gastroenterol. 2024 Nov 12;120(6):1334-1344.

Kelly, CR. ACG Clinical Guidelines: Prevention, diagnosis, and treatment of Clostridioides difficile infections. Am J Gastroenterol 2021 June;116(6):1124-1147.

Khanna S, et al. AGA clinical practice update on management of clostridioides difficile infection in inflammatory bowel disease: expert review. Gastroenterology. 2026 Jul;171(1):184-192.

Lacy BE, et al. ACG clinical guideline: Management of irritable bowel syndrome. Am J Gastroenterol. 2021 Jan 01;116(1):17-44.

Lahtinen P, et al. Randomised clinical trial: faecal microbiota transplantation versus autologous placebo administered via colonoscopy in irritable bowel syndrome. Aliment Pharmacol Ther. 2020 Jun;51(12):1321-1331.

Madsen AMA, et al. The effect of faecal microbiota transplantation on abdominal pain, stool frequency, and stool form in patients with moderate-to-severe irritable bowel syndrome: results from a randomised, double-blind, placebo-controlled study. Sc and J Gastroenterol. 2021 Jul; 56(7):761-769.

McDonald LC, et al. Clinical practice guidelines for Clostridium difficile infection in adults and children: 2017 update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clin Infec Diseases. 2018;66(7):987-994.

Minkoff NZ, et al. Fecal microbiota transplantation for the treatment of recurrent Clostridioides difficile (Clostridium difficile). Cochrane Database Syst Rev. 2023 Apr 25;4(4) CD013871.

National Institute for Health and Care Excellence (NICE) [Internet]. Faecal microbiota transplant for recurrent Clostridium difficile infection. HealthTech guidance [HTG638]. 2022 Aug 31 [accessed 2026 Aug 6]. Available from: https://www.nice.org.uk/guidance/htg638

Oliva-Hemker M, et al.; Section on Gastroenteroloy, Hepatology, and Nutrition; Committee on Infectious Diseases. Fecal microbiota transplantation: information for the pediatrician. Pediatrics. 2023 Dec 1;152(6):e2023062922.

Pai N, et al. Results of the first pilot randomized controlled trial of fecal microbiota transplant in pediatric ulcerative colitis: lessons, limitations, and future prospects. Gastroenterology. 2021;161(2):388-393.e3.

Peery AF, et al; on behalf of the AGA clinical guidelines committee. AGA clinical practice guideline on fecal microbiota–based therapies for select gastrointestinal diseases. Gastroenterol. 2024 Mar;166:409-434.

Poylin V, et al; prepared by the clinical practice guidelines committee of the American Society of Colon and Rectal Surgeons. The American Society of Colon and Rectal Surgeons clinical practice guidelines for the management of Clostridioides difficile infection. Dis Colon Rectum. 2021 Jun;64(6):650-668.

Rapoport E, et al. Adverse events in fecal microbiota transplantation: a systematic review and meta-analysis. Annals of Gastroenterology. 2022;35(2):150-163.

Rubin DT, et al. ACG Clinical Guideline: Ulcerative colitis in adults. Am J Gastroenterol 2019 Mar; 114(3): 384-413.

Sokol H, et al. Fecal microbiota transplantation to maintain remission in Crohn's disease: a pilot randomized controlled study. Microbiome. 2020 Feb;8(1):12, Article 12.

Tariq R, et al. Efficacy of fecal microbiota transplantation for recurrent C. difficile infection in inflammatory bowel disease. Inflamm Bowel Dis. 2020 Sept;26(9):1415-1420.

Tun KM, et al. Efficacy and safety of fecal microbiota transplantation in treatment of Clostridioides difficile infection among pediatric patients: a systematic review and meta-analysis. Microorganisms. 2022 Dec 12;10(12):2450.

U.S. Food & Drug Administration (FDA) [Internet]. Fecal microbiota products. 2023 Jun 07 [accessed 2026 Aug 6]. Available from: https://www.fda.gov/vaccines-blood-biologics/fecal-microbiota-products

Wang M, et al. Fecal microbiota transplantation for irritable bowel syndrome: a systematic review and meta-analysis of randomized controlled trials. Front Immunol. 2023 May 18;14:1136343.

Wang Y, et al. A meta-analysis of randomized controlled trials evaluating the effectiveness of fecal microbiota transplantation for patients with irritable bowel syndrome. BMC Gastroenterol. 2024 Jul 5;24(1):217.

Zhou S, et al. Fecal microbiota transplantation for induction of remission in Crohn's disease: A systematic review and meta-analysis. Int J Colorectal Dis. 2023;38(1):62.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Fecal microbiota transplant or fecal bacteriotherapy are not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 7/26 **Revised**: **Reviewed**:	
Date	**Summary of Changes**
11/1/2026	• New

MEDICAL POLICY

Medical Policy Title	**Focal Therapies for Prostate Cancer Treatment**
Policy Number	**7.01.01**
Current Effective Date	**September 1, 2026**
Next Review Date	**August 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Cryosurgery and high-intensity focused ultrasound (HIFU) for recurrent prostate cancer is considered **medically appropriate** when **ALL** of the following criteria have been met:

   A. Recurrence of prostate cancer after radiation therapy (as evidence by positive, repeat biopsy);

   B. Absence of metastatic disease.

II. Cryotherapy or other focal therapies (i.e., HIFU) performed for routine primary therapy for localized prostate cancer are considered **investigational**.

III. The following focal therapies for the routine treatment of prostate cancer are considered **investigational**. These treatments include, but are not limited to, **ANY** of the following:

   A. Vascular-Targeted Photodynamic, therapy (VTP);

   B. Irreversible Electroporation (IRE);

   C. NanoKnife for tissue ablation;

   D. Laser Interstitial Thermal Therapy (LITT);

   E. Transurethral Ultrasound Ablation (TULSA);

   F. Magnetic field induction (NanoTherm therapy);

   G. High energy water vapor thermotherapy.

RELATED POLICIES

Corporate Medical Policy

8.01.06 Photodynamic Therapy for Malignant Disease

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

DESCRIPTION

Cryosurgical Ablation

Cryosurgical ablation of the prostate is an alternative method of treatment for prostate cancer. The cryoablation technique involves the use of transrectal, ultrasound-guided, percutaneous placement of cryoprobes to freeze prostate tissue to produce well-demarcated areas of cell injury and destruction. Refinements in the technique, with transrectal ultrasonography, improved cryosurgical instrumentation, and the use of commercial urethral warmers have decreased the complications associated with the early attempts at cryosurgery. The benefits of cryosurgery of the prostate include a shorter surgical procedure time with minimal blood loss.

High Intensity Focused Ultrasound (HIFU)

HIFU is a noninvasive approach that uses precisely delivered ultrasound energy to achieve tumor cell necrosis without radiation or surgical excision. This technique is also referred to as ultrasonic ablation, sonablation or focal ultrasound surgery. HIFU involves the use of a transrectal probe to plan, perform, and monitor treatment in a real-time sequence to ablate the entire prostate gland or small discrete lesions. HIFU is a promising treatment for prostate cancer especially in patients with low and intermediate risk disease who chose to not undergo open surgery. HIFU is a minimally invasive, outpatient, radiation free procedure that patients can undergo then return home. This advancement in the treatment of prostate cancer is making it possible for patients with earlier stages of the disease to maintain their quality of life without open surgery. HIFU can also be used if disease recurs, despite what earlier treatment methods were deployed.

Vascular-Targeted Photodynamic Therapy (VTP) or Photodynamic Therapy (PDT)

VTP or PDT is a tissue-preserving treatment for low-risk prostate cancer which consists of intravenous 4 mg/kg padeliporfin over 10 min and optical fibers inserted into the prostate to cover the desired treatment zone and subsequent activation by laser light. For treating prostate cancer, the photosynthesizer TOOKAD soluble (WST11) is used. The technical term for this treatment is TOOKAD Soluble VTP therapy.

Irreversible Electroporation (IRE)

IRE is used as focal therapy to target areas of significant tumor burden to ablate tumors in situ or improve margins of resection. Primarily being used for pancreas, kidney, liver and prostate tumors. IRE destroys cancerous tumors with short electrical pulses without thermal heat disrupting permeabilization of cell membrane phospholipids. The NanoKnife System which became commercially available for research purposes in 2009 is being solely used for the surgical ablation of soft tissue tumors.

Laser Interstitial Thermotherapy (LITT)

LITT treatment produces focal thermal ablation leading to lesion cytoreduction through tissue coagulation, necrosis, and cellular apoptosis.

Trans-Urethral Ultrasound Ablation (TULSA)

TULSA is a transurethral prostate tissue ablation system that uses real-time MRI, robotically driven, directional thermal ultrasound and closed-loop temperature feedback control software. It provides incision- and radiation-free, whole or partial prostate gland ablation, protecting the urethra and rectum to preserve men's functional abilities.

Magnetic Field Induction (NanoTherm therapy)

The NanoTherm liquid containing the magnetic nanoparticles is specifically injected into the tumor or applied at the resection cavity wall in the course of the tumor resection.
The particles, which contain iron oxide, are then activated during six one-hour sessions in the NanoActivator by an externally applied, rapidly alternating magnetic field, which generates heat. This either destroys the tumor cells or sensitizes them to additional treatment approaches such as radiotherapy and/or chemotherapy (MagForce USA, Inc).

Transurethral Water Vapor Thermal Therapy

Transurethral water vapor thermal therapy is a transurethral needle ablation technique which injects radiofrequency-generated, sterile water vapor (~103 degrees C) into enlarged prostate tissue. As the steam encounters the prostatic tissue, it condenses back into water, releasing large amounts of thermal energy, disrupting the prostatic cell membranes and leading to cell death and necrosis. It takes approximately three months for the body to reabsorb dead tissue, decreasing prostate volume and relieving LUTS. The thermal energy is confined to the prostate, which reduces the risk of injury to other parts of the body. The procedure is performed under local anesthesia in an office or outpatient setting. Currently there is no literature or professional society that supports this therapy for prostate cancer.

SUPPORTIVE LITERATURE

HIFU

Maestroni et al (2021) conducted a systematic review that evaluated the safety and cancer control rates of HIFU following failure of External Beam Radiation Therapy (EBRT) for localized prostate cancer. The analysis of 1241 patients from predominantly retrospective studies. All patients underwent EBRT prior to HIFU for localized prostate cancer. The mean age was 68.6 years with a prostate specific antigen (PSA) value of 5.87 ng/mL before treatment. At the time of salvage HIFU, 38.3% patients were on androgen-deprivation therapy and 24.71% continued the therapy after the treatment. Follow-up was a mean follow-up of 24.3 months after salvage HIFU. The percentage of patients who had recurrence was 51.6% which was independent of the length of follow-up. The overall survival (OS) was 85.2% at five years and one study reported an OS of 72% at seven years. The authors concluded that salvage HIFU is effective in the treatment of radiorecurrent clinically localized prostate cancer. Limitations included analysis of predominantly retrospective studies, heterogeneity of data collected making it difficult to compare the results and the criterion for defining recurrence is not the same.

Ingrosso et al (2020) conducted a systematic review and meta-analysis that evaluated the role of nonsurgical salvage modalities in radiorecurrent prostate cancer and the associated clinical outcomes

with toxicity profiles. The meta-analysis included 64 case-series studies including 5585 patients. All patients underwent primary radiation therapy (RT) for localized prostate cancer. Clinical outcomes were measured using the Phoenix definition to determine biochemical control rates while toxicity was measured using the Common Terminology Criteria for Adverse Events (CTCAE) and Clavien-Dindo scales. Brachytherapy (BT) and cryotherapy (CRYO) were investigated in 22 studies, HIFU in 13 studies, and EBRT in seven studies. The median follow-up after salvage therapy was 31 months. Patients underwent different imaging modalities to assess local relapse including MRI and choline PET. Prostate biopsies were performed in 5546 patients, for which the median Gleason score was 7. Biochemical control rates were lowest for patients treated with HIFU and highest for patients treated with BT and EBRT. The lowest prevalence of incontinence was for patients treated with BT and the highest was among patients treated with HIFU. The authors concluded that nonsurgical therapeutic options, especially BT, showed good outcomes in terms of biochemical control and tolerability in the local recurrence setting. Limitations included high between-study heterogeneity potentially by the lack of prospective data and by the intrinsic bias for case series.

Irreversible Electroporation (IRE)

Faiella et al (2024) evaluated the most recent research from 2000 to 2023 to investigate the applications of IRE for prostate cancer, including the primary- and salvage-intent. Primary-intent IRE, in-field recurrence ranges from zero to 33%. Urinary continence after the treatment was greater than 86%. Preserved potency varied from 59-100%. Regarding complications, the highest occurrence rates are for those of Grades I and II (20–77% and 0–29%, respectively). Grade III complications represent less than 7%. Specific oncological outcomes, both PCa-specific survival and overall survival are 100%. Metastasis-free survival is 99.6%. In a long-term study, the Kaplan–Meier FFS rates reported are 91% at 3 years, 84% at 5 years, and 69% at 8 years. In the single study with salvage-intent IRE, the in-field recurrence was 7%. Urinary continence was still high (93%), but preserved potency was significantly lower than primary-intent IRE patients (23%). In addition, Grade III complications were slightly higher (10.8%). In conclusion, in males with localized low–intermediate-risk prostate cancer, IRE had an excellent safety profile and might have positive results for sexual and urinary function.

PROFESSIONAL GUIDELINE(S)

The American Urological Association (AUA), American Society for Radiation Oncology (ASTRO) and the Society of Urologic Oncology (SUO) released 2022 guidelines (amended 2026) for clinically localized prostate cancer. The guidelines offer the following recommendations regarding focal therapies:

- Clinicians should inform patients with low and intermediate-risk prostate cancer considering whole gland or focal ablation that there is a lack of high-quality data comparing ablation outcomes to radiation therapy, surgery, and active surveillance. (Expert Opinion)
- Clinicians should not recommend whole gland or focal ablation for patients with high-risk prostate cancer outside of a clinical trial. (Expert Opinion)

The National Comprehensive Cancer Network (NCCN) guidelines for Prostate Cancer Version 5.2026

recommend:

- Cryosurgery and high-intensity focused ultrasound (HIFU) as local therapy options for RT recurrence in the absence of metastatic disease.
- Cryotherapy or other local therapies are not recommended as routine primary therapy for localized prostate cancer due to lack of long-term data comparing these treatments to radiation or radical prostatectomy.

National Institute for Health and Care Excellence (NICE) notes that current evidence on the safety and efficacy of IRE for treating prostate cancer is inadequate in quantity and quality.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates prostate ablation devices as medical devices. All [device] including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: Medical Devices [accessed 2026 Jul 27]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Jul 27]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I) =Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
55873	Cryosurgical ablation of the prostate (includes ultrasonic guidance and monitoring)
55877 (E/I)	Ablation, irreversible electroporation, prostate, 1 or more tumors, including imaging guidance, percutaneous (Effective 01/01/26)
55880	Ablation of malignant prostate tissue, transrectal, with high intensity-focused ultrasound (HIFU), including ultrasound guidance
55899	Unlisted procedure, male genital system
0582T (E/I)	Transurethral ablation of malignant prostate tissue by high-energy water vapor thermotherapy, including intraoperative imaging and needle guidance

Code	Description
0601T (E/I)	Ablation, irreversible electroporation; 1 or more tumors, including Fluoroscopic and ultrasound guidance, when performed, open
0655T (E/I)	Transperineal focal laser ablation of malignant prostate tissue, including transrectal imaging guidance, with MR-fused images or other enhanced ultrasound imaging
0738T (E/I)	Treatment planning for magnetic field induction ablation of malignant prostate tissue, using data from previously performed magnetic resonance imaging (MRI) examination
0739T (E/I)	Ablation of malignant prostate tissue by magnetic field induction, including all intraprocedural, transperineal needle/catheter placement for nanoparticle installation and intraprocedural temperature monitoring, thermal dosimetry, bladder irrigation, and magnetic field nanoparticle activation

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HCPCS Codes

Code	Description
C2618	Probe/needle, cryoablation

ICD10 Codes

Code	Description
C61	Malignant neoplasm of prostate
C79.82	Secondary malignant neoplasm of genital organs
D07.5	Carcinoma in situ of prostate
R97.21	Rising PSA following treatment for malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate
Z92.3	Personal history of irradiation

REFERENCES

Abreu AL, et al. High intensity focused ultrasound hemigland ablation for prostate cancer: Initial outcomes of a United States series. J Urol. 2020 Oct;204(4):741-747.

Ahn H, et al. Diagnostic performance of MRI for prediction of recurrent prostate cancer after high-intensity focused ultrasound: a systematic review and meta-analysis. Prostate Int. 2023 Jun;11(2):59-68.

Bates AS, et al. A systematic review of focal ablative therapy for clinically localized prostate cancer in comparison with standard management options: limitations of the available evidence and recommendations for clinical practice and further research. Eur Urol Oncol. 2021 Jun;4(3):405-423.

Baude J, et al. Salvage radiotherapy with volumetric modulated arc therapy (VMAT) for recurrent prostate cancer after high-intensity focused ultrasound (HIFU): A large French retrospective series and literature review. Radiother Oncol. 2025 Feb;203:110665.

Cheetham P, et al. Long-term cancer-specific and overall survival for men followed more than 10 years after primary and salvage cryoablation of the prostate. J Endourol. 2010 Jun;24(7):1123-9.

Chin JL, et al. Long-term outcomes of whole gland salvage cryotherapy for locally recurrent prostate cancer following radiation therapy: A combined analysis of two centers. J Urol. 2021 Sep;206(3):646-654.

Chou R, et al. Treatments for localized prostate cancer: systematic review to update the 2002 U.S. Preventive Services Task Force Recommendation. Rockville (MD) 2011Oct.

Dahm P, et al. Therapies for clinically localized prostate cancer [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US). 2020 Sep. Report No.: 20-EHC022. PMID: 32986341.

Dhar N, et al. Primary full-gland prostate cryoablation in older men (> age of 75 years): results from 860 patients traced with the COLD Registry. BJU Int. 2011 Aug;108(4):508-12.

Donnelly BJ, et al. A randomized trial of external beam radiotherapy versus cryoablation in patients with localized prostate cancer. Cancer. 2010;116:323–30.

Duwe G, et al. Single-center, prospective phase 2 trial of high-intensity focused ultrasound (HIFU) in patients with unilateral localized prostate cancer: good functional results but oncologically not as safe as expected. World J Urol. 2023 May;41(5):1293-1299.

Eastham JA, et al. Clinically Localized Prostate Cancer: AUA/ASTRO Guideline Amendment [Internet]. 2026. [accessed 2026 Jun 16] https://auanet.org/guidelines-and-quality/guidelines/clinically-localized-prostate-cancer-aua/astro-guideline-2022

Enikeev D, et al. Whole-gland ablation therapy versus active surveillance for low-risk prostate cancer: a prospective study. Cent European J Urol. 2020;73(2):127-133.

Faiella E, et al. Irreversible electroporation (IRE) for prostate cancer (PCa) treatment: the state of the art. J Pers Med. 2024 Jan 25;14(2):137.

Guang ZLP, et al. Oncological and functional outcomes of whole-gland HIFU as the primary treatment for localized prostate cancer: a systematic review. Clin Genitourin Cancer. 2024 Aug;22(4):102101.

Guo RQ, et al. Cryoablation, high-intensity focused ultrasound, irreversible electroporation, and vascular-targeted photodynamic therapy for prostate cancer: a systemic review and meta-analysis. Int J Clin Oncol. 2021 Mar;26(3):461-484.

He Y, et al. The primary treatment of prostate cancer with high-intensity focused ultrasound: A systematic review and meta-analysis. Medicine (Baltimore). 2020 Oct 9;99(41):e22610.

Ingrosso G, et al. Nonsurgical salvage local therapies for radiorecurrent prostate cancer: a systematic review and meta-analysis. Eur Urol Oncol. 2020 Apr;3(2):183-197.

Maestroni U, et al. Oncologic outcome of salvage high-intensity focused ultrasound (HIFU) in radiorecurrent prostate cancer. A systematic review. Acta Biomed. 2021 Sep 2;92(4):e2021191.

Mäkelä P, et al. Acute and subacute prostate MRI findings after MRI-guided transurethral ultrasound ablation of prostate cancer. Acta Radiol. 2021 Dec;62(12):1687-1695.

Mäkelä P, et al. Safety and efficacy of MRI-guided transurethral ultrasound ablation for radiorecurrent prostate cancer in the presence of gold fiducial markers. Acta Radiol. 2023 Mar;64(3):1228-1237.

Morozov A, et al. A systematic review of irreversible electroporation in localised prostate cancer treatment. Andrologia. 2020 Aug 12:e13789.

National Comprehensive Cancer Network (NCCN) [Internet]. NCCN Clinical Practice Guidelines in Oncology: prostate cancer. Version 4.2024. [accessed 2026 Jun 16] https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf

Nogueira L, et. al. Developments in vascular-targeted photodynamic therapy for urologic malignancies. Molecules. 2020 Nov 19;25(22):5417.

Noun J, et al. Focal therapies for localized prostate cancer. Urol Clin North Am. 2026 Feb;53(1):115-134.

Parekh A, et al. Cancer control and complications of salvage local therapy after failure of radiotherapy for prostate cancer: a systematic review. Semin Radiat Oncol. 2013 Jul;23(3):222-34.

Rakauskas A, et al. Focal therapy for prostate cancer: Complications and their treatment. Frontiers in Surgery vol. 8 696242. 12 Jul. 2021.

Reddy D, et al. Cancer control outcomes following focal therapy using high-intensity focused ultrasound in 1379 men with nonmetastatic prostate cancer: a multi-institute 15-year experience. Eur Urol. 2022 Apr;81(4):407-413.

Reddy D, et al. Comparative healthcare research outcomes of novel surgery in prostate cancer (IP4-CHRONOS): a prospective, multi-centre therapeutic phase II parallel randomised control trial. Contemp Clin Trials. 2020 Jun;93:105999.

Sandberg M, et al. Focal Therapy for Localized Prostate Cancer: A Case Series with Cost Analysis. Curr Oncol. 2025 Aug 23;32(9):476.

Saouli A, et al. Salvage radical prostatectomy for recurrent prostate cancer: a systematic review (French ccAFU). Cancers (Basel). 2023 Nov 20;15(22):5485.

Shah TT, et al. Focal therapy compared to radical prostatectomy for non-metastatic prostate cancer: a propensity score-matched study. Prostate Cancer Prostatic Dis. 2021 Jan 28.

Simmerman E, et. al. Application of irreversible electroporation ablation as adjunctive treatment for Margin enhancement: safety and efficacy. J Surg Res. 2020 Feb;246:260-268.

Tan YG, et al. Patient-reported functional outcomes and oncological control after primary focal

cryotherapy for clinically significant prostate cancer: A Phase II mandatory biopsy-monitored study. Prostate. 2023 Jun;83(8):781-791.

Ullal AV, et al. A report on major complications and biochemical recurrence after primary and salvage Cryosurgery for prostate cancer in patients with prior resection of benign prostatic hyperplasia: a single-center experience. Urology. 2013 Sep;82(3):648-52.

Valle LF, et al. A systematic review and meta-analysis of local salvage therapies after radiotherapy for prostate cancer (MASTER). Eur Urol. 2021 Sep;80(3):280-292.

Ward JF, et al. Cryoablation for locally advanced clinical stage T3 prostate cancer: a report from the Cryo-Online database (COLD) Registry. BJU Int. 2014 May;113(5):714-8.

Ziglioli F, et al. Oncologic outcome, side effects and comorbidity of high-intensity focused ultrasound (HIFU) for localized prostate cancer. A review. Ann Med Surg (Lond). 2020;56:110-115. Published 2020 May 30.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Cryosurgery of Prostate (NCD 230.9) [accessed 2026 Jun 16]

Salvage High-intensity Focused Ultrasound (HIFU)Treatment in Prostate Cancer is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

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- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 5/26

Revised:

Reviewed:

Date	Summary of Changes
9/1/2026	• New

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: FOOT CARE

POLICY EFFECTIVE DATE:	6/1/2023
Policy Control #:	1370/20.000106
Next Annual Review:	May, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODE

See sections below.

DESCRIPTIONS

The examination, diagnosis, and treatment of conditions involving the human foot.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

Diabetic Services: Supplies, Pharmaceuticals, Equipment, Eye Exams, Education & Shoes, 1370/20.000047

Durable Medical Equipment, Prosthetics/Orthotics & Medical Supplies, 1370/20.000509

Physical Therapy, 1370/20.000057

POLICY STATEMENT

Routine Foot Care (11055, 11056, 11057, 11719, 11720, 11721, G0127, G0247, S0390)

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: FOOT CARE

Routine foot care includes the cutting or removal of corns and calluses, trimming or cutting of nails, treatment of simple ingrown nails, other hygienic and preventive maintenance care in the realm of self-care, and any services performed in the absence of localized illness, injury, or symptoms involving the foot.

CDPHP does not administer benefits for routine foot care as defined above. Foot care that would otherwise be considered routine may be covered only in the following circumstances when medically necessary:

1. Presence of a systemic condition, such as metabolic, neurologic, or peripheral vascular disease of sufficient severity that performance of such services by a nonprofessional person would place the patient at risk (e.g., a systemic condition that has resulted in severe circulatory deficits or areas of diminished sensation in the patient's legs or feet).

2. In certain circumstances, services normally considered routine may be covered if they are performed as a necessary and integral part of otherwise covered services, such as the diagnosis and treatment of ulcers, wounds, or infections.

3. Treatment of mycotic nails when there is evidence of a systemic illness causing severe circulatory problems or diminished sensation in the legs or feet; or marked limitation of ambulation, pain, and/or secondary infection resulting from the thickening and dystrophy of the infected toenail plate.

The following are examples of conditions that may justify coverage of foot care that would otherwise be considered routine:

- Anticoagulated patients
- Arteriosclerosis obliterans
- Atherosclerosis
- Burger's disease (thromboangiitis obliterans)
- Chronic thrombophlebitis
- Diabetes mellitus
- Immunocompromised patients
- Peripheral neuropathies involving the feet
- Peripheral vascular disease

Nail Debridement (11720, 11721)

Mycotic nail, or onychomycosis, is a fungal infection of the nail bed, matrix, and/or plate. The infection invades the nail bed and underside of the nail plate. The infection can cause discoloration and disfigurement of the nail. In severe conditions the nail may become loosened from the nail bed and a secondary infection may develop. The resulting thickened nails may become difficult to trim and may make walking painful.

CDPHP administers benefits for debridement of mycotic nails, once every 60 days, for the following indications:

- There is presence of a qualifying systemic illness causing a peripheral neuropathy; or

POLICY NAME: FOOT CARE

- In the absence of a systemic illness, the mycosis/dystrophy of the nail is causing secondary infection and/or pain, which results or would result in marked limitation of ambulation.

In addition, procedures for treating toenails are covered for the following conditions meeting the above criteria:

- Onychogryphosis (defined as an enlargement with increased thickening and curvature of the toenails), where the nail plate is causing symptomatic indentation of or minor laceration of the distal toe, eponychium, or adjacent toe.

- Onychauxis (defined as a thickening of the base of the nail bed) where the presence of the nail plate thickness is 3 millimeters or greater and the nail is friable or lytic.

Reimbursement for the debridement of mycotic nails may be made when definitive antifungal treatment options have been reviewed and discussed with the patient at the initial visit, and the physician documents the patient's physical status as being of such severity to meet the criteria for treatment listed above.

Surgical Treatment of Nails (11730, 11732, 11750, 11765)

CDPHP covers the surgical treatment of nails for the following medically necessary indications:

- Complicated wounds of the toes involving nail components
- Deformed nails that prevent wearing shoes or otherwise jeopardize the integrity of the toe
- Paronychia
- Subungual abscess
- Symptomatic onychauxis, onychocryptosis, or onychogryphosis causing functional impairment
- Trauma (crushing injury of the toes)

Onychocryptosis, or an ingrown nail, is the growth of the nail edge into the surrounding soft tissue, resulting in pain and/or inflammation. An infection may or may not be present. This condition most commonly occurs in the great toes. Surgical options to treat complicated onychocryptosis include avulsion of the nail, excision of the nail and nail matrix, and wedge excision of the soft tissue with removal of the offending portion of the nail. In general, surgical treatment of the nails requires the use of local anesthesia.

1. **Avulsion** of a nail (11730, 11732) involves the separation and removal of a border of, or the entire nail, from the nail bed to the eponychium.
   - Avulsion of a nail plate, partial or complete, is limited to one procedure per digit every three months.
   - In cases where the procedure is repeated before the three-month period, claims must be submitted with medical records documenting medical necessity.
   - In cases where an avulsion is performed on more than one digit per date of service, claims must be submitted with the appropriate digit modifier (TA, T1-T9).

Treatment of simple onychocryptosis with removal of the offending wing or spicule of the nail is considered to be routine foot care in the absence of infection, inflammation, or functional impairment. Trimming, cutting, clipping, or debriding of a nail distal to the eponychium is also

regarded as routine foot care. These ices should not be reported with codes 11730 or 11732.

2. **Excision** of the nail and the nail matrix (11750) is generally performed for severely deformed or ingrown nails and may be performed using surgical, laser, electrocautery, or chemical techniques.
   - Excision of nail and nail matrix, partial or complete, is limited to one per digit on a given date of service.
   - In cases where an excision of nail and nail matrix is performed on more than one digit per date of service, claims must be submitted with the appropriate digit modifier (TA, T1-T9).

3. **Wedge resection** (11765) of the soft tissue with removal of the offending portion of the nail is designed to relieve pressure on the nail/soft tissue. Generally, a wedge resection of the skin of the nail fold is performed to remove hypertrophic lateral nail folds that develop as a result of chronic ingrown toenails.

Only one of the following procedures will be allowed per nail, per same date of service:
- Partial or complete avulsion (11730-11732)
- Excision (11750)
- Wedge resection (11765)
- Incision and drainage (10060-10061)

Other Procedures

Benefits for injection of tendons, ligaments, and bursae (20550, 20551) are limited to three injections every 12 months.

Arthrocentesis (20600, 20604, 20605) is limited to three procedures every six months.

Therapeutic injections for neuroma (64455, 64632) will be limited to three injections within six months without submission of medical records. For refractory cases, coverage is available for an additional five injections (totaling eight). Documentation must be submitted in this instance.

Benefits are provided for electrical stimulation (97032) when used as a means of therapeutic treatment.

Ultrasound of the foot (76882) is considered to be an integral part of the ultrasonic guidance for needle placement (76942) and therefore is not separately reimbursed.

Radiology

Benefits will be provided for foot and ankle X-rays only (CPT codes 73600-73610; 73620-73660), and are subject to the following:

- Unilateral films for reported unilateral bone pathology
- Bilateral films only when a bilateral condition is reported
- X-rays for suspected foreign body are allowable, but follow-up films only with documentation that a foreign body was found and removed

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Physical Therapy

Benefits will be provided when rendered by a physical therapist.

CDPHP will not administer benefits for G0245, G0246, and G0247 (initial, follow-up and routine foot care for diabetic patients with loss of protective sensation) when reported on the same day of service as physical medicine and rehabilitation evaluation codes (97161-97164, 97165-97168, 97169-97172).

Laboratory

Benefits will be provided for lab tests that are necessary for the diagnosis or treatment of a patient's condition and that are not performed in conjunction with excluded services.

Casting and Strapping

Casting and strapping procedures for the purpose of immobilization will be allowed eight times per diagnosis per 90-day period in a calendar year. Additional casting and strapping services will require submission of office notes for medical record review.

Initial office visit will be allowed; however, subsequent office visits will not be allowed when performed in conjunction with the above procedures and for the same diagnosis.

Destruction of Warts

Treatment of warts on the foot is covered to the same extent as services provided for the treatment of warts located elsewhere on the body and is limited to 12 treatment visits. Treatment beyond the stated limitation will require submission of office notes, outlining the treatment to date and future treatment plan, along with the claim.

Extracorporeal Shock Wave Treatment (28890, 20999, 0101T)

Extracorporeal shock wave therapy (ESWT) is a noninvasive treatment option for musculoskeletal conditions that have failed to respond to conservative treatment. ESWT uses technology similar to lithotripsy in an attempt to relieve musculoskeletal symptoms of the specified affected area. There are two theories on the therapeutic effects of the shock waves. One theory is that the shock waves alleviate pain by increasing blood flow and decreasing inflammation in the affected area. Another theory is that the shock waves damage cell membranes, thus interfering with the transmission of pain signals.

CDPHP provides benefits for ESWT, using either a high-dose or low-dose protocol, when **all** the following criteria are met:

- The enrollee has a diagnosis of chronic plantar fasciitis or heel spur syndrome

Description	ICD-10 codes
Chronic plantar fasciitis	M72.2

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Heel spur syndrome	M77.30-M77.32

- ESWT is being performed as an alternative to surgery.
- Documentation demonstrates failure of at least three conservative therapies (e.g., rest, physical therapy, anti-inflammatory medications, local corticosteroid injections, heel orthotics, or strappings) after six months of treatment.

Benefits for ESWT are provided for up to three times per year. Services beyond the stated limitation will be subject to retrospective review.

CDPHP considers ESWT, for indications other than those listed above, experimental, investigational, or unproven.

Foot Orthotics

CDPHP will cover customized foot orthotics (L3000-L3030) for enrollees that have peripheral vascular disease that is diagnosed by formal vascular testing.

Benefits are limited to one pair of custom foot orthotics within one calendar year.

Claims submitted for custom foot orthotics (L3000-L3030) will be processed as durable medical equipment when the enrollee has a diagnosis of peripheral vascular disease that is diagnosed by formal vascular testing.

Foot orthotics (L3000-L3030) must be billed with modifier KX to ensure that coverage criteria are met, and that documentation exists to support the medical necessity.

POLICY CONSIDERATIONS

The patient's medical record must contain documentation that supports the medical necessity for services performed.

Foot examinations for members with diabetic sensory neuropathy (G0245, G0246) with loss of protection senses (LOPS) is covered, but no more than every six months.

The use of local anesthetics at the time of surgery is considered inclusive in the surgical allowance and is not allowed as a separate procedure.

Nerve blocks (CPT 64450), when performed at the same session as a surgical procedure, are considered preoperative anesthetics and global to the procedure.

Therapeutic nerve blocks performed for the theoretical purpose of increasing blood supply to the foot and toes are not considered to be medically necessary.

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All foot care services are subject to retrospective review.

EXCLUSIONS

Any services performed in the absence of localized illness, injury, or symptoms involving the foot.

Routine foot care (in the absence of systemic disease) to include, but not limited to, services or care in connection with any of the following:

- Cutting, paring, or removal of corns and calluses
- Flat or weak feet
- Fallen arches
- Chronic foot strain or symptomatic complaints of the feet
- Trimming, cutting, or clipping of nails
- Other hygienic and preventive maintenance self-care (e.g., cleaning and soaking of the feet, use of skin creams, etc.)

The term "flat feet" is defined as a condition in which one or more arches of the foot have flattened out. Services or devices directed toward the care or correction of such conditions, including the prescription of supportive devices, are considered routine foot care and are not covered.

Orthopedic shoes, unless the shoes are an integral part of a covered leg brace, are included in the cost of the brace. This exclusion does not apply to therapeutic shoes and inserts for individuals with diabetes or vascular disease.

Use of nerve blocks or injections (continuous or single-injection) for treatment of multiple neuropathies or peripheral neuropathies caused by underlying systemic diseases.

Combined electrochemical therapy (CET) for treatment of peripheral neuropathy (use of electronic signal therapy (ETS) in conjunction with local anesthetics). CPT code 64450 should not be used to report this service.

Comparison X-rays are not allowed in the absence of bilateral bone pathology.

Casting for the purpose of orthotic molds except when orthotics are covered as indicated above.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS: Subject to all terms and conditions noted above in the policy to include the following clarification.

Orthotic devices used to support a weak or deformed body part or eliminate motion in a diseased or injured body part, are covered. Medically necessary orthotic devices are covered except for those prescribed solely for use during sports.

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MEDICARE ADVANTAGE:

Subject to all terms and conditions noted above in the policy.

In addition to diagnosis listed within this policy, extracorporeal shock wave therapy (ESWT) is covered for enrollees diagnosed with epicondylitis (0102T) for whom more conservative therapy failed for at least six months, and as an alternative to surgery.

SELECT PLAN/HARP:

Subject to all terms and conditions noted above in the policy.

Subject to all terms and conditions noted above in application with the following product-specific coverage noted:

Routine hygienic care of the feet, the treatment of corns and calluses, the trimming of nails, and other hygienic care such as the cleaning or soaking of feet, are not covered in the absence of a pathological condition.

Covered services must include routine foot care provided by qualified provider types (e.g., podiatrist) when any enrollee's (regardless of age) physical condition poses a hazard due to the presence of localized illness, injury, or symptoms involving the foot, or when performed as a necessary and integral part of otherwise covered services such as the diagnosis and treatment of diabetes, ulcers, and infections.

Services provided by a podiatrist for persons under 21 years of age must be covered upon referral of a physician, registered physician assistant, certified nurse practitioner, or licensed midwife.

CDPHP utilizes the New York State Medicaid management information system provider manual (MMIS) to determine medical/surgical supply versus durable medical equipment, orthotic, or prosthetic.

Orthopedic footwear includes shoes, shoe modifications, and shoe additions that are covered when used to correct, accommodate, or prevent a physical deformity or range-of-motion malfunction in a diseased or injured part of the ankle or foot; to support a weak or deformed structure of the ankle or foot; or to form an integral part of a brace.

- Prescription footwear applies to all "L" codes listed in the prescription footwear section of the MMIS provider manual (4.6), as well as codes for diabetic shoes.

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Benefits are not provided for sneakers and athletic shoes, as they are not considered orthopedic shoes.

Prosthetics and orthotic devices are covered at 100 percent when medically necessary.

Medically necessary medical supplies related to foot care are a covered benefit and are billed to Medicaid Fee for Service as per the MMIS Medical Supplies, Procedure Codes & Coverage Guidelines manual.

Foot orthotics and shoe inserts (L3000-L3030, A5512-A5514) must be billed with modifier KX to ensure that coverage criteria are met, and that documentation exists to support the medical necessity.

SOURCES

1. Board Certified Dermatologist
2. Child Health Plus Contract, 8/2003
3. EPSDT (Early and Periodic Screening, Diagnostic, and Treatment)
4. Family Health Plus Contract, 10/2002
5. Gellman R, Burns S; Walking Aches and Running Pains. Primary Care; Clinics and Office Practice. Volume 23, Number 2. June 1996, pp 263-280.
6. Hayes, Inc., Directory Report: Extracorporeal Shock Wave Therapy for Chronic Plantar Fasciitis, August 2005. Updated search 2/2009.
7. HCFA, Carriers Manual Part 3, §2323 Foot Care and Supportive Devices for Feet.
8. http://cms.hhs.gov/manuals/14%5Fcar/3b2312.asp (accessed 9/25/02)
9. Medicaid Managed Care Model Contract, April 2002
10. Medicare Part B Answer Book, Podiatric Services, pp.19801-19806, 2001 edition.
11. National Government Services, Local Coverage Determination (LCD) for Extracorporeal Shock Wave Therapy for Musculoskeletal Indications (L28470), effective 1/1/12.
12. National Government Services, Local Coverage Determination (LCD) for Routine Foot Care and Debridement of Nails (L26426), effective revision date, 10/17/11.
13. National Government Services, Local Coverage Determination (LCD) for Surgical Treatment of Nails (L26424), effective revision date, 2/1/12.
14. New York State Medicaid Redesign Team: Medicaid Managed Care Benefit Changes, 2011-2012, www.health.ny.gov
15. NYS Education Department; Office of the Professions. Consumer Information on the Professions. Consumer Questions and Answers.
16. Other Payers
17. Hayes, Winifred S. Directory Report: Extracorporeal shock wave therapy for chronic plantar fasciitis. December 2, 2013, Accessed March 18, 2014.
18. Walters Kluwer Health, UpToDate Report: Plantar Fasciitis, Updated February 18, 2014. Accessed March 18, 2014.

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POLICY APPROVAL DATES

New: 07/93

Revised: 09/95,07/97, 12/98, 06/00, 08/00, 11/00, 01/01, 04/01, 01/02, 10/02, 09/03, 04/04, 09/04, 04/05, 06/05,12/05, 12/06, 06/07, 05/08, 01/09, 05/09, 01/10, 03/10, 5/10, 05/11, 09/11, 11/11, 05/12, 05/13, 01/14,03/14, 05/14, 05/15, 05/16, 05/17, 09/17, 05/17, 05/18, 11/18, 1/20, 5/21, 5/22, 5/23, 7/24, 1/25, 3/25

Reviewed: 04/94, 08/96, 08/97, 12/97, 5/19, 05/20, 5/24, 5/25, 5/26

POLICY HISTORY

Effective Date	Update
6/1/2023 * No change to effective date of policy	Clarified under foot orthotics that they are covered for peripheral vascular disease in first paragraph.
6/1/2023 * No change to effective date of policy	Added foot orthotic information for vascular disease back to policy
6/1/2023 * No change to effective date of policy	Added requirement of modifier KX for foot orthotics in the Select Plan/HARP section. Added information for foot orthotics for peripheral vascular disease.
6/1/2023 * No change to effective date of policy	No change to criteria. Removed information regarding foot orthotics as this information is housed in the Diabetic Services, 1370/20.000047 policy.
6/1/2023 * No change to effective date of policy	Clarified under Medicaid that medical supplies related to foot care are billed to Medicaid FFS.
6/1/2023	Removed codes 64450 and 64640 in the therapeutic injections for neuroma section as guidelines identify to report only codes 64455 or 64632 for this procedure.
6/1/2022	For custom foot orthotics, expanded code range to include codes between L3000-L3030.

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9/1/2021	Under "Other Procedures" added code 20604 to the limitation of three procedures every six months.
5/1/2020	Removed gait analysis (96000-96004) from the Exclusions section as it was transitioned to the Resource Coordination policy, Non-Covered Technologies, 1370/20.000444.

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MEDICAL POLICY

Medical Policy Title	**Gastric Electrical Stimulation**
Policy Number	**7.01.64**
Current Effective Date	**September 1, 2026**
Next Review Date	**January 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

Gastric electrical stimulation (GES)/gastric pacing is considered **investigational** for all indications, including, but not limited to, gastroparesis, to predict success of GES with temporary stimulation, any other gastrointestinal dysmotility disorder, and obesity.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

The U.S. Food and Drug Administration (FDA) granted Humanitarian Device Exemption (HDE) approval for the Enterra Therapy GES system (Medtronic, Inc.) in 2000. Under this exemption, the device is indicated for the treatment of chronic, intractable (drug-refractory) nausea and vomiting associated with gastroparesis of diabetic or idiopathic origin, in patients who have failed, cannot tolerate, or have contraindications to pharmaceutical therapy (FDA 2000). See Regulatory Status.

DESCRIPTION

Gastric electrical stimulation (GES), also referred to as gastric pacing, uses electrodes implanted on the antrum of the stomach to increase gastric contractions to aid peristaltic activity and to improve gastric emptying. There are currently two methods of electrical delivery, high energy/low frequency (gastric pacing) which has had only limited use in humans, and low energy/high frequency pulsing (neurostimulation). Gastric neurostimulators can be implanted permanently via laparoscopy or laparotomy, or temporarily placed to aid in the prediction of permanent placement success.

GES has been investigated primarily as a treatment for gastroparesis, a chronic disorder of gastric motility characterized by delayed emptying stomach in the absence of a mechanical obstruction. Currently available devices consist of a pulse generator, which can be programmed to provide electrical stimulation at different frequencies, connected to intramuscular stomach leads, which are implanted during laparoscopy or open laparotomy.

GES has also been investigated as a treatment of obesity. It is used to increase a feeling of satiety

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with subsequent reduction in food intake and weight loss. The exact mechanisms resulting in changes in eating behavior are uncertain but may be related to neurohormonal modulation and/or stomach muscle stimulation.

SUPPORTIVE LITERATURE

Gastric Electrical Stimulation for the Treatment of Gastroparesis

For individuals who have gastroparesis who receive GES, the evidence includes nonrandomized studies, randomized controlled trials (RCTs) and systematic review and meta-analysis of RCTs. Several crossover RCTs have been published. Relevant outcomes are symptoms and treatment-related morbidity.

The evidence available from studies is insufficient to support that gastric electrical stimulation is effective for the treatment of patients with gastroparesis. Though the evidence does suggest that GES can relieve nausea and vomiting and may also reduce the need for nutritional support in some patients with intractable gastroparesis, there was no documentation of improved gastric emptying or enhanced gastric motility. The studies included small numbers of patients, had limited follow-up, and were inadequate to establish that GES is an effective or durable treatment for gastroparesis. Long-term results of GES need to be validated in longer-term, randomized trials.

The data presented to the FDA documenting probable benefit of the GES system were based on a multi-center, double-blind crossover study referred to as the Worldwide Anti-vomiting Electrical Stimulation Study (WAVESS) (Abell 2003). The study included 33 patients with intractable idiopathic or diabetic gastroparesis. In the initial phase of the study, all patients underwent implantation and were randomly and blindly assigned to either stimulation ON or stimulation OFF for the first month of the study, with crossover to the opposite mode for the second month. The baseline vomiting frequency was 47 episodes per month, which declined in both the ON mode and the OFF mode to 23 and 29 episodes, respectively. However, no statistically significant differences in the number of vomiting episodes were found between the OFF and ON groups, suggesting a placebo effect. In questioning patients as to which month of treatment they preferred (ON versus OFF), a greater number of patients preferred the month of treatment in the ON mode. In the second phase of the study, patients received stimulation consistent with their preference for the ON or OFF mode. At six- and 12-month follow-up, vomiting episodes continued to decline, although only 15 patients were available for follow-up.

Abell et al (2011) evaluated temporary GES in a randomized, placebo-controlled, crossover trial of 58 patients with gastroparesis symptoms. The study measured the effects of 72 hours of temporary GES on gastroparesis symptoms and consisted of two consecutive 4-day sessions (session 1 and session 2). In session 1, vomiting decreased in both groups, greater with stimulation, resulting in a day 3 difference of −1.02 ($p < .001$). Scores did not return to baseline during washout, and on day 4 the difference persisted at −1.08 ($p = .005$). In session 2, vomiting slightly decreased with stimulation and slightly increased without it. At day 8, the nonactivated group had non-significantly greater vomiting ($p = .762$). An overall treatment effect of a slight, non-significant daily decrease in average vomiting scores ($p = .116$) was observed by pooling stimulation effects across sessions.

Levinthal et al (2017) conducted a meta-analysis of 5 RCTs (n=185) and 13 non-RCTs did not find a significant benefit of GES on the severity of symptoms associated with gastroparesis (Levinthal 2017). Patients generally reported improved symptoms at follow-up whether or not the device was turned on, suggesting a placebo effect.

Ducrotte et al (2020) evaluated permanent GES, utilizing Enterra System, in a cross-over trial of 172 patients diagnosed with refractory and chronic vomiting. After GES implantation, patients were randomized to receive stimulation or no stimulation, then were crossed over to the other treatment after 4 months. The primary endpoints were vomiting score (0 is daily vomiting and 4 is no vomiting) and the Gastrointestinal Quality of Life Index. The median vomiting score with device turned on was 2, compare to a vomiting score of 1 with the device turned off ($p<.002$). However, over 50% of patients reported similar vomiting scores during the on and off period. There was no difference between groups in the quality-of-life measure (73.3 in the on phase and 71.1 in the off; $p=.06$). Delayed gastric emptying was not different in the on versus off period. Limitations of this trial include the use of an unvalidated scale for the primary endpoint, inclusion of only refractory patients, and only 4-month duration of treatment. The authors concluded that this trial showed that GES is effective in reducing the frequency of refractory vomiting and nausea in a subset of patients with chronic vomiting.

Saleem et al (2024) conducted a systematic review and meta-analysis to address the limited use of gastric electrical stimulation (GES) due to conflicting results of studies. The authors aimed to assess the efficacy of GES for patients with gastroparesis and gastroparesis-like symptoms. A total of nine RCT (n=730 participants), which included seven blinded trials and a large (n=172 participants) cross over study by Durcotte and colleagues in 2020. Included studies were deemed of moderate quality and low risk of bias. Outcomes were divided into blind RCTs and open trials. Pooled blinded RCT studies showed positive significant results in total symptoms score (TSS) with the GES group compared with controls at the 4-day, 2-month, 4-month, and sustained at the 12-month follow-up (-4.5 to -7.65; $p<.00001$). The analysis of blinded RCT showed no significant difference between the groups in frequency of weekly vomiting episodes (WVF) (MD= 1.76; $p = 0.43$); in contrast, the analysis of open trials showed significant positive results in WVF ($p<0.00001$). The open trials analysis found significant positive results ($p<0.00001$) in TSS, in pre- and post-nausea symptoms severity (NSS), and in vomiting severity symptoms (VSS) at 12 months after treatment ($p<0.00001$). A significant positive result in gastric emptying retention after two hours or four hours after treatment. The total analysis favored post-GES compared with pre-GES (MD = 18.15% gastric retention; 95% CI, 13.05−23.35; $p<0.00001$). Limitations of this analysis include significant heterogeneity among studies that could not be resolved due to high variation of follow-up durations, the use of a variety of different scoring systems which limited the number of studies that could combined into summary statistics, and the possibility of confounding effects from concurrent pharmacologic therapy that were not controlled. The authors concluded that GES appears beneficial, with significant improvement in TSS, weekly vomiting frequency, gastric emptying study and quality of life. Additional blinded RCTs could further establish the criteria for patient selection and GEST settings for optimal effects.

Cassidy et al (2024) conducted a prospective, single-center cohort study evaluating clinical outcomes

of gastric electrical stimulation (GES) in 157 adults with refractory gastroparesis managed through a multidisciplinary preoperative optimization protocol. Patients were followed for up to five years, with outcomes assessed using the Gastroparesis Cardinal Symptom Index (GCSI), medication usage, hospitalization rates, patient satisfaction, and device-related interventions. The authors reported significant and sustained improvement in symptom severity across all GCSI domains at 1- and 5-years post-implantation ($p < 0.05$). Medication use, particularly prokinetic and antiemetic agents, decreased substantially, and gastroparesis-related hospitalizations were reduced by 91% at one year compared to baseline ($p < 0.05$). Patient satisfaction remained high (87.1% at 1 year; 79.7% at 5 years). Device-related complications, including lead dislocation and erosion, were infrequent, with explantation occurring in fewer than 3% of patients. Limitations included the lack of a randomized control group, single-center design, and potential selection bias, which reduce the certainty of evidence and limit generalizability. The study concluded that, in carefully selected and medically optimized patients, GES can provide durable symptom relief and reduce healthcare utilization, supporting its role as part of a multidisciplinary treatment approach for refractory gastroparesis.

Gastric Electrical Stimulation for the Treatment of Obesity

Shikora et al (2009) reported on a double-blind RCT that assessed GES for the treatment of obesity. In the Screened Health Assessment and Pacer Evaluation (SHAPE) trial, all participants (n=190) received an implantable gastric stimulator and were randomized to have the stimulator turned on or off. All patients were evaluated monthly, participated in support groups, and reduced their dietary intake by 500 kcal/d. At 12-month follow-up, there was no statistically significant difference in excess weight loss between the treatment group (weight loss, 11.8%) and the control group (weight loss, 11.7%) using intention-to-treat analysis (p=.717).

Small case series and uncontrolled prospective trials (2002 to 2004) have reported positive outcomes for weight loss and maintenance of weight loss along with minimal complications (Cigaina 2002 and 2003; D'Argent 2004; De Luca 2004; Favretti 2004). However, interpretation of these uncontrolled studies is limited.

Paulus et al (2020) conducted a multi-center, phase 1, open prospective clinical trial to assess the safety of the Exilis gastric electrical stimulation (GES) system and to investigate whether the settings can be adjusted for comfortable chronic use in subjects with morbid obesity. Gastric emptying and motility and meal intake were evaluated. Participants (n=20) were implanted with the Exilis and underwent two blinded baseline test days (GES ON versus OFF), after which long-term, monthly follow-up continued for up to 52 weeks. The procedure was safe, and electrical stimulation was well tolerated and comfortable in all subjects. No significant differences in gastric emptying halftime ($p > 0.05$), food intake ($p > 0.05$), insulin AUC ($p > 0.05$), and glucose AUC ($p > 0.05$) were found between GES ON and OFF. At week 4, 13, and 26, a significant ($p < 0.01$) reduction in weight loss was observed but not at week 52. The authors concluded that GES with the Exilis system was considered safe, reduction in weight loss was significant by short lasting. Further research is needed to gain insight in optimal stimulation paraments and lead localization.

PROFESSIONAL GUIDELINE(S)

In 2025, Staller et al published the American Gastroenterological Association (AGA) Clinical Practice Guideline on Management of Gastroparesis, issuing a conditional recommendation against the routine use of GES for the treatment of refractory gastroparesis. Based on a very low certainty of evidence, the AGA recommends reserving this procedure for select patients with medically refractory gastroparesis.

In 2022, the American College of Gastroenterology (ACG) Clinical Guidelines for Gastroparesis states that GES may be considered for control of gastroparesis symptoms as a humanitarian use device (conditional recommendation, low quality of evidence) (Camilleri 2022).

In 2014, the National Institute for Health and Care Excellence (NICE) issued evidence-based guidance on GES for gastroparesis that the current evidence on the efficacy and safety of gastric electrical stimulation for gastroparesis is adequate to support the use of this procedure with normal arrangements for clinical governance, consent, and audit. NICE acknowledged that some patients do not get any benefit from GES and recommend that patients should be informed of this during the consent process.

REGULATORY STATUS

The Enterra Therapy System (Medtronic) was granted FDA approval in 2000 under the Humanitarian Device Exemption (HDE) program and received an MRI-conditional labeling upgrade in 2024.

HDE is an FDA regulatory pathway for Class III medical devices intended to treat or diagnose conditions affecting no more than 8,000 individuals in the United States per year. Under HDE, manufacturers are exempt from demonstrating effectiveness; instead, FDA must determine that the device does not pose an unreasonable or significant risk and that the probable benefit outweighs the potential risks. As mandated by federal regulations, use of an HDE device requires approval and oversight by an Institutional Review Board (IRB) or an appropriate local committee to ensure compliance with the FDA-approved indication(s) (FDA 2019).

Currently, no GES devices have received FDA approval for any other indication, including for the treatment of obesity. Transneuronix, Inc., acquired by Medtronic in 2005, developed an implantable gastric stimulator, Transcend IGS, which is available in Europe for treatment of obesity.

The United States Food and Drug Administration (FDA) regulates gastric electrical stimulators as medical devices. All gastric electrical stimulators require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Dec 11]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. on our website by the date that the FDA posts the information on our website. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls-and-early-alerts [accessed 2025 Dec 11]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
43647 (E/I)	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum
43648 (E/I)	revision or removal of gastric neurostimulator electrodes, antrum
43881 (E/I)	Implantation or replacement of gastric neurostimulator electrodes, antrum, open
43882 (E/I)	Revision or removal of gastric neurostimulator electrodes, antrum, open
64590	Insertion or replacement of peripheral or gastric neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal peripheral or gastric neurostimulator pulse generator or receiver
95980 (E/I)	Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient measurements) gastric neurostimulator pulse generator/transmitter; intraoperative, with programming
95981 (E/I)	subsequent, without reprogramming
95982 (E/I)	subsequent, with reprogramming

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HCPCS Codes

Code	Description
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1787	Patient programmer; neurostimulator
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system

Code	Description
L8679	Implantable neurostimulator, pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non- rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implanted neurostimulator, replacement only

ICD10 Codes

Code	Description
E66.01 – E66.9	Overweight and obesity (code range)
E08.43	Diabetes mellitus due to underlying condition with diabetic autonomic (poly)neuropathy
E09.43	Drug or chemical induced diabetes mellitus with neurological complications with diabetic autonomic (poly)neuropathy
E10.43	Type 1 diabetes mellitus with diabetic autonomic (poly)neuropathy
E11.43	Type 2 diabetes mellitus with diabetic autonomic (poly)neuropathy
E13.43	Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy
K31.84	Gastroparesis

Code	Description
R11.0 - R11.2	Nausea and vomiting (code range)

REFERENCES

Abell TL, et al. A double-masked, randomized, placebo-controlled trial of temporary endoscopic mucosal gastric electrical stimulation for gastroparesis. Gastrointest Endosc. 2011 Sep;74(3):496–503.e3.

Abell TL, et al. Gastric electrical stimulation for medically refractory gastroparesis. Gastroenterol. 2003 Aug;125(2):421-8.

Camilleri M, et al. ACG clinical guideline: gastroparesis. Am J Gastroentrol. 2022 Aug 01;117(8):1197-1220. PMID: 35926490.

Cassidy DJ, et al. Clinical outcomes of a large, prospective series of gastric electrical stimulation patients using a multidisciplinary protocol. J Am Coll Surg. 2024 Oct 1;239(4):341-346.

Chu H, et al. A meta-analysis: The treatment of high-frequency gastric electrical stimulation for gastroparesis. J Gastroenterol Hepatol. 2012 Jun;27(6):1017-26.

Cigaina V. Gastric pacing as therapy for morbid obesity: preliminary results. Obes Surg. 2002 Apr;12(Suppl 1):12S-6S.

Cigaina V, et al. Gastric pacing for morbid obesity: plasma levels of gastrointestinal peptides and leptin. Obes Res. Dec 2003;11(12):1456-62. PMID 14694209

D'Argent J. Gastric electrical stimulation as therapy of morbid obesity: preliminary results from the french study. Obes Surg. 2002 Apr;12(Suppl 1):21S-5S.

Ducrotte P, et al.; ENTERRA research group. Gastric electrical stimulation reduces refractory vomiting in a randomized crossover trial. Gastroenterology. 2020 Feb;158(3):506-514.e2.

Favretti F, et al. Treatment of morbid obesity with the Transcend implantable gastric stimulator (IGS): a prospective survey. Obes Surg. 2004 May;14(5):666-70. PMID 15186636

Gourcerol G, et al; ENTERRA research group. impact of gastric electrical stimulation on economic burden of refractory vomiting: a French nationwide multicentre study. Clin Gastroenterol Hepatol. 2022 Aug;20(8):1857-1866.e1. Epub 2020 Nov 13.

Lacy et al., AGA Clinical Practice Update on Management of Medically Refractory Gastroparesis: Expert Review. Clin Gastroenterol and Hepatol. 2022 Mar:20:491-500.

Li WJ, et al. Perioperative transcutaneous electrical acupoint stimulation for improving postoperative gastrointestinal function: A randomized controlled trial. J Integr Med. 2021 May;19(3):211-218.

Maisiyiti A and Chen JD. Systematic review on gastric electrical stimulation in obesity

treatment. Expert Rev Med Devices. 2019 Oct;16(10):855-861.

McCallum RW, et al. Gastric electrical stimulation with Enterra therapy improves symptoms from diabetic gastroparesis in a prospective study. Clin Gastroenterol Hepatol. 2010 Nov;8(11):947-54; quiz e116.

McCallum RW, et al. Gastric electrical stimulation with Enterra therapy improves symptoms of idiopathic gastroparesis. Neurogastroenterol Motil. 2013 Oct;25(10):815-e636.

National Institute for Clinical Excellence (NICE). Guidance [Internet]. Gastroelectrical stimulation for gastroparesis. Interventional procedures guidance [IPG489]. 2014 May [accessed 2025 Dec 3]. Available from: https://www.nice.org.uk/guidance/ipg489

Paulus G, et al. Multicenter, Phase 1, open prospective trial of gastric electrical stimulation for the treatment of obesity: First-in-human with a novel implantable system. Obes Surg. 2020 May; 30,1952–1960.

Rajamanuri M, et al. A systematic review of the therapeutic role of gastric pacemakers in adults with gastroparesis. Cureus. 2021 Sep;13(9):e18152.

Saleem S, et al. Gastric electrical stimulation for the treatment of gastroparesis or gastroparesis-like symptoms: A systemic review and meta-analysis. Neuromodulation. 2024 Feb;27(2):221-228 Epub 2022 Dec 2. PMID 36464562

Samann JS, et al. Gastric electric stimulator versus gastrectomy for the treatment of medically refractory gastroparesis Surgical. Endoscopy. 2022 Mar; 36:7561-7568.

Setya A, et al. Gastric electrical stimulation: An emerging therapy for children with intractable gastroparesis. World J Gastroenterol. 2019 Dec 28;25(48):6880-6889.

Shada A, et al. Wisconsin's Enterra therapy experience: A multi-institutional review of gastric electrical stimulation for medically refractory gastroparesis. Surgery. 2018 Oct;164(4):760-765.

Shikora SA, et al. Implantable gastric stimulation for the treatment of clinically severe obesity: Results of the SHAPE trial. Surg Obes Relat Dis. 2009 Jan-Feb;5(1):31-37. Epub 2008 Oct 1.

Soliman H and Gourcerol G. Gastric electrical stimulation: role and clinical impact on chronic nausea and vomiting. Frontiers in Neuroscience. 2022 May 10;16:909149.

Staller K, et al.; AGA Clinical Guidelines Committee. AGA clinical practice guideline on management of gastroparesis. Gastroenterology. 2025 Oct;169(5):828-861.

U.S. Food and Drug Administration [Internet]. Guidance document: Humanitarian Device Exemption (HDE) program. 2019 Sep [accessed 2025 Dec 17]. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-device-exemption-hde-program

U.S. Food and Drug Administration. [Internet]. Humanitarian Device Exemption (HDE); Gastric electrical stimulation (GES) system. Enterra Medical. Decision date 2000 Mar 31 [accessed 2025 Dec 3]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfhde/hde.cfm?id=h990014

Yin J, et al. Gastric neuromodulation with Enterra System for nausea and vomiting in patients with

gastroparesis. Neuromodulation. 2012 May-Jun;15(3):224-31.

Zoll B, et al. Gastric electric stimulation for refractory gastroparesis. J Clin Outcomes Manag. 2019 Jan;26(1):27-38

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Gastric electrical stimulation is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 5/26

Revised:

Reviewed:

Date	Summary of Changes
9/1/2026	• New: Service was previously referenced on Non-Covered Technology policy 1370/20.000444.

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: GENDER REASSIGNMENT THERAPIES

POLICY EFFECTIVE DATE:	2/1/2026
Policy Control #:	1370/20.000447
Next Annual Review:	September 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

Various Codes

DESCRIPTIONS

Gender reassignment therapy encompasses all the psychological, medical and surgical procedures involved in the transition from one gender presentation to another and may include hormone replacement therapy and various surgical procedures as well as psychological counseling and an extended period of time living completely in the desired gender role.

In accordance with the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders, Fifth edition (DSM-5), gender dysphoria in adolescents and adults is defined as:

A. A marked incongruence between one's experienced/expressed gender and assigned gender, of at least six months duration, as manifested by at least two of the following:
    1. A marked incongruence between one's experienced/expressed gender and primary and/or secondary sex characteristics (or in young adolescents, the anticipated secondary sex characteristics).
    2. A strong desire to be rid of one's primary and/or secondary sex characteristics because of a marked incongruence with one's experienced/expressed gender (or in young adolescents, a desire to prevent the development of the anticipated secondary sex characteristics).
    3. A strong desire for the primary and/or secondary sex characteristics of the other gender.

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4. A strong desire to be of the other gender (or some alternative gender different from one's assigned gender).
5. A strong desire to be treated as the other gender (or some alternative gender different from one's assigned gender).
6. A strong conviction that one has the typical feelings and reactions of the other gender (or some alternative gender different from one's assigned gender).

B. The condition is associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

Experimental or Investigational Services, 11.01.03

Pharmacy Policies:

Gender Affirming Pharmacological Therapies, 1350/20.000535

POSITION STATEMENT

CDPHP administers benefits for medically necessary gender reassignment therapies when all of the clinical criteria, and supporting provider documentation, outlined below are met:

General Surgical Criteria

The following requirements must be met for health care professionals assessing transgender and gender diverse adults for physical treatments:

- Licensed by their statutory body and hold, at a minimum, a master's degree or equivalent training in a clinical field relevant to this role and granted by a nationally accredited statutory institution.
- Competent using the latest edition of the World Health Organization's International Classification of Diseases (ICD) for diagnosis. practicable.
- Ability to identify co-existing mental health or other psychosocial concerns and distinguish these from gender dysphoria, incongruence, and diversity.
- Ability to assess capacity to consent for treatment.
- Have experience or be qualified to assess clinical aspects of gender dysphoria, incongruence, and diversity.
- Undergo continuing education in health care relating to gender dysphoria, incongruence, and diversity.
- Liaise with professionals from different disciplines within the field of transgender health for consultation and referral, if required.

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POLICY NAME: GENDER REASSIGNMENT THERAPIES

The following medical necessity criteria for gender-affirming medical and surgical treatment must all be met:

- Health care professionals assess transgender and gender diverse (TGD) adults for gender-affirming medical and surgical treatment:
- Treatment is requested by a TGD person when the experience of gender incongruence is marked and sustained.
- Ensure fulfillment of diagnostic criteria prior to initiating gender-affirming treatments
- Identify and exclude other possible causes of apparent gender incongruence prior to the initiation of gender-affirming treatments.
- Ensure that any mental health conditions that could negatively impact the outcome of gender-affirming medical treatments are assessed, with risks and benefits discussed, before a decision is made regarding treatment.
- Ensure any physical health conditions that could negatively impact the outcome of gender-affirming medical treatments are assessed, with risks and benefits discussed, before a decision is made regarding treatment.
- Assess the capacity to consent for the specific physical treatment prior to the initiation of this treatment.
- Assess the capacity of the gender diverse and transgender adult to understand the effect of gender-affirming treatment on reproduction and explore reproductive options with the individual prior to the initiation of gender-affirming treatment.
- As part of the assessment for gender-affirming hormonal or surgical treatment, professionals who have competencies in the assessment of transgender and gender diverse people wishing gender-related medical treatment consider the role of social transition together with the individual.
- Transgender and gender diverse adults who fulfill the criteria for gender-affirming medical and surgical treatment require a single opinion for the initiation of this treatment from a professional who has competencies in the assessment of transgender and gender diverse people wishing gender-related medical and surgical treatment.

Surgical (Irreversible) Intervention

1. Requirements for mastectomy for transitioning individuals assigned female at birth:

    - All criteria above under General Surgical Criteria is met; and
    - Surgeons assess transgender and gender diverse people for risk factors associated with breast cancer prior to breast augmentation or mastectomy.
    - **I**f the member is under 18 years of age, **ONE** of the following additional criteria must be met:
        - The qualified professional's letter documents the member's emotional and

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cognitive maturity required to provide informed assent for the mastectomy

or

- The surgeon documents documentation that all legally responsible parties (e.g., parent[s] or guardian[s]) consent to the mastectomy and confirm the surgery aligns with the member's needs and wishes.

2. Requirements for gonadectomy (hysterectomy oophorectomy, salpingectomy for transitioning individuals assigned female at birth; and orchiectomy for transitioning individuals assigned male at birth):
   - All criteria above under General Surgical Criteria is met; and
   - Age 18 years or older; *and*
   - Surgeons confirm reproductive options have been discussed with the individual prior to gonadectomy; *and*
   - Evidence they have tolerated a minimum of 6 months of hormone therapy (unless hormone replacement therapy or gonadal suppression is not clinically indicated or the procedure is inconsistent with the patient's desires, goals, or expressions of individual gender identity).

3. Requirements for genital reconstructive surgery (i.e., vaginectomy, urethroplasty, metoidioplasty, phalloplasty, scrotoplasty, and placement of a testicular prosthesis and erectile prosthesis for transitioning individuals assigned female at birth; penectomy, vaginoplasty, vulvoplasty,labiaplasty, and clitoroplasty for transitioning individuals assigned male at birth):
   - All criteria above under General Surgical Criteria is met; and
   - Age 18 years and older; *and*
   - If significant medical or mental health concerns are present, they must be reasonably well controlled; *and*
   - At least six months of continuous hormone therapy as appropriate to the member's gendergoals (unless it is documented within the clinical record that the member has a medical contraindication or is otherwise unable to take hormones); *and*
   - Twelve months of living in a gender role that is congruent with their gender identity (real life experience).

Procedures Covered with an Administrative Review of a Qualified Medical Professional's Determination of Medical Necessity

Please note: Prior Authorization Coverage will be available for the following gender reassignment surgeries, services, and procedures, based upon an administrative prior authorization review of a determination of medical necessity made by a qualified medical professional as stated above under General Surgical Criteria section:

- Mastectomy, reduction mammoplasty, hysterectomy, salpingectomy, oophorectomy,

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vaginectomy, urethroplasty, metoidioplasty, phalloplasty, scrotoplasty, penectomy, orchiectomy, vaginoplasty, labiaplasty, clitoroplasty, and/or placement of a testicular prosthesis and penile prosthesis

- Breast augmentation provided that the patient has completed a minimum of 6 months or more of hormone therapy as clinically indicated based on whether the individual has had sufficient benefit from hormone treatment prior to surgery.
- Electrolysis when required for vaginoplasty or phalloplasty.
    - Note: Authorization/approval for vaginoplasty/phalloplasty needs to be granted prior to approval for electrolysis.

Procedures Covered with Justification of Medical Necessity: Prior Authorization Required

Benefits are not provided for any procedures that are performed solely for the purpose of improving an individual's appearance. The following procedures and services will not be covered, unless justification of medical necessity for treatment of the member's gender dysphoria is provided and prior authorization is received following the criteria outlined above under General Surgical Criteria.

- Abdominoplasty, blepharoplasty, neck tightening, or removal of redundant skin
- Breast augmentation
- Breast, brow, face, or forehead lifts
- Brow reduction, augmentation
- Calf, cheek, chin, nose, hip or pectoral implants
- Collagen injections
- Drugs to promote hair growth or loss
- Electrolysis, unless required for vaginoplasty or phalloplasty
- Facial bone reconstruction, reduction, or sculpturing, including jaw shortening and Rhinoplasty
- Facelift/mid-facelift (following alteration of underlying skeletal structure) (+/- Platysmaplasty)
- Gluteal augmentation
- Hair transplantation and/or hair line advancement
- Lip reduction/Lip augmentation
- Liposuction
- Monsplasty or mons reduction
- Tattooing (i.e., nipple-aereola)
- Thyroid chondroplasty (i.e., Tracheal shave)
- Voice surgery
- Speech Therapy/Voice Coaching

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POLICY NAME: GENDER REASSIGNMENT THERAPIES

POLICY CONSIDERATIONS

The medical necessity criteria in this policy are based upon the Standards of Care (SOC) for the Health of Transgender and Gender Diverse People, Eighth Version, published by the World Professional Association for Transgender Health (WPATH) (2022), The Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5). American PsychiatricAssociation, and NYS Law 18 CRR-NY 505.2 on Gender Dysphoria Treatment.

Gender reassignment surgery and related services, determined to be medically necessary, are covered under the enrollee's medical benefit unless such services are specifically identified as a contract exclusion.

The following related non-surgical treatment services are covered without need for medical necessity review:

- Comprehensive primary care services including all preventive care.
- Mental health care consisting of ambulatory, intermediate, and acute services for psychiatric and substance use disorders, including psychotherapy related to gender dysphoria, but also to address any issues that may interfere with the desired transition.
- Reproductive & Sexual Health Care including the following:
  - Office based care by PCP, OB/GYN, urologist, endocrinologist.
  - All recommended gynecological and urological cancer screenings before, during, and ongoing after gender affirming treatments.
  - Contraception (including for menstrual suppression)

Detransitioning: Please note that gender affirming surgery is generally considered an irreversible intervention. Although infrequent, reversal of prior gender affirming surgery may be covered when the medical necessity criteria for the requested treatment above are met.

Health care professionals assessing adults who wish to detransition and seek gender-related hormone intervention, surgical intervention, or both, should utilize a comprehensive multidisciplinary assessment that will include additional viewpoints from experienced health care professional in transgender health and that considers, together with the individual, the role of social transition as part of the assessment process

Requests for gender reassignment surgery for patients with chromosomal abnormalities will be reviewed on an individual case basis.

The Endocrine Society published a clinical practice guideline for endocrine treatment of transsexual persons (2009). As part of this guideline, the Endocrine Society recommends that transsexual persons consider genital sex reassignment surgery only after both the physician responsible for endocrine transition therapy and the mental health professional find surgery advisable; that surgery be recommended only after completion of at least one year of consistent

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POLICY NAME: GENDER REASSIGNMENT THERAPIES

and compliant hormone treatment, (unless it is documented within the clinical record that the member has a medical contraindication or is otherwise unable or unwilling to take hormones); and that the physician responsible for endocrine treatment medically clear the individual for sex reassignment surgery and collaborate with the surgeon regarding hormone use during and after surgery.

- For both adults and adolescents, hormonal treatment for gender dysphoria must be administered and monitored by a qualified healthcare practitioner as therapy requires ongoing medical management, including physical examination and laboratory evaluation studies to manage dosage, side effects, etc. Lifelong maintenance is usually required.

In regard to procedures that involve reassignment of gender, CDPHP accepts the enrollee's treating provider's determination of the enrollee's anatomical/body part size, shape, feature, presentation, or assessment as part of those procedures' service coverage criteria.

- Photographic documentation is not required as part of the authorization process.

Surgical Revision/Correction

If a surgical revision or correction becomes medically necessary for a previously approved surgical treatment, the revision/correction will be treated as related to the original approved surgical treatment and not as a completely new gender affirming procedure requiring a new and separate prior authorization process. This does not include reversals of gender affirming surgical procedures in cases of regret.

EXCLUSIONS

Conversion therapy is not a covered benefit. Conversion therapy refers to any practice by a mental health professional that seeks to change an individual's sexual orientation or gender identity, including efforts to change behaviors, gender expressions, or to eliminate or reduce sexual or romantic attractions or feelings toward individuals of the same sex.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS: Subject to all terms and conditions noted above in the policy.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted above in the policy.

SELECT PLAN/HARP: Subject to all terms and conditions noted above in the policy.

In addition, the following will apply:

- Cryopreservation, storage, and thawing of reproductive tissue, and all related services and charges are not a covered benefit.
- CDPHP will provide for at least one attempt to conduct a

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peer-to-peer consultation with the ordering provider prior to issuing any adverse determination.

As per DFS, although the minimum age for Medicaid coverage of gender reassignment surgery is generally 18 years of age, the revised regulations allow for coverage for individuals under 18 in specific cases if medical necessity is demonstrated and prior approval is received.

SOURCES OF INFORMATION

1. American Psychiatric Association (2013). *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5™), pp. 452-459.
2. Becker S, Bosinski HA, Clement U, et al. Standards for treatment and expert opinion on transsexuals. The German Society for Sexual Research, The Academy of Sexual Medicine and the Society for Sexual Science. Fortschr Neurol Psychiatr. 1998;66(4):164-169.
3. CDPHP contract language.
4. Becker S, Bosinski HA, Clement U, et al. Standards for treatment and expert opinion on transsexuals. The German Society for Sexual Research, The Academy of Sexual Medicine and the Society for Sexual Science. Fortschr Neurol Psychiatr. 1998;66(4):164-169.
5. Centers for Medicare and Medicaid Services. National Coverage Determination: Transsexual Surgery. NCD #140.3. http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd. Accessed 3/7/2008.
6. Centers for Medicare and Medicaid Services Manual System, Transmittal 169: Invalidation of National Coverage Determination 140.3 – Transexual Surgery, 6/27/14, http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R169NCD.pdf
7. Department of Health and Human Services Departmental Appeals Board Appellate Division Decision No. 2576, NCD 140.3 Transexual surgery, http://www.hhs.gov/dab/decisions/dabdecisions/dab2576.pdf
8. Day P. Trans-gender Reassignment Surgery. Tech Brief Series. New Zealand Health Technology Assessment. NZHTA Report February 2002, Volume 1, Number 1. Accessed October 12, 2007. Available at URL address: http://nzhta.chmeds.ac.nz/publications.htm#tech
9. World Professional Association for Transgender Health. The Harry Benjamin International Gender Dysphoria Association's Standards of Care for Gender Identity Disorders - 8th Version. February 2023, https://www.wpath.org/soc8/chapters
10. World Professional Association for Transgender Health. Standards of Care for the Health of Transsexual, Transgender, and Gender Non-Conforming People - 7th Version, September 2011, www.wpath.org
11. MedlinePlus. Gender Dysphoria, http://www.nlm.nih.gov/medlineplus/ency/article/001527.htm
12. HAYES Medical Technology Directory™. Sex reassignment surgery and associated therapies for the treatment of gender identity disorder. Lansdale, PA: HAYES, Inc.; ©2006 Winifred S. Hayes, Inc. 2004 Dec 1. Last updated search 1/2009.

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13. Other payers.
14. Hembree W, Cohen-Kettenis P, Delemarre-van de Waal, et.al. Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline. Journal of Clinical Endocrinology Metabolism, September 2009, 94(9):3132-3154.
15. March 2015 Medicaid Update article, "New York State Medicaid Updates Regulations", http://www.health.ny.gov/health_care/medicaid/program/update/2015/mar15_mu.pdf.
16. Regulations at 18 NYCRR § 505.2(l) outline the specific requirements, under both New York State fee-for-service Medicaid and Medicaid Managed Care, for coverage of transition-related care and services for persons diagnosed with gender dysphoria https://govt.westlaw.com/nycrr/Document/I50d12a98cd1711dda432a117e6e0f345?viewType=FullText&originationContext=documenttoc&transitionType=CategoryPageItem&contextData=(sc.Default)
17. Centers for Medicare and Medicaid Services. Decision Memo for Gender Dysphoria and Gender
Reassignment Surgery (CAG-00446N), August 30, 2016.
https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=282
18. NYS Department of Health Medicaid Update: Conversion Therapy, February 2016 Volume 32 Number 02, https://www.health.ny.gov/health_care/medicaid/program/update/2016/2016-02.htm
19. NYS Department of Health Medicaid Update: Gender Reassignment Surgery Update, April 2017 Volume 33 - Number 4 https://www.health.ny.gov/health_care/medicaid/program/update/2017/apr17_mu.pdf
20. New York State Department of Health Office of Health Insurance Programs Notification: Criteria Standards for the Authorization and Utilization Management of Hormone Therapy and Surgery for the Treatment of Gender Dysphoria, effective 9/1/18.
21. NYS statutes and regulations including, but not limiting to, 42 CFR Part 438, New York State Public Health Law Article 49, 18 NYCRR 505.2(l) and the Medicaid Managed Care/Family Health Plus/HIV Special Needs Plan/Health and Recovery Plan Model Contract.

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POLICY APPROVAL DATES

New:	05/08
Revised:	05/09, 05/11, 05/12, 05/14, 09/14, 03/15, 05/15, 01/16, 12/16, 05/17, 09/18, 11/19, 11/20, 10/23, 4/24, 8/24, 3/26

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Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.
(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: GENDER REASSIGNMENT THERAPIES

Reviewed: 05/10, 05/13, 05/18, 05/19, 7/21, 05/22, 05/23, 5/24, 9/26

POLICY HISTORY

Effective Date	Update
2/1/2026	Mandatory updates added to policy as per Office of Mental Health Standard of Care Version 81 (SOC 8).
9/1/2024 *No change to effective date for this update	Updated verbiage for male to female and female to male procedures. Removed additional coverage criteria from Medicare Advantage section.
9/1/2024	Removed Hormone Therapies section from policy as a separate pharmacy policy was created for these treatments. Added Gender Affirming Pharmacological Therapies 1350/20.000535 to the Related Policies section. Updated references to WPATH SOC 8 guidelines. Added statement about coverage for Detransitioning.
7/1/2024	Updated prior authorization requirements for surgical intervention section.
11/1/2023	Updated services in "prior authorization required" section, as clinical review is required for all.
1/1/2021	Revised in accordance with NYS regulations.

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(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: GENDER REASSIGNMENT THERAPIES

9/1/2021	Added reference to Experimental & Investigational policy. Added specific licensures to the term "Qualified mental health professional." Updated Medicare section under product variations – CMS only requires 1 letter for both top & bottom surgeries. Added DFS contract language for Medicaid under product variations – DFS allows for under 18 in specific cases if medical necessity is proven and PA obtained.

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Disclaimer Notice

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Background

Glycogen Storage Disease Type Ia, or Von Gierke Disease, is a subtype of autosomal recessive disorders caused by an inactivating mutation in G6PC, the gene that codes the glucose-6-phosphatase-a enzyme (G6Pase-a). Between meals, blood glucose homeostasis is maintained by G6PT and G6Pase-a that hydrolyzes G6P to glucose in the final step of gluconeogenesis and glycogenolysis in the liver, kidneys, and intestines. The G6PT transports G6P from the cytoplasm to the endoplasmic reticulum, where it should be hydrolyzed to glucose and inorganic phosphates by G6Pase-a. The detrimental mutation in G6Pase-a causes metabolic imbalance, primarily seen as severe hypoglycemia alongside increased G6P levels following a short period of not eating. This causes overactivation of other metabolic pathways causing ailments including hepatomegaly, hypercholesterolemia, lactic acidemia, osteoporosis, hepatocellular adenomas, and more.

GSD-1a affects around 6,000 people in commercially accessible geographies (areas where a sponsor can legally and operationally deliver investigational/approved products), with a disease prevalence of around 1 in 100,000, with around 80% of cases being type 1a. The mutation is genetically inherited, with the strongest risk factor being familial history of GSD-1a or other related GSD1 disorder. There are no known racial or ethnic risk factors for this disease. GSD-1a is often diagnosed early in life as a neonate or an infant. Some patients present with hypoglycemia and lactic acidosis in the neonatal period. However, most do not show clinical symptoms until they are a few months old, with symptomatic hypoglycemia or hepatomegaly often being the first symptom. Guidelines from the European Study on GSD-1 (eSGSD-1) recommend that diagnosis is initially made based on clinical presentation and biochemical abnormalities. Genetic testing for identification of pathogenic variants of the G6PC1 gene confirms diagnosis. If inconclusive, liver biopsies are often performed to assess the presence of mutation

The core goals of management of the disease is to maximize time in euglycemia, avoid fasting, and limit disease related metabolic complications. Children under 3 years old typically receive a nocturnal nasogastric infusion of glucose to avoid hypoglycemia. Patients over 3 years of age are prescribed uncooked cornstarch, which is a slow-releasing carbohydrate that prolongs euglycemia between meals. Dietary interventions are often effective with very few deaths or developmental effects, however, are disruptive to daily life and prone to error. About 95% of patients reported hypoglycemia despite their best efforts to manage it. Adjunct therapies have also been used to manage complications of the disease such as ACE-I for renal dysfunction and lipid lowering agents for hypercholesterolemia. Liver transplantation is considered for patients with unresectable hepatocellular adenomas that are not responsive to dietary therapy. If left untreated, adenomas can progress to severe compression, hemorrhage, and hepatocellular carcinomas.

Genglycos (pariglasgene brecaparvovec) utilizes a modified adeno-associated virus serotype 8 (AAV8) vector to deliver a functional copy of the G6Pase gene directly into the liver. Once delivered, liver cells are able to produce active G6Pase that respond to usual hormonal signals, such as insulin or cortisol. Accelerated approval was based on the Phase 3 GlucoGene Study (NCT05139316). The effectiveness of Genglycos was evaluated in a randomized, double-blind, placebo-controlled study in patients with GSDIa followed over 48 weeks after dosing. Patients treated with Genglycos demonstrated a statistically significant mean reduction from baseline in daily cornstarch intake of 31% compared to placebo, the study's primary endpoint. A mean reduction from baseline of one cornstarch dose per day was seen in the Genglycos group compared to placebo, the study's secondary endpoint. Genglycos-treated patients experienced a numerical (mean 3%) increase in the percentage of glucose values in the hypoglycemic range (< 70 mg/dL) compared to placebo.

Across two clinical studies of Genglycos including the randomized clinical study, serious adverse reactions reported in Genglycos-treated patients included anaphylaxis, adrenal insufficiency (a condition where the adrenal glands do not produce enough stress hormones), high lactate levels, and hypoglycemia. The most commonly reported adverse reactions included increased transaminases (elevation of liver enzymes), nausea, headache, constipation, and hyperglycemia. Genglycos-treated patients had a higher rate of hypertriglyceridemia (high blood triglyceride levels), a metabolic marker of GSDIa, compared to placebo-treated patients (29% vs 8%). The prescribing information contains warnings about the risks of anaphylaxis, liver toxicity, adrenal insufficiency, and risk of tumorigenicity (development of tumors). Genglycos should not be used during pregnancy.

Summary	
Effective Date of Policy:	10/1/2026
Indications	Reduce daily cornstarch intake as an adjunct to nutritional management in adult and pediatric patients 8 years of age and older with glycogen storage disease type Ia (GSDIa)
ICD10 Diagnosis Codes	E74.01
HCPCS	J3590 (non-specific)
Availability	suspension for intravenous infusion with a concentration of 3.0×10^{13} gc/mL
Duration	6 months to allow one-time administration

Required Criteria for Approval

Commercial/Essential/Exchange:

Based on a review of the available peer-reviewed evidence, pariglasgene brecaparvovec (Genglycos) is considered not medically necessary for the treatment of Glycogen Storage Disease Type 1a. (Von Gierke Disease)

In the 48 weeks, randomized, double-blind, placebo-controlled, phase 3 "GlucoGene" trial (NCT05139316), pariglasgene brecaparvovec demonstrated a statistically significant reduction in total daily cornstarch intake and frequency of cornstarch dosing. The study showed a 41.3% daily cornstarch dose reduction in the treatment group compared to 10.3% in the placebo group. It also showed a mean reduction of 1.1 cornstarch doses per day in the treatment group as compared to 0.2 in the placebo group. Secondary endpoints included a non-statistically significant reduction in the number of night-time cornstarch doses as well as the percent of patients that were able to eliminate the need for nighttime dosing. However, there is **insufficient evidence to conclude that these improvements translate into clinically meaningful patient outcomes**. As stated in the Genglycos package insert, FDA approval was based on reduction in daily cornstarch intake, not based on clinical benefit from confirmatory trials.

Additional clinical data from the phase 3 trial "GlucoGene" is limited. A secondary endpoint of maintenance of glucose control at week 48 in the treatment group (glucose values at or above 70 mg/dL) was shown to be noninferior to placebo. The phase 1/2 trial (NCT03517085) assessed clinical endpoints, including the mean time in minutes/g of carbohydrates to hypoglycemia and average monthly time in euglycemia with cornstarch dosing. The study revealed that the mean percent increase of normalized time to hypoglycemia during baseline to week 51 was 46%. This endpoint was not proven to be statistically significant and did not demonstrate clinical benefit. Average monthly time in euglycemia with cornstarch dosing was seen to have increased despite reductions in daily cornstarch intake. This datapoint was not proven to be statistically significant.

GSD-Ia is a rare and heavily burdensome disease. The frequency and quantity of cornstarch dosing, including nocturnal administration, are inhibitory to patients' quality of life. While treatment with Genglycos reduced daily cornstarch requirements, **uncertainty remains regarding whether the magnitude of this reduction translates into clinically meaningful improvements in patient outcomes beyond treatment burden itself.** Therefore, disease rarity, first-in-indication status, and unmet need were not considered sufficient to resolve the uncertainty surrounding the clinical impacts of the observed benefit.

Reconsideration of Medical Necessity

This determination will be reconsidered if new evidence addresses the uncertainty regarding the clinical and statistical significance of pariglasgene brecaparvovec (Genglycos) treatment-attributable benefit. Evidence that may support reconsideration includes:

- A prespecified, statistically controlled responder analysis demonstrating a clinically meaningful incremental benefit versus placebo or an appropriate active comparator;
- Replication or confirmation of clinically meaningful responder benefit in an additional adequately designed study;
- Demonstration of sustained benefit beyond the currently established 48-week controlled treatment period;
- Statistically and clinically meaningful between-group improvement in patient-centered outcomes such as reductions in life-threatening GSD-related events, glycemic control, metabolic control, etc.;
- Longer-term evidence that more broadly characterizes the benefit-risk profile.
- Evidence demonstrating a clinically meaningful reduction in treatment burden, including frequency of cornstarch dosing, overnight feeding requirements, or caregiver impacts
- Results from confirmatory studies verifying that reductions in cornstarch requirements translate into clinically meaningful benefits

Medicare Advantage/Medicaid/HARP:

1. Must be at least 8 years of age **AND**
2. Prescribed by or in consultation with a geneticist, metabolic disease specialist, endocrinologist, hepatologist experienced, and/or specializes in the treatment of GSD-1a **AND**
3. Must have documentation of a diagnosis of GSD-1a based on one of the following:
    a. Identification of biallelic pathogenic variants in G6PC1 (GSD-1a) **OR**
    b. Liver biopsy with enzymatic confirmation **AND**

4. Prescriber must attest that the patient is clinically stable on current disease management interventions, such as the use of uncooked cornstarch (adequate nutrition, stable glucose control, no recent hospitalizations within the last 3 months due to GSD-1a related hypoglycemia) **AND**
5. Patient must **NOT** have detectable, pre-existing AAV8 antibodies prior to therapy **AND**
6. Patient must **NOT** have any of the following:
    a. Liver cirrhosis or fibrosis of any stage **OR**
    b. Present liver adenoma measuring > 5 cm (*Medicaid ONLY*) **OR**
    c. Present liver adenoma measuring between 3-5 cm with a documented annual growth rate of ≥ 0.5 cm (*Medicaid ONLY*) **OR**
    d. History of liver transplantation (*Medicaid ONLY*) **OR**
    e. Current pregnancy (*Medicaid ONLY*) **AND**
7. Must continue dietary adjustments and/or cornstarch as deemed fit in collaboration with prescriber **AND**
8. Must have scheduled access to corticosteroid therapy beginning 2 weeks post-infusion for a minimum of 8 weeks with monitoring of hepatic enzymes and adrenal function
9. Recommended dosage for GSD-1a is a single lifetime infusion of 1.0×10^{13} gc/kg of body weight
10. Genglycos (pariglasgene brecaparvovec) is indicated for one-time single-dose intravenous use only and therefore will not be authorized for retreatment. Retreatment will be considered experimental/investigational.
11. Genglycos (pariglasgene brecaparvovec) is considered experimental/investigational when the above criteria are not met.
12. Genglycos (pariglasgene brecaparvovec) to treat other indications will be considered experimental/investigational.
13. Approval will be for 6 months to allow one-time administration

Policy Guidelines

1. Utilization Management are contract dependent. Refer to specific contract/benefit language for exclusions.
    a. Coverage criteria may be dependent on the contract renewal date.
    b. Coverage of drugs listed in this policy are contract dependent.
    c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit
    d. Not all contracts/benefits cover all medical infusible drugs.
2. Clinical documentation must be submitted for each request (initial and recertification [if applicable]) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging and other objective or subjective measures of benefit. Requested dosing must remain consistent with FDA-approved dosing recommendations.
3. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
4. Unless otherwise indicated within drug specific criteria, the drugs listed in this policy are administered by a healthcare professional and therefore are covered under the medical benefit.
5. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
6. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.
7. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
8. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.
9. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS permits a Medicare Advantage Organization (MAO) to establish its own coverage determinations in accordance with 42 CFR § 422.101(b)(6). Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan. Step therapy requirements may be imposed in addition to LCD/NCD requirements.

10. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
11. The requested site of care may impact approval timeframe and is subject to review.
12. The following applies to all gene and cellular therapies unless otherwise specified within the drug-specific coverage criteria:
    a. Administration, Retreatment, and Treatment with Additional or Other Gene/Cellular Therapies
        i. One-Time Administration
            1. Most gene and cellular therapies, whether autologous, allogeneic ("off-the-shelf"), or in vivo gene-transfer therapies, are designed and studied as one-time treatments.
            2. Repeat dosing, reinfusion, or sequential therapy with other gene or cellular products has not been established as safe, effective, or clinically appropriate.
        ii. Retreatment/Repeat Administration
            1. Retreatment with the same gene or cellular therapy product is considered experimental and investigational because:
                a. Clinical trials evaluated these therapies as single-administration interventions
                b. Safety, efficacy, and durability of a second administration have not been established
                c. Risks of immune activation, insertional mutagenesis, or vector immunity may be increased with repeat dosing
        iii. Treatment with an Additional or Other Gene/Cellular Therapy
            1. Treatment with an additional or different gene or cellular therapy after prior exposure to any gene or cellular therapy is also considered experimental and investigational, unless supported by evidence demonstrating (a-c):
                a. Anticipated clinical benefit beyond available standard therapies
                b. Safety of sequential administration
                c. Justification for selecting a second gene/cellular intervention after a prior one
            2. This includes, but is not limited to:
                a. Switching between CAR-T products (e.g., CD19 → CD19 or CD19 → BCMA)
                b. Switching between autologous and allogeneic cellular therapies
                c. Sequential use of CAR-T, TCR-T, NK-cell therapies, or other genetically engineered cell therapies
                d. Receiving a gene therapy after previous gene or cellular therapy exposure
                e. Receiving an in vivo gene therapy following any prior vector-based therapy
        iv. Prior Gene/Cell Therapy Exposure
            1. An individual is generally not eligible for additional gene or cellular therapy if they have previously received:
                a. Any autologous cellular therapy (e.g., CAR-T, TCR-T, TIL),
                b. Any allogeneic genetically modified cellular therapy,
                c. Any in vivo gene therapy (e.g., AAV, lentiviral vector)
                d. Any ex vivo gene-modified cell product
                e. Are being considered for any other gene or cellular therapy without documented evidence supporting safety and anticipated benefit.

References

		Updated	Accessed
	Glycogen Storage Disease Type I. National Organization for Rare Disorders. Available at: https://rarediseases.org/rare-diseases/glycogen-storage-disease-type-i/	12/2019	10/2026
	Genglycos [prescribing information]. Ultragenyx Pharmaceutical Inc. Novato, CA	8/2026	10/2026
	FDA Approves First Therapy for Patients aged 8 years and older with Glycogen Storage Disease Type Ia. US FDA. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-therapy-patients-aged-8-years-and-older-glycogen-storage-disease-type-ia	8/2026	10/2026
	Turner-Bowker DM, Butler J, Egan S, et al. Trial Interviews to Explore Glycogen Storage Disease Type Ia Patient Experiences Following Gene Therapy. *J Health Econ Outcomes Res.* 2026;13(1):39-47. Published 2026	2/2026	10/2026

	Feb 12. doi:10.36469/001c.155666		
	Weinstein DA, Derks TG, Rodriguez-Buritica DF, et al. Safety and Efficacy of DTX401, an AAV8-Mediated Liver-Directed Gene Therapy, in Adults With Glycogen Storage Disease Type I a (GSDIa). *J Inherit Metab Dis*. 2025;48(2):e70014. doi:10.1002/jimd.70014	10/2025	10/2026
	Chou JY, Jun HS, Mansfield BC. Glycogen storage disease type I and G6Pase-β deficiency: etiology and therapy. *Nat Rev Endocrinol*. 2010;6(12):676-688. doi:10.1038/nrendo.2010.189	8/2010	10/2026

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted in above application.
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 10/1/2026

New: 10/2026

Revised	Reviewed

Revision Date	Changes Made

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Background

Geographic Atrophy (GA) is the progressive, irreversible advanced form of dry age-related macular degeneration (AMD), a leading cause of blindness. GA is caused by the gradual breakdown of light-sensitive cells in the macula, resulting in the growth of irreversible lesions in the retinal pigment epithelium (RPE) that can lead to impaired vision or blindness. Progressive GA can eventually affect the fovea, or central part of the macula, which is responsible for high-acuity vision. More than half of all patients with GA experience significant impairment of everyday vision, and about 20% of patients develop severe vision loss with visual acuity of 20/200 or worse. AMD occurs in progressive stages of severity, which are defined as early, intermediate, or advanced. GA occurs only in the intermediate or advanced stages of AMD. In the intermediate stage, GA affects the RPE, but the center of the fovea is not involved; in the advanced stage of AMD, GA also affects the foveal center. GA is progressive and irreversible, leading to central visual impairment and permanent loss of vision. The estimated prevalence of GA in the U.S. population over 40 years of age is 0.81% (in at least one eye), but this prevalence increases to 3.5% in people 75 years of age and older. Approximately 11 million people in the United States have AMD, and about 1 million of those have GA.

Pegcetacoplan was approved for geographic atrophy (GA) February 17, 2023The efficacy and safety of pegcetacoplan for GA was determined by Phase 3 DERBY and OAKS studies. DERBY and OAKS were Phase 3, multicenter, randomized, double-masked, sham-controlled studies comparing the efficacy and safety of intravitreal pegcetacoplan with sham injections in patients with GA secondary to AMD. The primary objective of the studies was to evaluate the efficacy of pegcetacoplan in patients with GA assessed by change in the total area of GA lesions from baseline as measured by fundus autofluorescence at 12 months. In the OAKS trial, pegcetacoplan reduced the rate of GA lesion growth by 22% (p=0.0003) and 16% (p=0.0052) compared with pooled sham injection in patients administered a monthly and once-every-other-month dose of the drug, respectively, after a year. Both monthly and every-other-month (EOM) intravitreal pegcetacoplan reduced the rate of GA lesion growth through 24 months compared to sham: by 22% at the monthly frequency or 18% at EOM in the OAKS study and by 18% at the monthly frequency or 17% EOM in the DERBY study. No difference was noted between pegcetacoplan and sham groups in outcomes measuring visual function at 24 months. In the DERBY study, pegcetacoplan failed to significantly cut lesion growth rate compared with sham in both cohorts, with rates of 12% (p=0.0528) and 11% (p=0.075), respectively.

When the studies were combined in a prespecified analysis combining the primary endpoints from both DERBY and OAKS trials, lesion growth at 12 months was reduced by 17% (P < .0001) with monthly pegcetacoplan treatment and by 14% (P = .0012) with every other month pegcetacoplan treatment compared with pooled sham. Therapy was well tolerated in both studies, with a pooled rate of new-onset exudations of 6% in the monthly groups and 4.1% in every other month groups. There were two confirmed cases of infectious endophthalmitis and one case of suspected infectious endophthalmitis in the injection eye across 6,331 injections. There were 13 intraocular inflammation events and no cases of retinal vasculitis or retinal vein occlusion.

Izervay (avacincaptad pegol) was the second approved agent for GA. The efficacy of Izervay was evaluated in two randomized, double-masked, sham-controlled, multicenter pivotal studies. GATHER1 was a Phase II/III 18-month study; GATHER2 was a Phase III study with 12 months of data. Patients 50 years of age or older with GA secondary to AMD and best-corrected visual acuity (BCVA) between 20/25 and 20/320 were eligible to participate in the studies.[17] In addition, patients had to have nonfoveal GA, in part within 1.5 mm from the foveal center, and total GA area had to be between 2.5 and 17.5 mm2, as determined by fundus autofluorescence (FAF) images. For multifocal GA lesions, at least one focal lesion had to be at least 1.25 mm2. GATHER1 consisted of two simultaneous parts. In Part 1, patients were randomized 1:1:1 to receive avacincaptad pegol (ACP) 1mg, ACP 2 mg, or sham. In part 2, patients were randomized 1:2:2 to receive ACP 2 mg (one 100 µl injection + 1 sham administration), ACP 4 mg (two 2 mg injections, total volume 200 µl), or sham (2 sham administrations). Investigators administered monthly intravitreal injections of ACP or sham for a duration of 18 months. The primary endpoint was the mean change from baseline in GA lesion area as measure by FAF over 12 months

(measured at baseline, Month 6 and Month 12). Secondary endpoints included the mean change in best-corrected visual acuity (BCVA) as well as low luminance best-corrected visual acuity (LL-BCVA) from baseline to month 12.

In GATHER2, patients were randomly assigned 1:1 to monthly avacincaptad pegol 2 mg or sham. At month 12, randomization was repeated for patients receiving ACP 2 mg, with these patients randomly assigned 1:1 to either continue receiving monthly ACP 2 mg or to receive ACP 2 mg every other month through to month 23. All patients receiving sham on day 1 continued to receive sham throughout the study. The primary endpoint was GA lesion size as measure by FAF for at least three timepoints (measured at baseline, Month 6 and Month 12). Secondary endpoints included the change in best-corrected visual acuity (BCVA) as well as low luminance best-corrected visual acuity (LL-BCVA) from baseline to month 12.

In both GATHER1 and GATHER2, compared with sham, Izervay significantly reduced the rate of GA growth (0.10 mm/year in GATHER1 [P<0.01] and 0.05 mm/year in GATHER2 [P<0.01] {with square root transformed data}).[12] However, secondary endpoints were not met in either of the GATHER trials. In GATHER1, ACP 2 mg or 4 mg did not have an impact on the mean change in BCVA or low luminance BCVA from baseline to month 12, compared to the corresponding sham groups. In GATHER2 at 12 months, there were no substantial differences in mean changes in BCVA or LL-BCVA between the treatment groups.

Avacincaptad pegol was generally well tolerated in both clinical trials. The most common ocular adverse effects occurring across both trials were conjunctival hemorrhage (13% in the Izervay group vs 9% in the sham), increased intraocular pressure (9% in Izervay vs 1% sham), and choroidal neovascularization (7% in the Izervay group vs 4% in the sham group). There are currently no reports of retinal vasculitis with Izervay to date.

Summary	
Effective Date of Policy:	3/26/26
Indications	Geographic atrophy (GA)
ICD10 Diagnosis Codes	Select subcodes of H35
Availability	Izervay: 20 mg/mL solution in a single-dose glass vial Syfovre: single-dose glass vial containing 0.1 mL of 150 mg/mL solution
Duration (depending on LOB)	Commercial: N/A Medicaid and Medicare: Initial: 1 year Continuation: 1 year

Required Criteria for Initial Approval		
All of the following conditions for the requested indication must be met in order to approve therapy		
Drug and Indication	**Inclusion**	**Recommended Dosing**
Izervay (avacincaptad pegol) **Geographic Atrophy Secondary to Age-Related Macular Degeneration** (FDA approved) ICD10: select subcodes of H35 HCPCS: J2782	**Commercial:** Based upon our criteria and assessment of the peer-reviewed evidence, the use of Izervay (avacincaptad pegol) has not been medically proven to be effective and, therefore, is considered not medically necessary for the treatment of geographic atrophy. The justification for Izervay (avacincaptad pegol) to be considered not medically necessary is as follows: • Based upon our assessment of the peer-reviewed medical literature, there is inconclusive evidence that the drug has a definite positive effect on health outcomes. • Based upon our assessment of the peer-reviewed medical literature, there is inconclusive evidence that the drug, over time, leads to improvement in health outcomes (e.g., the beneficial effects of the service outweigh any harmful effects). • Based upon our assessment of the peer-reviewed medical literature, there is inconclusive evidence that the drug provides improvement in health outcomes in standard conditions of medical practice, outside the clinical investigatory settings. **Medicaid and Medicare:** 1. The patient must be 50 years of age or older **AND** 2. Izervay must be prescribed by an ophthalmologist **AND** 3. The patient must have a diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) a. GA must be confirmed by an appropriate imaging test (such as fundus autofluorescence [FAF], retinal fundus photography, optical coherence tomography [OCT]) **AND** 4. The patient must have best-corrected visual acuity (BCVA) of 20/320 or better using the Snellen Eye Chart 5. **For New Starts Only**: Must have serious side effects or treatment failure to Syfovre 6. Initial and recertification approvals will be for 1 year. a. Recertifications will require provider attestation that the patient has not experienced severe vision loss (to the level of hand motion [HM] or worse range) or unacceptable toxicity to the drug. 7. Izervay will not be approved for use at intervals less than 21 days. 8. Documentation must be submitted confirming which eye (left or right), if not both, is being treated.	• 2 mg (0.1 mL of 20 mg/mL solution) administered by intravitreal injection to each affected eye once monthly (approximately 28 ± 7 days)
Syfovre (pegcetacoplan) **Geographic Atrophy Secondary to Age-Related Macular Degeneration** (FDA approved) ICD10: select subcodes of H35 HCPCS: J2781	**Commercial:** Based upon our criteria and assessment of the peer-reviewed evidence, the use of Syfovre (pegcetacoplan) has not been medically proven to be effective and, therefore, is considered not medically necessary for the treatment of geographic atrophy. The justification for Syfovre (pegcetacoplan) to be considered not medically necessary is as follows: • Based upon our assessment of the peer-reviewed medical literature, there is inconclusive evidence that the drug has a definite positive effect on health outcomes. • Based upon our assessment of the peer-reviewed medical literature, there is inconclusive evidence that the drug, over time, leads to	• 15 mg (0.1 mL of 150 mg/mL solution) administered by intravitreal injection to each affected eye once every 25 to 60 days

improvement in health outcomes (e.g., the beneficial effects of the service outweigh any harmful effects).
- Based upon our assessment of the peer-reviewed medical literature, there is inconclusive evidence that the drug provides improvement in health outcomes in standard conditions of medical practice, outside the clinical investigatory settings.

Medicaid and Medicare:
1. The patient must be 50 years of age or older **AND**
2. Syfovre must be prescribed by an ophthalmologist **AND**
3. The patient must have a diagnosis of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)
    a. GA must be confirmed by an appropriate imaging test (such as fundus autofluorescence [FAF], retinal fundus photography, optical coherence tomography [OCT]) **AND**
4. The patient must have best-corrected visual acuity (BCVA) of 20/320 or better using the Snellen Eye Chart
5. Initial and recertification approvals will be for 1 year
    a. Recertifications will require provider attestation that the patient has not experienced severe vision loss (to the level of hand motion [HM] or worse range) or unacceptable toxicity to the drug
6. Documentation must be submitted confirming which eye (left or right), if not both, is being treated

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department

References

		Updated	Accessed
1	Liao DS, Grossi FV, El Mehdi D, et al. Complement C3 Inhibitor Pegcetacoplan for Geographic Atrophy Secondary to Age-Related Macular Degeneration: A Randomized Phase 2 Trial. Ophthalmology. 2020;127(2):186-195. doi:10.1016/j.ophtha.2019.07.011	7/2019	11/2025
2	National Library of Medicine (U.S.). (May 2018 -). Study to Compare the Efficacy and Safety of Intravitreal APL-2 Therapy With Sham Injections in Patients With Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration. Identifier: NCT03525600. https://clinicaltrials.gov/ct2/show/study/NCT03525600	6/2022	11/2025
3	National Library of Medicine (U.S.). (May 2018 -). A Study to Compare the Efficacy and Safety of Intravitreal APL-2 Therapy With Sham Injections in Patients With Geographic Atrophy (GA) Secondary to Age-Related Macular Degeneration. Identifier: NCT03525613. https://clinicaltrials.gov/ct2/show/study/NCT03525613	6/2022	11/2025
4	Syfovre [pegcetacoplan injection] Prescribing Information. Apellis Pharmaceuticals, Inc.	7/2025	11/2025
5	Izervay [avacincaptad pegol] Prescribing Information. Astellas Pharma US, Inc	3/2025	11/2025
6	National Library of Medicine (U.S.). (May 2018 -). Zimura in Participants With Geographic Atrophy Secondary to Dry Age-Related Macular Degeneration: NCT02686658. https://clinicaltrials.gov/study/NCT02686658	6/2025	11/2025
7	Khanani AM, Patel SS, Staurenghi G, et al. Efficacy and safety of avacincaptad pegol in patients with geographic atrophy (GATHER2): 12-month results from a randomised, double-masked, phase 3 trial. *Lancet*. 2023;402(10411):1449-1458. doi:10.1016/S0140-6736(23)01583-0	10/2023	11/2025

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted in above application.
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application if administered under the Medical Benefit. Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program.

CDPHP Pharmacy Services 3/26/2026

New: 12/2025

Revised	Reviewed
3/2026	

Revision Date	Changes Made
3/2026	Made applicable to Medicare

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Policy/Procedure Name: Givlaari (givosiran) **Control Number: 1350/20.0000385**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care for enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Givlaari is an aminolevulinate-synthase-1-directed small interfering molecule. It is a double-stranded small interfering RNA, which causes degradation of *aminolevulinate synthase 1* (ALAS1) mRNA in hepatocytes through RNA interference, reducing elevated levels of liver *ALAS1* mRNA. This mechanism results in lowered circulating levels of neurotoxic intermediates 5-aminolevulinic acid (ALA) and porphobilinogen (PBG), factors associated with attacks and disease manifestations of acute hepatic porphyria (AHP).

Acute hepatic porphyria includes a family of rare, genetic diseases in which there is a defect, or deficiency, in one of the enzymes within the heme biosynthetic pathway in the liver, resulting in accumulation of porphyrins, a heme precursor that can be toxic to the tissues at high levels, and neurotoxic heme intermediates ALA and PBG. There are four subtypes, including acute intermittent porphyria (AIP), hereditary coproporphyria (HCP), and variegate porphyria (VP) (all autosomal dominant disorders), and lastly aminolevulinic acid dehydratase deficiency porphyria (ALAD or ADP), which is very rare.

The symptoms of AHP are due to visceral, peripheral, autonomic, and central nervous system involvement. The attacks occur intermittently and may sometimes be life-threatening due to neurologic complications (seizures, paralysis). Symptoms may become chronic, especially after many attacks. The most common presenting symptom is neuropathic abdominal pain; however, the episodic neurological attacks include a variety of symptoms that include severe abdominal and back pain, acute polyneuropathy, psychosis, and even seizures. Management for AHP includes intravenous hemin and carbohydrate (glucose) loading, which are used during the acute attacks. These therapies downregulate hepatic delta-aminolevulinic acid synthase (ALAS1), the rate-limiting enzyme for heme biosynthesis in the liver. For mild attacks, glucose (oral not preferred due to nausea/vomiting associated with attacks) may be utilized, and for more severe attacks, hemin has a more potent effect and would be an appropriate choice. Other supportive care should be administered in addition to the above noted therapies, and should aim at reducing symptoms until the attack resolves.

Givlaari was studied in the Phase 3 ENVISION trial where therapy was administered to 94 individuals with AHP. Therapy was administered in a 1:1 fashion against placebo for a duration of six months in a double-blind method. Efficacy was measured by the rate of porphyria attacks that required hospitalizations, urgent health care visits or IV hemin administration. AHP patients receiving Givlaari experienced 70% fewer porphyria attacks compared to placebo (1.9 attacks vs. 6.5 attacks in placebo [95% CI: 60% to 80%]). Similar reductions were seen in IV hemin use, with an average reduction of 77% in the annualized number of days on hemin as well as reductions in urinary ALA (91% and 83% reduction at three and six months) and urinary PBG. Additionally, results listed that 46 Givlaari patients were projected to have an average of 3.2 porphyria attacks per year after six months versus the expected average of 12.5 attacks per year for the 43 subjects in the placebo arm. Lastly, 50 percent of the Givlaari-treated patients were free from AHP attacks during the six-month treatment period, compared to 16.3 percent in the placebo arm. There are several safety concerns with this therapy, including hepatic and renal toxicity, as well as anaphylactic and injection site reactions (injection site reactions may include recall reactions).

Summary

Effective date of policy:	2/12/2026
Indications	Treatment of adults with acute hepatic porphyria E80.20, E80.21, E80.29
Availability	189 mg/mL single-dose vial HCPCS Code: J0223
Duration	Initial: Six months Continuation: Six months

Criteria for Initial Approval		
All of the following conditions for the requested indication must be met in order to approve Givlaari therapy:		
Indication	**Inclusion**	**Recommended Dosing Regimen**
Treatment of adults with acute hepatic porphyria (AHP) (FDA approval) ICD10: E80.20, E80.21, E80.29	• Enrollee is at least 18 years of age • Must be prescribed by a healthcare professional experienced in the diagnosis and management of acute hepatic porphyria such as a hepatologist, hematologist, gastroenterologist, neurologist • Must have a diagnosis of acute hepatic porphyria including one of the following 4 subtypes: Acute Intermittent Porphyria (AIP), Hereditary Coproporphyria (HCP), Variegate Porphyria (VP), ALA dehydratase-deficiency porphyria (ADP) confirmed by: o Elevated levels of the porphyria precursor porphobilinogen (PBG) or aminolaevulinic acid (ALA) in urine or plasma within the previous year **and/or** o Genetic testing confirming a mutation consistent with AIP, HCP, VP, ADP • Have active symptomatic disease with at least 2 documented porphyria attacks within the past 6 months prior to initiation, requiring hospitalization, urgent healthcare visits or intravenous Panhematin (hemin for injection) administration at home • Factors or triggers contributing to acute hepatic porphyria attacks have been identified and addressed including but not limited to evaluation of hormonal (endocrine) factors, avoidance of alcohol, quitting smoking, dietary modifications, discontinuation of medications that may precipitate attacks of acute porphyria, when possible (see considerations for link to medications deemed unsafe in those with AHP) • Current body weight and requested dose regimen must be submitted for initial review	• Subcutaneous administration by a healthcare provider only o 2.5 mg/kg administered once monthly **Dosing based on actual body weight**

Exclusion Criteria

Therapy will not be approved if any of the following exist:

- Diagnosis of porphyria that is NOT confirmed as acute hepatic porphyria (such as porphyria cutanea tarda, hereditary erythropoietic porphyria, hepatoerythropoietic porphyria, erythropoietic protoporphyria)
- Impending liver transplantation or history of prior liver transplantation. Recipients of liver transplantation previously approved for Givlaari will not be permitted additional coverage of Givlaari after successful liver transplantation
- Dose exceeding 2.5mg/kg once a month

Continuation Criteria

- Requests will be reviewed per criteria every six months
- Current body weight and requested dose regimen must be submitted for each recertification request
- Recertification after the initial 6 months of coverage requires documentation of all the following:
  - Documentation supporting a reduction in frequency of acute hepatic porphyria attacks requiring hospitalization, urgent healthcare visits or intravenous hemin administration at home (for acute treatment and/or prophylaxis) from baseline levels,
  - Enrollee has not experienced unacceptable or unmanageable toxicity such as anaphylactic reactions, hepatic toxicity, renal toxicity, or severe injection site reactions

- Enrollee has not received a liver transplant

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.
- The following two resources are recommended to reference for a list of medications deemed UNSAFE to use in those with AHP
  - American Porphyria Foundation: https://porphyriafoundation.org/drugdatabase/drug-safety-database-search/

References

		Updated	Accessed
1	Sood GK, MD, Anderson KE, MD, FACP. Acute intermittent porphyria: Management. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com	3/2022	2/2024
2	ENVISION: A Study to Evaluate the Efficacy and Safety of Givosiran (ALN-AS1) in Patients With Acute Hepatic Porphyrias (AHP). NCT: NCT03338816. Available at: https://clinicaltrials.gov/ct2/show/NCT03338816	6/2022	2/2024
3	Givlaari prescribing information, Alnylam Pharmaceuticals, Inc., Cambridge, MA 02142.	4/2024	3/2025
4	Balwani M, Wang B, Anderson KE, et al. Acute hepatic porphyrias: Recommendations for evaluation and long-term management. Hepatology. 2017;66(4):1314-1322. doi:10.1002/hep.29313	10/2017	2/2024

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted in above application.
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 2/12/2026

New: 4/2020

Revised	Reviewed
6/2023, 2/2026	6/2024, 6/2025

Revision Date	Changes Made
6/2023	Removed Inclusion Criteria including requirement for a high carbohydrate diet.
2/2026	Updated prescribers, diagnosis Added criteria current body weight must be included with requested dosing regimen Updated exclusion criteria

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MEDICAL POLICY

Medical Policy Title	**Heart and Heart-Lung Transplant**
Policy Number	**7.02.06**
Current Effective Date	**July 1, 2026**
Next Review Date	**July 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Heart Transplant

I. Human heart transplantation is considered **medically appropriate** for select adults with end stage heart disease that is unresponsive to any other medical or surgical therapeutic measures and when specific recipient selection criteria have been met.

   A. Acceptable indications for cardiac transplantation include:

      1. Hemodynamically compromised individuals with heart failure must meet **one** of the following indications:

         a. Maximal oxygen consumption (Vo2) < 10 ml/kg/min with achievement of anaerobic metabolism;

         b. Refractory cardiogenic shock; **or**

         c. Documented dependence on intravenous inotropic support to maintain adequate organ perfusion;

      2. Severe ischemia consistently limiting routine activity not amenable to bypass surgery or angioplasty; **or**

      3. Recurrent symptomatic ventricular arrhythmias refractory to all accepted therapeutic modalities.

   B. Probable indications for cardiac transplantation include:

      1. Symptomatic heart failure with peak Volume of Oxygen at its maximum (VO2max) less than 14 ml/kg/min;

      2. Recurrent unstable ischemia not amenable to bypass surgery or angioplasty; **or**

      3. Instability of fluid balance or renal function that is not caused by the individual's inability to comply with regime of weight monitoring, flexible use of diuretic drugs, and salt restriction.

   C. Inadequate indications for cardiac transplantation include:

1. Ejection fraction < 20% with mild to moderate symptoms;
2. History of functional class (New York Heart Association [NYHA] Class) III or IV symptoms or transient need for inotropic support on a suboptimal medical regime (see Professional Guidelines section);
3. Previous ventricular arrhythmias that are now controlled;
4. Maximal VO2max greater than 15 ml/kg/min without other indications.

Heart and Lung Transplant

II. Heart-lung transplantation for carefully selected individuals with end-stage cardiac and pulmonary disease that is unresponsive to any other medical or surgical therapeutic measures is considered **medically appropriate** when recipient selection criteria have been met.

A. Acceptable indications for heart-lung transplantation include, but are not limited to the following:

1. Irreversible primary pulmonary hypertension with heart failure;
2. Non-specific severe pulmonary fibrosis;
3. Eisenmenger complex with irreversible pulmonary hypertension and heart failure;
4. Cystic fibrosis with severe heart failure;
5. Chronic obstructive pulmonary disease with heart failure;
6. Emphysema with severe heart failure; **or**
7. Pulmonary fibrosis with uncontrollable pulmonary hypertension or heart failure.

B. General contraindications for all solid organ transplantation include, but are not limited to the following:

1. Presence of malignancy (other than non-melanoma skin cancers) unless malignancy has been completely resected or upon medical review, it is determined that malignancy has been treated with small likelihood of recurrence and acceptable future risks;
2. Psychosocial instability (e.g., patterns of non-adherence to medical therapies to such a degree that it may jeopardize the success of a transplant);
3. History of ongoing or recent substance abuse (e.g., nicotine addiction);
4. Active peptic ulcer disease;
5. Severe peripheral vascular disease;
6. Other irreversible end-stage, life-limiting illnesses or conditions that are not attributed to heart or lung disease;
7. Neuromuscular neurological disorder that necessitates chronic placement with no anticipated likelihood of improvement;

8. Systemic disease that could be exacerbated by immunosuppression; **or**
9. Acquired immune deficiency syndrome (AIDS) unless **all** of the following criteria are met:
    a. CD4 count greater than 200 cells/mm3;
    b. HIV-1RNA undetectable;
    c. On stable anti-retroviral therapy > three (3) months; **and**
    d. Meets all other criteria for transplantation.

C. Heart transplantation is contraindicated for the following indications including, but not limited to:
1. For heart transplantation alone:
    a. Pulmonary hypertension;
    b. Severe pulmonary disease (a forced expiratory volume in 1 second [FEV1] of less than 50% predicted) despite optimal medical therapy;
    c. Irreversible hepatic dysfunction;
    d. Irreversible renal dysfunction.

RELATED POLICIES

Corporate Medical Policy

7.02.10 Lung and Lobar Lung Transplant

POLICY GUIDELINE(S)

I. Approval for all transplants, including arrangements with an approved transplant center, may be required through prior authorization.

II. Recipients considered for thoracic transplantation will be evaluated by the transplant center for potential difficulties that would complicate and diminish the success of transplantation. Consideration will be given to the individual's risk of death without transplantation, along with the presence and severity of potential contraindications to transplantation.

III. Pre-transplant evaluation documentation should include **ALL** the following clinical information. (If testing is unable to be performed, the rationale for not performing the testing must be included in the documentation):

A. Clinical Evaluation:
1. Confirmation of diagnosis;
2. Identification of comorbidities;
3. Treatment of co-morbidities;
4. Current assessment of co-morbidities;

5. Consult notes (if applicable).

B. Psycho-Social Evaluation:

1. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol, or nicotine/substance abuse).

C. Performance Status:

1. Karnofsky performance score;

2. Eastern Cooperative Oncology Group (ECOG) performance status;

3. Palliative Performance Scale (PPS) score; or

4. Lansky Play-Performance scale (for age 1 to 16 years)

D. Oral Health Evaluation

E. Lab Tests:

1. Complete Blood Count (CBC), metabolic profile;

2. Serologies: Cytomegalovirus (CMV), Hepatitis B and C;

3. Human Immunodeficiency Virus (HIV) Testing.

F. Cardiac Assessment:

1. 12 Lead electrocardiogram (EKG);

2. Stress (exercise, nuclear, or dobutamine);

3. Echocardiogram (Echo) or Multigated Acquisition (MUGA) Scan.

G. Pulmonary Assessment:

1. Chest X-ray;

2. Pulmonary function tests (PFTs); for high-risk respiratory failure including but not limited to: Chronic obstructive pulmonary disease (COPD), asthma, emphysema, alpha 1-antitrypsin deficiency, hepatopulmonary syndrome, or significant smoking history;

H. Age-Appropriate Screening Tests: Please refer to the U.S Preventive Services Task Force (USPSTF) website for list of age-appropriate screening guidelines. [https://uspreventiveservicestaskforce.org/uspstf/] [accessed 2026 June 16]

IV. Transplant reauthorization is required annually while on the transplant waiting list, using the same criteria as pre-testing requirements (See Policy Guideline III). If the individual health condition remains unchanged from the previous year, some testing may be waived. If testing is not performed, a rationale must be provided, and documentation must be dated within the last 11 months, unless otherwise specified (e.g., age-related testing).

DESCRIPTION

A heart transplant involves replacing a diseased heart with a healthy donor heart. It is considered for individuals with end stage heart failure who have not responded to other treatments. Heart transplants are usually indicated for individuals suffering from severe heart disease, congenital heart defects, life threatening arrhythmias not controlled by other therapies, and intractable angina not amenable to revascularization. The combined heart-lung transplantation is intended to prolong survival and improve function in individuals with end-stage cardiopulmonary or pulmonary disease that have been unresponsive to any other therapy. These procedures are performed on selected individuals with end stage heart and pulmonary disease.

SUPPORTIVE LITERATURE

Heart and heart/lung transplantation represents the only curative approach for carefully screened individuals with end-stage or congenital heart and pulmonary disease. Transplantation is limited due to the profound shortage of donor hearts and lungs.

Sertic et al (2020) compared outcomes of adults diagnosed with Eisenmenger syndrome (ES) who had a heart-lung transplant (HLT) or bilateral lung transplant (BLT) with the repair of a cardiac defect. Information was obtained from the United Network for Organ Sharing (UNOS) database of heart-lung transplantation from 1987 to 2018. During the study period a total of 442 adults with ES had thoracic transplantation (316 HLT and 126 BLT). BLT recipients had a higher median BMI (22.4 kg/m2 vs 21.3 kg/m2), lower bilirubin level at listing (0.8 vs 1.0 mg/dL), and longer wait-list time to receive a transplant (500 vs 336.5 days). Both groups had similar in-hospital mortality following transplant (BLT 27.8% and HLT 26.6%). BLT recipients had significantly longer allograft ischemic time (5.9 vs 3.7), longer hospital stays (32 vs 23 days), and a higher rate of bronchial strictures. Overall survival was similar between patients who underwent double-lung transplantation and those who underwent heart/lung transplantation at 1-year (63.1% vs 68.0%, respectively), 5 years (38.5% vs 47.3%), and 10 years (30.2% vs 30.5%) post-transplant (p=.6). Overall survival did not differ among patients who received transplantation between 1987 to 1999 and those who received transplantation between 2000 to 2018 (p=.7).

Having HIV is no longer an absolute contraindication for transplantation. Advances in donor and recipient selection, improved surgical techniques, new immunosuppressive drugs, and better management of infections have improved long term survival of HIV positive (HIV+) recipients.

Koval et al (2019) conducted a multicenter retrospective study of heart and lung transplantation outcomes in HIV individuals. There were a total of 29 recipients from 14 states. Of the 29 recipients, there were 21 heart transplants, seven (7) lung transplants, and one heart-lung transplant reported. The median age was 48 years for heart transplants and 57 years for lung transplant recipients. The median time spent on the wait list was 82 days (range, 9−757) for heart transplant and 42 days (range, 4−200) for lung transplant. Baseline CD4+ T-cell counts were 398 cells/ml for hearts and 536 cells/ml for lungs. Two heart transplant recipients had detectable HIV RNA at time of transplantation, all others were transplanted with undetectable HIV viral load. All patients were on a 3-drug antiviral regimen at the time of transplantation. Prior opportunistic infection was present in 6 patients, 2 with multiple significant past infections (e.g., cytomegalovirus (CMV), Pneumo-cystic jirovecii pneumonia, Mycobacterium avium complex, and Mycobacterium tuberculosis infection). Acute cellular rejection

(ACR) was reported in 14 of 21 (67%) heart and 2 lung transplants at 1-year post-transplant. Six malignancies were identified during the follow up (5 heart and 1 lung). Two of these cases developed within the first-year post transplantation. Most were non-melanoma skin cancers, but they also included glioblastoma and prostate cancer. Researchers concluded that thoracic organ transplantation is an effective and feasible treatment option for patients with ES.

PROFESSIONAL GUIDELINE(S)

The New York Heart Association (NYHA) Heart Failure Classification System is a risk stratification tool for heart failure and determines clinical trial eligibility, candidate selection for drugs, devices, and transplants. The NYHA classification system categorizes heart failure severity into four classes based on physical activity limitations and symptoms.

Class I	Individual has cardiac disease but no limitation of physical activity.
Class II	Individual has slight limitation of physical activity. They are comfortable at rest but ordinary physical activity results in fatigue
Class III	Marked limitations of physical activities individuals are countable at rest but less than ordinary activity causes fatigue palpitations or shortness of breath.
Class IV	Symptoms of heart failure at rest (e.g., angina, shortness of breath) and physical activity increases discomfort.

The American College of Cardiology/American Heart Association (ACC/AHA) Guideline for the Management of Hypertrophic Cardiomyopathy (2024) provides the following recommendation for the management of individual with hypertrophic cardiomyopathy. The following are some key recommendations:

- Individuals with Class III-IV symptoms and risk factors for atrial fibrillation (AF) are considered high risk. Annual extended ambulatory rhythm monitoring is recommended in such individuals to detect subclinical AF (Class I recommendation).
- Cardiopulmonary exercise is recommended in advanced heart failure (NYHA Class III-IV) to assess transplant candidacy (Class I recommendation).
- Transplant evaluation is recommended in advanced HF or life-threatening arrhythmias refractory to guideline directed medical therapy (Class I recommendation).

The International Society for Heart and Lung transplantation (ISHLT) published updated comprehensive guidelines for the care of heart transplantation recipients building on their 2010 guidance. The 2023 update incorporates new evidence, expanded pediatric considerations, and detailed clinical recommendations across the transplant continuum. The guidelines are organized by four Task Force teams, each focusing on the keys phase or domain of the heart transplantation. The following are some Class I recommendations:

- During the pre-transplant optimization phase frailty should be assessed using the standard tool

like the modified Fried criteria.

- A multidimensional nutritional assessment tool should be used to screen for malnutrition or risk thereof.
- Long term mechanical circulatory support is recommended in patients with high-risk features such as inotrope dependency or reversible contraindication.
- In pediatric patients, extracorporeal membrane oxygenation (ECMO) should be used as a bridge to transplant in cases of refractory heart failure.
- Asymptomatic moderate to severe rejection should prompt adjustments of maintenance immunosuppressive therapy.
- Donor hearts with ischemic time greater than 4 hours should only be used under specific favorable conditions.
- All transplant patients should be screened for alcohol tobacco and illicit drug use.
- Live vaccines are contraindicated post-transplant.

REGULATORY STATUS

Solid organ transplants are considered surgical procedures and are therefore not regulated by the Food and Drug Administration (FDA). However, the FDA through its Center for Biologics Evaluation and Research does regulate human cells and tissues intended for implantation transplantation or infusion under code of Federal Regulation Title 21, parts 1270 and 1271. Available from: Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products: Small Entity Compliance Guide; Guidance for Industry [accessed 2026 Jun 16]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
33933	Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy
33944	Backbench standard preparation of cadaver donor heart/lung allograft prior to

Code	Description
	transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation
33945	Heart transplant, with or without recipient cardiectomy

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
Not Applicable	

REFERENCES

Benden C, et al. The registry of the international society for heart and lung transplantation: fifteenth pediatric lung and heart-lung transplantation report-2012. J Heart Lung Transplant. 2012; 31(10):1087-95.

Bravo-Jaimes K, et al. Impact of the new UNOS donor heart allocation system on waitlist outcomes and early posttransplant mortality among adults with congenital heart disease Am J Transplant. 2022 Apr;22(4):1123-1132.

Koval CE, et al. Heart or lung transplant outcomes in HIV-infected recipients. J Heart Lung Transplant. 2019 Dec;38(12):1296-1305.

Khush KK, et al. The international thoracic organ transplant registry of the International Society of Heart and Lung transplantation: 37th adult heart transplantation report-2020. focus on deceased donor characteristics. J Heart Lung Transplant. 2020:Oct;39(10):1003-1015.

Liu J, et al. Impact of new UNOS allocation criteria on heart transplant practices and outcomes. Transplant Direct. 2020 Dec 15;7(1):e642.

Maurer JR, et al. International guidelines for the selection of lung transplant candidates. Developed by the International Society for Heart and Lung Transplantation, American Thoracic Society, American Society of Transplant Physicians, and European Respiratory Society. Heart Lung. 1998 Jul-Aug;27(4):223–9.

Ommen SR, et al. 2024 AHA/ACC/AMSSM/HRS/PACES/SCMR Guideline for the management of hypertrophic cardiomyopathy: A report of the American heart association/American College of cardiology joint committee on clinical practice guidelines. Circulation. 2024 Jun 4;149(23):e1239-e1311.

Riggs KW, et al. Pediatric heart-lung transplantation: A contemporary analysis of outcomes. Pediatr Transplant. 2020 May;24(3):e13682.

Sertic F, et al. Not all septal defects are equal: Outcomes of bilateral lung transplant with cardiac defect repair vs combined heart-lung transplant in patients with Eisenmenger Syndrome in the United States. Chest. 2020 Nov;158(5):2097-2106.

Shin MS, et al. Modern outcomes of heart-lung transplantation: assessing the impact of the updated US allocation system. European Journal of Cardio-Thoracic Surgery. 2023 Dec; 63(1) doi:10.1093/ejcts/ezac559.

Steinman TI, et al. The clinical practice committee of the American Society of Transplantation. Guidelines for the referral and management of patients eligible for solid organ transplantation. Transplant. 2001;71(9):1189-204.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Heart Transplants (NCD 260.9) [accessed 2026 Jun 16]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 2/26

Revised:

Reviewed: 9/26

Date	Summary of Changes
7/1/2026	• New

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Policy/Procedure Name: Hemophilia B Gene Therapy **Control Number: 1350/20.000466**

Disclaimer Notice

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Background

Hemophilia B is an X-linked, male predominant condition of inherited deficiency of Factor IX, resulting in a disruption in the clotting cascade and an increased tendency of bleeding. The national prevalence of Hemophilia B can be estimated around 30,000-33,000.
The severity of disease can be classified as mild (Factor IX levels 5-40% of normal), moderate (Factor IX levels 1-5% of normal), or severe (Factor IX levels < 1% of normal). Those with severe disease are at risk for serious, life-threatening bleeding including bleeding into the muscles, a joint (hemarthrosis), or more rarely intracranial bleeding. These bleeding episodes lead to substantial disability due to loss of mobility and pain, as well as ongoing join inflammation and damage causing further bleeding into the affected joints.

Management of this disease is factor replacement therapy with pure FIX Clotting Factor Concentrates (CFC), administered intravenously several times per week either on an as needed or prophylaxis basis, according to The World Federation of Hemophilia. Specifically, those with severe disease it is strongly recommended that they be treated with prophylaxis, however the patient's phenotypic disease state should be individually considered (bleeding phenotype, joint status, individual pharmacokinetics, and patient self-assessment/preference). The WFH Guidelines for the Management of Hemophilia outlines prophylaxis regimens, citing that high dose/high frequency prophylaxis ensures FIX levels above 1 IU/dL and achieves the lowest annual joint bleeding rates (AJBR) and best long-term joint outcomes, achieving less than 3 AJBR per year, along with other favorable outcomes.

Hemgenix (etranacogene dezaparvovec) is an adeno-associated virus vector-based gene therapy for the treatment of adults with Hemophilia B who currently use Factor IX prophylaxis therapy or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes. This single-dose therapy consists of a viral vector carrying a gene for clotting Factor IX. The gene is expressed in the liver to produce Factor IX protein which in turn increases Factor IX blood levels and limiting bleeding occurrences.

Hemgenix was evaluated in the Phase 3 HOPE-B trial, which was a prospective, open-label, single-dose, single-arm, multi-national study (N = 54). The study enrolled adult male subjects aged 19 to 75 years, with severe or moderately severe Hemophilia B, who received a single intravenous dose of Hemgenix and entered a follow-up period of five years, which is on-going. The lead-in period, before Hemgenix, intended for subjects to receive standard of care Factor IX prophylaxis replacement therapy. The subjects then received Hemgenix and followed for certain intervals, thereafter. Efficacy evaluation with data up to 18 months post-treatment was used, and included non-inferiority of annualized bleeding rate (ABR) post-Hemgenix compared to the lead-in period. *All bleeding episodes, regardless of investigator assessment, were counted.* The estimated mean ABR for months seven through 18 months after Hemgenix was 1.9 bleeds/year (95% CI 1.0, 3.4), compared to an estimated mean ABR of 4.1 (95% CI 3.2, 5.4). The ABR ratio (Month 7-18 post treatment/lead-in) was 0.46, demonstrating non-inferiority of ABR following Hemgenix, compared to before infusion. As a secondary outcome, patients produced mean FIX activity of 39% at 6 months and 36.7% at 24 months after Hemgenix infusion. Importantly, two subjects were not able to stop routine Factor IX prophylaxis following Hemgenix, and one additional subject received prophylaxis for approximately 20 weeks following therapy (days 396-534). One subject with numerous cardiovascular and urologic risk factors, aged 75 years at screening, died of urosepsis and cardiogenic shock at Month 15 post-dose (at age 77 years) unrelated to treatment. Another subject received around 10% of the intended dose of Hemgenix due to an infusion-related hypersensitivity reaction. In December 2022, additional data was released. The ABR for all bleeds was reduced by 64% during months 7-24 of the study (mean ABR 1.51 vs. 4.18 during the lead-in period; p=0.0002), sustaining the same bleed reduction that satisfied the study's primary endpoint.

ICER published the Final Evidence Report on Gene Therapies for Hemophilia A and B on December 22, 2022. This report states[8]:

Patients treated with etranacogene dezaparvovec had an 80% reduction in treated joint bleeds and similar reductions in other bleeds when compared with their bleeding rates on factor prophylaxis prior to gene therapy. No patients successfully treated with etranacogene dezaparvovec had to go back on factor prophylaxis during the first 18 months of therapy. It is not yet clear that the initial increase in factor IX levels will be maintained for decades, though the results are encouraging. Finally, the reduction in burden of therapy – no longer needing weekly or more frequent IX factor therapy is a major benefit for patients. Because of the uncontrolled study design, small numbers of patients studied and relatively short follow-up, there is still considerable uncertainty about the long-term net benefits of etranacogene dezaparvovec compared with factor IX prophylaxis. In particular, there are uncertainties about the long-term impact of the therapy on liver function and the risk for hepatocellular carcinoma. We conclude that there is moderate certainty of a small or substantial health benefit with high certainty of at least a small net health benefit (B+) for etranacogene dezaparvovec compared with factor IX prophylaxis.

Summary	
Effective Date of Policy:	2/12/2026
Indications	Treatment of adults with Hemophilia B (congenital Factor IX deficiency) who: • Currently use Factor IX prophylaxis therapy, or • Have current or historical life-threatening hemorrhage, or • Have repeated, serious spontaneous bleeding episodes.
ICD10 Diagnosis Codes	D67 Hereditary factor IX deficiency
HCPCS Code	J1411
Availability	Customized kit to meet dosing requirements for each patient with a nominal concentration of 1×10^{13} gc/mL
Duration	Approval will be for 6 months to allow one-time administration

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy:

Specific Indication	Inclusion Criteria	Recommended Dosing

Hemgenix (etranacogene dezaparvovec-drlb)
 	
Indication
Treatment of adults with Hemophilia B who currently use Factor IX prophylaxis therapy or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes.
(FDA approval)
 	
ICD10: D67
	• Enrollee is at least 18 years of age
	• Therapy is being prescribed by or in consultation with a hematologist at a Hemophilia Treatment Center
	• Enrollee has a diagnosis of congenital Hemophilia B (Factor IX deficiency), with severity being defined by clotting factor levels ≤2% of normal circulating factor IX, confirmed by lab results
	• There must be documentation that the patient has current or historical life-threatening hemorrhages, or have repeated, serious spontaneous bleeding episodes into the joints or muscles (refer to Table 1 in considerations) despite continuous routine prophylaxis with factor IX replacement therapy
	  o Patients on prophylactic factor IX therapy must have had a minimum of 150 exposure days
	  o Use of Hemgenix due to convenience will not be considered medically necessary and will not be authorized
	• Documentation (i.e.. lab results) must be submitted confirming that the patient does not have active factor IX inhibitors, or a history of factor IX inhibitors
	  o Bethesda assay must have been completed within 6 months of the request is acceptable unless recent immune-tolerance induction or clinical change that suggest assessment is warranted
	• Lab results must be submitted confirming that the patient was screened for neutralizing antibodies (NAbs) against adeno-associated viral vector serotype 5 (AAV5) and was negative
	• Enrollee has current weight within the past 30 days of request
	• Enrollee has not received any previous gene therapy for the treatment of Hemophilia B within their lifetime.
	
	Retreatment with etranacogene dezaparvovec-drlb (Hemgenix) has not been proven to be safe and effective. Retreatment will be considered investigational when FDA approved gene therapy, or any other gene therapy under investigation, has been previously administered
	
	Only one administration of Hemgenix will be authorized for the lifetime of the member.
		See FDA Prescribing Information for dosing, dosing of Hemgenix not to exceed 2 x 10^{13} genome copies (gc) per kg of body weight.
		
		Administer Hemgenix as an intravenous infusion after dilution with 0.9% normal saline at a constant infusion rate of 500 ml/hour (8 mL/min)
		
		Therapy must be prescribed by a qualified treatment center to administer

Exclusion Criteria

Therapy will not be approved if any of the above noted Inclusion Criteria are NOT met OR any of the below Exclusion Criteria are met:

- Patients with any of the following will not be eligible for coverage (documentation, including laboratory results [taken within the past 3 months], is required):
  - An active Hepatitis B or C infection
  - Uncontrolled human immunodeficiency virus (HIV) (defined as a CD4+ count ≤ 200/μL)
  - Thrombocytopenia (defined as a platelet count below 50 × 109/L)
  - Advanced liver disease (suggestive of or equal to METAVIR Stage 3 disease, e.g., a FibroScan™ score of ≥9 kPa is considered equivalent)
  - A known coagulation disorder other than hemophilia B

Continuation Criteria

- Not applicable, only one administration of Hemgenix will be authorized for the lifetime of the member.

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.
- Physician acknowledges that CDPHP will request documentation, not more frequently than biannually, of follow-up patient assessments including Factor IX activity and Factor IX inhibitors, as well as documentation of relevant clinical status (bleeding events, etc.) while the patient is under the care of the physician.
- Enrollees receiving Hemgenix therapy should have liver function monitored weekly for least three months to mitigate the risk of potential hepatotoxicity, continue monitoring liver enzymes in those who develop elevations until a return to baseline.
  - Consider corticosteroid treatment should elevations occur

Table 1: Sites of bleeding in hemophilia

Serious	• Joints (hemarthrosis) • Muscles, especially deep compartments (iliopsoas, calf, forearm) • Mucous membranes of the mouth, nose, and genitourinary tract
Life-threatening	• Intracranial • Neck/throat • Gastrointestinal

References

		Updated	Accessed
1	National Hemophilia Foundation Guidelines on Care and Hemophilia B. Available at: https://www.hemophilia.org/bleeding-disorders-a-z/types/hemophilia-b		7/24
2	Srivastava A, Santagostino E, Dougall A, et al. WFH Guidelines for the Management of Hemophilia, 3rd edition. Haemophilia. 2020: 26(Suppl 6): 1-158. https://doi.org/10.1111/hae.14046	8/20	7/24
3	National Organization for Rare Disorders – Hemophilia B. Available at: https://rarediseases.org/rare-diseases/hemophilia-b/	9/23	7/24
4	World Federation of Hemophilia. Online Registry of Clotting Factor Concentrates. World Federation of Hemophilia website. Montreal, Canada: World Federation of Hemophilia; 2020. Available at: https://elearning.wfh.org/resource/online-cfc-registry/		7/24
5	FDA News Release. FDA Approves First Gene Therapy to Treat Adults with Hemophilia B. Released November 22, 2022. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-treat-adults-hemophilia-b	11/22	9/23
6	Hemgenix prescribing information, CSL Behring LLC, Kankakee, IL 19406. Revised 11/2022. Reviewed 12/2022.	11/22	9/23

7	Von Drygalski A, et al. Etranacogene dezaparvovec (AMT-061 phase 2b): normal/near normal FIX activity and bleed cessation in hemophilia B. Blood Adv. 2020 Aug 11; 4(15):3668. Available at: https://pubmed.ncbi.nlm.nih.gov/32777062/	8/20	9/23
8	ICER. Gene Therapy for Hemophilia B and An Update on Gene Therapy for Hemophilia A: Effectiveness and Value Final Evidence Report. Available at: https://icer.org/wp-content/uploads/2022/05/ICER_Hemophilia_Final_Report_12222022.pdf	12/22	9/23
9	ICER California Technology Assessment Forum Public Meeting on Hemophilia A & B: Policy Roundtable. Available at: https://www.youtube.com/watch?v=iZNGaNacRCc	11/22	9/23
10	Hemgenix (Etranacogene Dezaparvovec) Clinical Trial (NCT 03569891). Available at: https://www.clinicaltrials.gov/ct2/show/NCT03569891 (HOPE-B Phase 3 trial)	3/23	9/23
11	Pipe SW, Leebeek FWG, Recht M, Key NS, Castaman G, Miesbach W, Lattimore S, Peerlinck K, Van der Valk P, Coppens M, Kampmann P, Meijer K, O'Connell N, Pasi KJ, Hart DP, Kazmi R, Astermark J, Hermans CRJR, Klamroth R, Lemons R, Visweshwar N, von Drygalski A, Young G, Crary SE, Escobar M, Gomez E, Kruse-Jarres R, Quon DV, Symington E, Wang M, Wheeler AP, Gut R, Liu YP, Dolmetsch RE, Cooper DL, Li Y, Goldstein B, Monahan PE. Gene Therapy with Etranacogene Dezaparvovec for Hemophilia B. N Engl J Med. 2023 Feb 23;388(8):706-718. doi: 10.1056/NEJMoa2211644. PMID: 36812434.	2/23	9/23
12	Beqvez [package insert]. New York, NY. Pfizer Inc. 2024 April.	4/24	7/24
13	A Study to Evaluate the Efficacy and Safety of Factor IX Gene Therapy With PF-06838435 in Adult Males With Moderately Severe to Severe Hemophilia B (BENEGENE-2). Clinical Trial (NCT03861273). Available at: https://clinicaltrials.gov/study/NCT03861273	5/24	7/24
14	Safety and Effectiveness of Giroctocogene Fitelparvovec or Fidanacogene Elaparvovec in Patients with Hemophilia A or B Respectively. Clinical trial (NCT05568719). Available at: https://clinicaltrials.gov/study/NCT05568719	5/24	7/24

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE CHOICES: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 2/12/2026

New: 12/2022

Revised	Reviewed
9/2024, 9/2025, 2/2026	12/2023

Revision Date	Changes Made
9/2024	Renamed policy from "Hemgenix - Etranacogene Dezaparvovec" to "Hemophilia B Gene Therapy" Added inclusion criteria For Beqvez Updated exclusion criteria to include exclusions for Beqvez Added weight criteria to Hemgenix
9/2025	Removed criteria for Beqvez following its discontinuation
2/2026	Updated approval timeframe to 6 months Added hematologist at a Hemophilia Treatment Center Updated factor activity level from <1% to ≤2% Reworded exclusion criteria

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Policy/Procedure Name: Hereditary Angioedema (HAE) Policy **Control Number: 1350/20.000559**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Hereditary angioedema (HAE) is an autosomal dominant disease that is caused by a deficiency in functional C1 esterase inhibitor, which leads to increases in bradykinin levels. The increase in bradykinin produces an increase in vascular permeability which leads to episodes of nonpruritic, nonpitting, subcutaneous or submucosal edema. Symptoms involve the arms, legs, hands, feet, bowels, genitalia, trunk, face, tongue, or larynx and typically begin in early childhood (2-3 years of age). Attacks can be precipitated by minor trauma and stress but may occur without an apparent trigger.

The following are measured to help confirm a diagnosis of HAE:

- Serum complement factor 4 (C4)
- C1 inhibitor (C1-INH) antigenic protein
- C1 inhibitor (C1-INH) functional level

HAE can be broadly divided into 2 fundamental types: HAE-C1INH (HAE due to a deficiency of C1- INH) or HAE-nl-C1INH (HAE with normal C1-INH). HAE-C1INH is further divided into 2 subtypes: type I HAE, characterized by deficient levels of C1INH protein and function; and type II HAE, characterized by the normal level of C1INH protein that is dysfunctional, resulting in diminished C1INH functional activity. HAE-nl-C1INH (previously referred to as type III HAE), in which the C4, C1-INH protein, and C1-INH functional activity are all normal or near normal, is not as well understood as HAE-C1INH.

HAE can be treated by Andembry (garadacimab), Berinert (Human C1 Esterase Inhibitor), Cinryze (Human C1 Esterase Inhibitor), Ekterly (sebetralstat), Haegarda (Human C1 Esterase Inhibitor), Kalbitor (Ecallantide), Firazyr (Icatibant), Sajazir (Icatibant), Ruconest (Recombinant C1 Esterase Inhibitor), Takhzyro (Lanadelumab-flyo) or Orladeyo (Berotralstat), each of which is FDA approved to reduce edema symptoms. Berinert, Cinryze, Haegarda, and Ruconest treat HAE by replacing Human C1 Esterase Inhibitor deficiencies. Andembry is an activated factor XII inhibitor (monoclonal antibody) that prevents the conversion of pre-kallikrein to kallikrein. Ekterly and Kalbitor treat HAE attacks by inhibiting plasma kallikrein which cleaves high molecular weight kininogen and results in bradykinin release. Firazyr, Sajazir and generic Icatibant inhibits bradykinin from binding the B2 receptor. Takhzyro is a plasma kallikrein inhibitor (monoclonal antibody). Orladeyo is an oral kallikrein.

Summary

Effective Date of Policy:	8/13/2026

Required Criteria for Approval

To be considered for drug treatment, individuals must meet the following criteria as well as the drug specific criteria listed below.

1. Medication must be prescribed by an allergist, immunologist, hematologist, or dermatologist
2. Must have a confirmed diagnosis of HAE based on the following:
    a. HAE-C1INH (HAE due to a deficiency of C1-INH: Type 1 or II HAE)
        i. A history of recurrent angioedema in the absence of concomitant urticaria and no concomitant use of medication known to cause angioedema (i.e., ACE-inhibitors, estrogens, angiotensin II receptor blockers, DPP-IV inhibitors, and neprilysin inhibitors) **AND**
        ii. Low C1INH antigenic or functional level **AND**
        iii. Low C4 level (either at baseline or during an attack) OR
    b. HAE-nl-C1INH (HAE with normal C1-INH)
        i. A history of recurrent angioedema in the absence of concomitant urticaria and no concomitant use of medication know to cause angioedema (i.e., ACE-inhibitors, estrogens, angiotensin II receptor blockers, DPP-IV inhibitors, and neprilysin inhibitors) **AND**
        ii. Documented normal or near normal C4, C1-INH antigen, and C1-INH function AND
        iii. Demonstration of EITHER:
            1. A mutation associated with the disease (i.e., mutations of the F12 gene, ANGPT1 gene, PLG gene, or KNG1 gene) **OR**

2. A positive family history of recurrent angioedema and documented lack of efficacy of high-dose antihistamine therapy (i.e., cetirizine at 40 mg/day or the equivalent) for at least one month

Acute Treatments

Berinert (Human C1 Esterase Inhibitor) – Medical or Rx

1. Must have a diagnosis of **acute** attacks associated with hereditary angioedema (progress notes required)
2. Must be used for acute attacks--Safety and efficacy as prophylactic therapy has not been established and therefore will not be covered
3. Berinert has been proven to be both safe and effective in adult and pediatric patients
4. **For New starts only**: For patients 18 years of age and older, requests for Berinert will require documentation of therapeutic failure, severe intolerance, **OR** a contraindication to generic icatibant.
    a. Applies to Commercial, Essential Plan, Exchange, Child Health Plus, Medicare Advantage, Medicaid and HARP members when requested under the **medical benefit**
    b. Applies to Commercial, Essential Plan, Exchange, and Child Health Plus members when request under the **pharmacy benefit**
5. Berinert will be reviewed under the **medical benefit** when administered by a health care professional. If the member transitions to self-administration, then Berinert can be authorized under the **pharmacy benefit**.
6. The recommended dose is 20 units per kg by IV infusion.
7. Maximum quantity limit of 10 vials per 30 days on Rx benefit
8. Authorization on the medical benefit will be for 1 month initially then every 6 months
9. Authorization on the pharmacy benefit will be for 6 months at a time
10. Recertification will require documentation of decrease in severity or duration of attacks. Documentation including frequency of administration will also be required at time of recertification to monitor for appropriate use.

Ekterly (sebetralstat) - Rx

1. Must have a diagnosis of **acute** attacks associated with hereditary angioedema (progress notes required)
2. Must be used for acute attacks- Safety and efficacy as prophylactic therapy has not been established and therefore will not be covered
3. Safety and efficacy in children under the age of 12 has not been established and therefore will not be covered.
4. Ekterly is an oral medication and will therefore be covered under the **pharmacy benefit**
5. For patients 18 years of age and older, requests for Ekterly will require documentation of therapeutic failure, severe intolerance, **OR** a contraindication to generic icatibant
6. The recommended dose is 600 mg (2 x 300mg tablets) orally at the earliest recognition of an acute HAE attack. A second 600 mg dose may be taken 3 hours after the first dose if response is inadequate, or if symptoms worsen or recur. Maximum of 4 tablets (1,200 mg) in a 24-hour period.
7. Quantity limit of 4 tablets per 30 days.
8. Authorization will be for 6 months at a time.
    a. Recertification will require documentation of a decrease in severity or duration of attacks. Documentation including frequency of administration will also be required at the time of administration to monitor for appropriate use.

Icatibant (generic for Firazyr), Sajazir (generic for Firazyr), and brand Firazyr - Rx

1. Must have a diagnosis of **acute** attacks associated with hereditary angioedema (progress notes required)
2. Must be used for acute attacks--Safety and efficacy as prophylactic therapy has not been established and therefore will not be covered
3. Firazyr, Sajazir, and icatibant have potential to attenuate antihypertensive effects of ACE inhibitors and should not be administered to patients taking ACE inhibitors since there are no clinical trials in this population
4. Safety and Efficacy in anyone under 18 years old is not established and therefore will not be covered.
5. Firazyr, Sajazir, and icatibant can be self-administered upon recognition of an HAE attack after training under the guidance of a health care professional and therefore will be covered under the **pharmacy benefit.**
6. Step therapy applies: Both initial and recertification/continuation of therapy requests for brand Firazyr will require documentation of therapeutic failure, severe intolerance, or a contraindication to a trial with generic Icatibant.
7. The recommended dose is 30mg subcutaneously injected into abdominal area; if response is inadequate or symptoms recur additional injections of 30mg may be administered at intervals of at least 6 hours with no more than 3 doses per 24-hour period.
8. Quantity limit of #3 (3 ml each) pre-filled syringes – 9 ml/30 days.
9. Authorization will be for 6 months at a time.
    a. Recertification will require documentation of decrease in severity or duration of attacks. Documentation including frequency of administration will also be required at time of recertification to monitor for appropriate use.

Kalbitor (ecallantide) - Medical

1. Must have a diagnosis of **acute** attacks associated with hereditary angioedema (progress notes required)
2. Must be used for acute attacks--Safety and efficacy as prophylactic therapy has not been established and therefore will not be covered
3. Safety and efficacy have not been established in children under the age of 12 and therefore will not be covered
4. Anaphylaxis has been reported after administration of Kalbitor. Because of the risk of anaphylaxis, it should only be administered by a healthcare professional with appropriate medical support to manage anaphylaxis and HAE and is therefore covered under the **medical benefit**.
5. **For New starts only:** For patients 18 years of age and older, requests for Kalbitor will require documentation of therapeutic failure, severe intolerance, **OR** a contraindication to generic icatibant.
6. The recommended dose of Kalbitor is 30 mg (3 mL), administered subcutaneously in three 10 mg (1 mL) injections. If the attack persists, an additional dose of 30 mg may be administered within a 24-hour period.
7. Authorization will be for 1 month initially then every 6 months
    a. Recertification will require documentation of decrease in severity or duration of attacks. Documentation including frequency of administration will also be required at time of recertification to monitor for appropriate use.

Ruconest (C1 esterase inhibitor [recombinant]) – Medical or Rx

1. Must have a diagnosis of **acute** attacks associated with hereditary angioedema (progress notes required)
2. Ruconest will not be covered for laryngeal attacks as efficacy has not been established in patients with laryngeal HAE attacks
3. Safety and efficacy in children under the age of 13 has not been established and therefore will not be covered
4. Ruconest will be reviewed under the **medical benefit** when administered by a health care professional. If the member transitions to self-administration, then Ruconest can be authorized under the **pharmacy benefit**.
5. **For New starts only**: For patients 18 years of age and older, request for Ruconest will require documentation of therapeutic failure, severe intolerance, OR a contraindication to generic
   Icatibant
    a. Applies to Commercial, Essential Plan, Exchange, Child Health Plus, Medicare Advantage, Medicaid and HARP members when requested under the **medical benefit**
    b. Applies to Commercial, Essential Plan, Exchange, and Child Health Plus members when request under the **pharmacy benefit**
6. For patients < 84 kg, the recommended dose is 50 IU per kg by IV injection. For patients ≥ 84 kg, the recommended dose is 4200 IU (2 vials). If the attack symptoms persist, an additional (second) dose can be administered at the recommended dose level.
    a. Maximum dose is 4200 IU (2 vials) with no more than 2 doses (4 vials) within a 24-hour time-period
7. Quantity limit of 100 ml (4 vials) per 30 days.
8. Authorization on the medical benefit will be for 1 month initially then every 6 months
9. Authorization on the pharmacy benefit will be for 6 months at a time
10. Recertification will require documentation of decrease in severity or duration of attacks. Documentation including frequency of administration will also be required at time of recertification to monitor for appropriate use.

Prophylactic Treatments

Andembry (garadacimab) - Rx

1. Must have a diagnosis of hereditary angioedema (progress notes required)
2. Must be used as prophylaxis – not for acute treatment
3. For long term prophylaxis, the patient must meet the following:
    a. History of at least one laryngeal attack or at least two severe HAE attacks (i.e., debilitating cutaneious or gastrointestinal episodes) per month that resulted in loss of work/school productivity or ER/unscheduled doctor visits **OR** disability for > 5 days per month due to HAE
4. Safety and efficacy in children under the age of 12 has not been established and therefore will not be covered.
5. Andembry is intended for self-administered or administration by a caregiver and therefore will be covered under the **pharmacy benefit.**
6. Requests for Andembry will require documentation of therapeutic failure, severe intolerance, **OR** a contraindication to Haegarda **AND** Takhzyro
7. The recommended dose is an initial loading dose of 400 mg (two 200 mg injections) administered subcutaneously on the first day of treatment, followed by a maintenance dosage of 200 mg administered subcutaneously every month.
8. Quantity limit of 1.2 mL (1 injection) per 28 days.
    a. A quantity limit of 2.4 mL (2 injections) will be allowed for the initial month of therapy in order to obtain the proper loading dose.
9. Authorization will be provided for 6 months at a time

Recertification will require documentation of decrease in the severity, duration, and/or frequency of attacks.

Cinryze (Human C1 Esterase Inhibitor) – Medical or Rx

1. Must have a diagnosis of hereditary angioedema (progress notes required)
2. Must be used as a prophylaxis – not for acute treatment

3. Cinryze will be allowed for short-term prophylaxis if being requested prior to medical, surgical, or dental procedure. Approval will be for one month only.
4. For long term prophylaxis, the patient must meet the following:
    a. History of at least one laryngeal attack or at least two severe HAE attacks (i.e., debilitating cutaneous or gastrointestinal episodes) per month that resulted in loss of work/school productivity or ER/unscheduled doctor visits **OR** disability for > 5 days per month due to HAE
5. Safety and efficacy in children under the age of 6 has not been established and therefore will not be covered
6. Cinryze will be reviewed under the **medical benefit** when administered by a health care professional. If the member transitions to self-administration, then Cinryze can be authorized under the **pharmacy benefit.**
7. For New Starts only: Requests for Cinryze for long term prophylaxis will require documentation of therapeutic failure, severe intolerance, **OR** a contraindication to Haegarda **AND** Takhzyro.
    a. This step does not apply to requests for short-term prophylaxis prior to medical, surgical, or dental procedure.
8. The recommended dose for pediatric patient's ages 6-11 years old is 500 IU (1 vial) IV infusion over 5 minutes every 3-4 days. This dose may be adjusted according to individual response, up to 1000 IU (2 vials) every 3-4 days.
9. The recommended dose for adolescent and adult patients (12 years old and above) is 1000 IU (2 vials) administered IV infusion over 10 minutes every 3-4 days.
10. Quantity limit of 20 vials per 30 days.
    a. Requests for quantities in excess of the establish quantity limit for adolescent and adult patients (12 years old and above), will be considered based on Cinryze package labeling:
        i. For patients who have not responded adequately to 1000 unit every 3 or 4 days, doses up to 2000 IU (not exceeding 80 U/kg) every 3 or 4 days may be considered based on individual patient response.
    b. Requests will require documentation of a previous trial with the standard dosage (1000 IU) and outcome of the trial, to document the need for the increased dose.
    c. No more than 50 vials per 30 days will be authorized.
11. Authorization on either the medical benefit or the pharmacy benefit will be for 6 months.
    a. Recertification will require documentation of decrease in the severity, duration, and/or frequency of attacks. Documentation including frequency of administration will also be required at time of recertification to monitor for appropriate use.

Dawnzera (donidalorsen) - Rx

1. Must have a diagnosis of hereditary angioedema (progress notes required)
2. Must be used as a prophylaxis – not for acute treatment
3. For long term prophylaxis, the patient must meet the following:
    a. History of at least one laryngeal attack or at least two severe HAE attacks (i.e., debilitating cutaneous or gastrointestinal episodes) per month that resulted in loss of work/school productivity or ER/unscheduled doctor visits **OR** disability for > 5 days per month due to HAE
4. Safety and efficacy in children under the age of 12 has not been established and therefore will not be covered
5. Dawnzera is intended for self-administration or administration by a caregiver and therefore will be covered under the **pharmacy benefit.**
6. Requests for Dawnzera will require documentation of therapeutic failure, severe intolerance, **OR** a contraindication to Haegarda **AND** Takhzyro.
7. The recommended dose is 80mg administered subcutaneously every 4 weeks. A dosage of 80mg subcutaneously every 8 weeks may be considered.
8. Quantity limit of 0.8 mL (1 injection) per 28 days.
9. All recertification requests (initial and subsequent) will require documentation of the frequency and severity of attacks experienced and the frequency of administration of Dawnzera to monitor for appropriate use.
10. Initial authorization will be provided for 9 months.
    a. If 0 attacks have occurred during the prior 6 months while on the medication, a trial with an extended dosing interval of 80 mg every 8 weeks will be required.
    b. If documentation is provided that the patient is not attack free (has experienced at least 1 attack), but has had a decrease in severity, duration and/or frequency of attacks while on the medication compared to baseline, a dosing frequency of 80mg every 4 weeks can be continued.
    c. If documentation is provided that the patient has not experienced a decrease in severity, duration and/or frequency of attacks while on the medication compared to baseline (no benefit from the medication), further treatment will not be authorized.
11. Subsequent recertification requests will be for 6 months at a time and will be reviewed using the same criteria as above:
    a. If 0 attacks have occurred during the prior 6 months while on the medication, a trial with an extended dosing interval of 80 mg every 8 weeks will be required.
    b. If documentation is provided that the patient is not attack free (has experienced at least 1 attack), but has had a decrease in severity, duration and/or frequency of attacks while on the medication compared to baseline, a dosing frequency of 80mg every 4 weeks can be continued.

c. If documentation is provided that the patient has not experienced a decrease in severity, duration and/or frequency of attacks while on the medication compared to baseline (no benefit from the medication), further treatment will not be authorized.

Haegarda (Human C1 Esterase Inhibitor) - Rx

1. Must have a diagnosis of hereditary angioedema (progress notes required)
2. Must be used as a prophylaxis – not for acute treatment
3. Haegarda will be allowed for short-term prophylaxis if being requested prior to medical, surgical, or dental procedure. Approval will be for one month only.
4. For long term prophylaxis, the patient must meet the following:
   a. History of at least one laryngeal attack or at least two severe HAE attacks (i.e., debilitating cutaneous or gastrointestinal episodes) per month that resulted in loss of work/school productivity or ER/unscheduled doctor visits **OR** disability for > 5 days per month due to HAE
5. Safety and efficacy in children under the age of 6 has not been established and therefore will not be covered
6. Haegarda can be self-administered after training under the guidance of a healthcare professional and therefore will be covered under the **pharmacy benefit.**
7. The recommended dose is 60 IU per kg body weight by subcutaneous injection twice weekly.
   a. Quantity limit of 16 vials per 28 days (defined as the combined total amount of 2000 unit vials **AND** 3000-unit vials)
   b. Requests will require documentation of patient's weight to verify requested dosing is in accordance with the FDA approved dosing.
   c. Requests for dosing every three days will require documentation of a previous trial of twice weekly dosing that did not lead to a decrease in the severity, duration and/or frequency of attacks.
8. Authorization will be for 6 months at a time.
   a. Recertification will require documentation of decrease in the severity, duration, and/or frequency of attacks. Documentation including frequency of administration will also be required at time of recertification to monitor for appropriate use

Orladeyo (berotralstat) - Rx

1. Must have a diagnosis of hereditary angioedema (progress notes required)
2. Must be used as a prophylaxis – not for acute treatment
3. For long term prophylaxis, the patient must meet the following:
   a. History of at least one laryngeal attack or at least two severe HAE attacks (i.e., debilitating cutaneous or gastrointestinal episodes) per month that resulted in loss of work/school productivity or ER/unscheduled doctor visits **OR** disability for > 5 days per month due to HAE
4. Safety and efficacy in children under the age of 2 has not been established and therefore will not be covered
5. Orladeyo is an oral medication and will therefore be covered under the **pharmacy benefit**.
6. The recommended dose for ages 12 and older is 150 mg orally once daily. Dose reductions to 110 mg orally once daily are recommended for moderate-severe hepatic impairment and can be considered in patients with persistent GI reactions.
7. Oral pellets are indicated for pediatric patients age 2 to less than 12 years of age. Dosage is weight based and administered once daily.
8. Quantity limit of 28 capsules or 28 pellet packets per 28 days.
9. Authorization will be for 6 months at a time.
   a. Recertification will require documentation of decrease in the severity, duration, and/or frequency of attacks.

Takhzyro (lanadelumab-flyo) – Medical or Rx

1. Must have a diagnosis of hereditary angioedema (progress notes required)
2. Must be used as a prophylaxis – not for acute treatment
3. For long term prophylaxis, the patient must meet the following:
   a. History of at least one laryngeal attack or at least two severe HAE attacks (i.e., debilitating cutaneous or gastrointestinal episodes) per month that resulted in loss of work/school productivity or ER/unscheduled doctor visits **OR** disability for > 5 days per month due to HAE
4. The prescribing information has the following recommended dosages based on age:
   a. The recommended starting dosage in adult and pediatric patients 12 years of age and older is 300mg subcutaneously every two weeks.
   b. The recommended starting dosage in pediatric patients 6 to less than 12 years of age is 150 mg administered subcutaneously every two weeks.
   c. The recommended dosage in pediatric patients 2 to less than 6 years of age is 150 mg administered subcutaneously every four weeks.
5. The product is commercially available in the following dosage forms and has the following quantity limits:
   a. 150 mg/mL pre-filled syringe, quantity limit of 1 mL per 28 days
   b. 300 mg/2 mL pre-filled syringe, quantity limit of 2 mL per 28 days
   c. 300 mg/2 mL single-dose vial, quantity limit of 2 mL per 28 days
6. Takhzyro 150 mg/mL syringe can be considered for coverage under the **pharmacy benefit** (caregiver administered) or **medical benefit** (healthcare provider administer).

   a. Requests for Takhzyro 150mg/mL syringe under the **medical benefit** (health care provider administered) for patients < 12 years of age will require documentation of an inability to self-inject or documentation of an inability of a caregiver to administer the medication. Clinical justification may include but is not limited to history of significant tremor, dexterity limitations, cognitive impairment.
   b. Coverage under the medical benefit for patients 12 years of age and older will be excluded
   c. Once a patient turns 12 years old, they will be required to obtain treatment under the pharmacy benefit, as the 300mg/2mL syringe/vial is not covered under the medical benefit (see below).
7. Takhzyro 300 mg/2 mL pre-filled syringe and single-dose vial can be self-administered after training under the guidance of a health care professional and therefore will be covered under the **pharmacy benefit only** for all lines of business.
8. All recertification requests (initial and subsequent) will require documentation of the frequency and severity of attacks experienced and the frequency of administration of Takhzyro to monitor for appropriate use.
9. Requests for Adult and Pediatric Patients 12 years of Age and Older:
   a. Initial approval will be for 9 months.
      i. If 0 attacks have occurred during the prior 6 months while on the medication, a trial with an extended dosing interval of 300 mg every four weeks will be required based on package labeling which states that a dose of 300 mg every four weeks is also effective.
      ii. If documentation is provided that the patient is not attack free (has experienced at least 1 attack), but has had a decrease in severity, duration, and/or frequency of attacks while
      on the medication compared to baseline, a dosing frequency of 300 mg every 2 weeks can be continued.
      iii. If documentation is provided that the patient has not experienced a decrease in severity, duration, and/or frequency of attacks while on the medication compared to baseline (no benefit from the medication), further treatment will not be authorized.
   b. Subsequent recertification requests will be for 6 months at a time and will be reviewed utilizing the same criteria above:
      i. If documentation has been submitted that 0 attacks have occurred during the 6 months prior, a trial with 300 mg every four weeks will be required.
      ii. If documentation is provided that the patient is not attack free (has experienced at least 1 attack), but has had a decrease in severity, duration, and/or frequency of attacks while
      on the medication compared to baseline, a dosing frequency of 300mg every 2 weeks can be continued.
      iii. If documentation is provided that the patient has not experienced a decrease in severity, duration, and/or frequency of attacks while on the medication compared to baseline (no benefit from the medication), further treatment will not be authorized.
10. Requests for Pediatric Patients 6 to less than 12 years of age:
   a. Initial approval will be for 9 months.
      i. If 0 attacks have occurred during the prior 6 months while on the medication, a trial with an extended dosing interval of 150 mg every four weeks will be required based on package labeling which states that a dose of 150 mg every four weeks may be considered if the patient is well-controlled (e.g., attack free) for more than 6 months
      ii. If documentation is provided that the patient is not attack free (has experienced at least 1 attack), but has had a decrease in severity, duration, and/or frequency of attacks while
      on the medication compared to baseline, a dosing frequency of 150mg every 2 weeks can be continued.
      iii. If documentation is provided that the patient has not experienced a decrease in severity, duration, and/or frequency of attacks while on the medication compared to baseline (no benefit from the medication), further treatment will not be authorized.
   b. Subsequent recertification requests will be for 6 months at a time and will be reviewed utilizing the same criteria above:
      i. If documentation has been submitted that 0 attacks have occurred during the 6 months prior, a trial with 150 mg every four weeks will be required.
      ii. If documentation is provided that the patient is not attack free (has experienced at least 1 attack), but has had a decrease in severity, duration, and/or frequency of attacks while.
      on the medication compared to baseline, a dosing frequency of 150mg every 2 weeks can be continued.
      iii. If documentation is provided that the patient has not experienced a decrease in severity, duration, and/or frequency of attacks while on the medication compared to baseline (no benefit from the medication), further treatment will not be authorized.
11. Requests for Pediatric Patients 2 to less than 6 years of age:
   a. Initial approval and subsequent recertification requests will be approved for 6 months at a time.
      i. Recertification requests will require documentation that the patient has had a decrease in severity, duration, and/or frequency of attacks while on the medication compared to baseline.
      ii. If documentation is provided that the patient has not experienced a decrease in severity, duration, and/or frequency of attacks while on the medication compared to baseline (no benefit from the medication), further treatment will not be authorized.

Considerations

1. Utilization Management are contract dependent. Refer to specific contract/benefit language for exclusions.
   - Coverage criteria may be dependent on the contract renewal date.
   - Coverage of drugs listed in this policy are contract dependent.

- Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit.
- Not all contracts/benefits cover all medical infusible drugs.

2. Clinical documentation must be submitted for each request (initial and recertification [if applicable]) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging and other subjective or subjective measures of clinical benefit. For recertification, continued approval requires documentation demonstrating that the requested product is providing ongoing benefit to the patient, evidenced by improvement or stability in the disease state or condition, and that continued use remains medically necessary. Ongoing use of the requested product must continue to align with the current policy's preferred formulary. Recertification reviews may result in a requirement to trial more cost-effective treatment alternatives as they become available (e.g., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must remain consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
3. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
4. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
5. This policy is applicable to drugs that are included on a specific drug formulary (Pharmacy benefit only). If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for review guidelines.
6. Dosing and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
7. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
8. A normal C4 particularly during an edema attack should make one question the diagnosis of HAE
9. Some medications may trigger or worsen angioedema events in patients with HAE and should be avoided including estrogen contraceptives, hormone replacement therapy, and ACE-Inhibitors.
10. Individuals' who are authorized for prophylactic Andembry, Cinryze, Dawnzera, Haegarda, Takhzyro or Orladeyo and have an acute attack while on therapy, should be re-evaluated to determine if there is an identifiable cause (adherence, misdiagnosis, etc.) for the breakthrough.
11. Individuals will only be authorized for **one acute** HAE medication at onetime.
12. Individuals will only be authorized for **one prophylactic** HAE medication at onetime.
13. The above quantity limits have been established in order to be sufficient to cover a patient in the event of an attack. Due to lack of evidence for more frequent administration, requests for quantities in excess of the established limits will not be approved. In the event, a patient is completely out of medication, a one-time override for early refill may be considered. One-time overrides will be approved after the submission of documentation (via provider progress notes, hospital progress notes, etc.) clarifying the patient's exacerbation details including date of exacerbation, date of medication administration, dose administered, as well asresponse.
14. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations.
15. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers participating in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
16. The requested site of care may impact approval timeframe and is subject to review.
17. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.

References

		Accessed
1	Bruce L. Zuraw, M.D. Hereditary Angiodema. N Engl J Med 2008; 359:1027-1036.	4/2025
2	2010 International consensus algorithm for the diagnosis, therapy, and management of hereditary angioedema. Bowen et al. Allergy, Asthma & Clinical Immunology 2010, 6:24	4/2025
3	Zuraw BL, Bork K, et al. Hereditary angioedema with normal C1 inhibitor function: Consensus of an international expert panel. Allergy Asthma Proc 33:S145-S156,2012	4/2025
4	Zuraw BL, Bernstein JA, et al. A focused parameter update: Hereditary angioedema, acquired C1 inhibitor deficiency, and angiotensin-converting enzyme inhibitor-associated angioedema. J Allergy Clin Immunol 2013 June;131(6):1491-3	4/2025

5	Zuraw BL, Banerji A, et al. US Hereditary Angioedema Association Medical Advisory Board 2013 recommendations for the management of hereditary angioedema due to C1 inhibitor deficiency. J Allergy Clin Immunol Pract. 2013 Sep-Oct;1(5):458-67	4/2025
6	Craig, Timothy et al. WAO Guideline for the Management of Hereditary Angioedema. World Allergy Organ J. 2012 Dec; 5(12): 182–199.	4/2025
7	Mauer et al. The international WAO/EAACI guideline for the management of hereditary angioedema– the 2017 revision and update. World Allergy Organization Journal. 2018 11:5.	4/2025
8	Busse et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract. 2020 Sept 6;S2213-2198(20)30878.	4/2025
9	Berinert (prescribing information). Kankakee, IL: CSL Behring LLC; 2021 Sep.	4/2025
10	Cinryze (prescribing information). Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; 2024 Nov.	4/2025
11	Firazyr (prescribing information). Lexington, MA: Takeda Pharmaceuticals America, Inc.; 2024 Jan.	4/2025
12	Haegarda (prescribing information). Kankakee, IL: CSL Behring LLC; 2022 Jan.	4/2025
13	Orladeyo (prescribing information). Durham, NC: BioCryst Pharmaceuticals, Inc. 2024 Oct.	4/2025
14	Ruconest (prescribing information. Warren NJ: Pharming Healthcare Inc.; 2024 Apr.	4/2025
15	Takhzyro (prescribing information. Cambridge, MA: Takeda Pharmaceuticals U.S.A., Inc.; 2025 Jan.	4/2025

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE CHOICES:	Subject to all terms and conditions noted in above application if administered under the medical benefit Pharmacy benefit: Not applicable
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application if administered under the medical benefit Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program.

CDPHP Pharmacy Services 8/13/2026

Date	Notes
06/2025	New Policy
09/2025	Added Andembry (garadacimab) to policy Added Ekterly (sebetralstat) to policy
12/2025	Added language regarding concomitant use of acute attack agents Step therapy added for Berinert and Ruconest - documentation of therapeutic failure, severe intolerance, OR a contraindication to generic icatibant Added Dawnzera (donidalorsen)
2/2026	Brand Name Firazyr step therapy criteria updated • Removed Sajazir (branded generic icatibant product) from the step therapy requirement, now only requires the true generic icatibant and reworded to both initial and recertification/continuation of therapy requests for brand Firazyr will require documentation of therapeutic failure, severe intolerance, or a contraindication to a trial with generic Icatibant.
5/14/26	Applicable to pharmacy and medical benefit therapies Added therapies available through medical benefit
8/13/26	Added weight based dosing to Ruconest Updated language for consistency throughout the policy Updated policy considerations section

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: HIGH-RISK OBSTETRICAL NOTIFICATION

POLICY EFFECTIVE DATE: 3/1/2024
Policy Control #: 1370/20.000198
Next Annual Review: March 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

DESCRIPTION

CDPHP offers case management services for all pregnant women with high-risk criteria to achieve the goal of improving the quality of maternity care, improving birth outcomes, and providing continuity of care. This policy describes the CDPHP process to identify high-risk obstetrical patients for case management services.

RELATED POLICIES/DOCUMENTS

Payment Policies:

Notification of Inpatient Hospitalizations, 1550/20.000174

POSITION STATEMENT

CDPHP requires Obstetrical and Family Practice physicians to notify CDPHP of obstetrical patients meeting high-risk criteria as soon as they are identified. This notification effectively serves as a referral to the CDPHP case management services, so notifications should include patient records that captures the prenatal risk assessment standards or American Congress of Obstetricians and Gynecologists (ACOG) forms for the case manager's use. Additionally, CDPHP requires notification of a member's loss of pregnancy so that the appropriate resources can be provided. CDPHP also partners with a third party, Ovia Health, to offer eligible members pregnancy support through a digital app called Ovia Pregnancy. Members who log high-risk

conditions through this application will be referred for CDPHP care management services as well.

Providers should send notifications by the following means:

- Fax or email a completed CDPHP High-Risk Pregnancy Referral form (attached) with patient records or ACOG forms to (518) 641-3303 or pregnancy@cdphp.com.

The high-risk notification should include the following information:

- Enrollee name
- Enrollee identification number
- Reason for referral
- Referring physician
- Date of last menstrual period (LMP) or estimated due date (EDD)

Fax or email a completed CDPHP Loss of Pregnancy/Unsuccessful Birth Referral form (attached) to (518) 641-3303 or pregnancy@cdphp.com. The loss notification should include the following information:

- Enrollee name
- Enrollee identification number
- Reason for referral
- Referring physician
- Date of physician notification

POLICY CONSIDERATIONS

Patients meeting one or more priority risk criteria (listed below) identified by a pregnancy risk screening are the eligible target population for high-risk pregnancy case management:

- History of preterm birth (less than 37 weeks)
- Tobacco use or substance abuse
- Depression or anxiety before or during pregnancy
- Chronic conditions that may complicate pregnancy (e.g., high blood pressure, HIV/AIDS, heart problems, diabetes, asthma, obesity, seizures, lupus)
- Teen pregnancy (under age 18)
- Unsafe living environment (domestic violence or unstable housing)
- Other

CDPHP assigns a case manager to any obstetrical patient identified as high risk to assist the physician and member with treatment coordination, compliance with medical treatment, and identification of potential resources available to the patient.

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: HIGH-RISK OBSTETRICAL NOTIFICATION

The High-Risk Pregnancy Referral form is attached to this policy and can also be found on the provider portal.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. Member Contract Language.
2. CDPHP Resource Coordination Program Description.
3. CDPHP secure physician interface, www.cdphp.com.

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POLICY APPROVAL DATES

New:	11/98
Revised:	01/00, 11/00, 02/02, 10/03, 08/04, 05/05, 03/09, 03/10, 03/12, 03/17, 09/17, 3/21, 3/22, 3/23, 3/24
Reviewed:	01/03, 04/06, 03/07, 03/08, 03/11, 03/13, 03/14, 03/15, 03/16, 01/18, 3/19, 3/20, 3/25, 3/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
3/1/2024	Updated that the referral form is found on the provider portal.

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: HIGH-RISK OBSTETRICAL NOTIFICATION

4/1/22 *No Change to effective date of policy	Under the Position Statement, added the following: CDPHP also partners with a third party, Ovia Health, to offer pregnancy support through a digital app called Ovia Pregnancy. Members who log high-risk conditions through this app will be referred for CDPHP care management services as well.
4/1/22	Removed references to Mom 2 B program and attached updated forms.
7/1/21	Added attachment for Loss of Pregnancy/Unsuccessful Birth Referral form and related information to Position Statement.

This Resource Coordination Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI) and Capital District Physicians' Healthcare Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

High-Risk Pregnancy Referral Form

Instructions: Please provide this referral form and relevant patient records/ACOG forms using HIPAA required safeguards via fax to (518) 641-3303 or via e-mail to pregnancy@cdphp.com.

CDPHP depends on timely notification of pregnancy to provide your patients with resources and education to support them with a healthy pregnancy. Additionally, CDPHP offers case management services for high-risk pregnancies to provide continuity of care, improve the quality of maternity care, and improve birth outcomes.

Demographic Information

Member Name: _____

Member Identification #: _____

Member Date of Birth: _____

Referring Physician: _____

Member Phone #: _____

Member EDD: _____

High-Risk Pregnancy Referral Reason *(Check all that apply)*

- ◯ Hx of Preterm Birth (less than 37 weeks)
- ◯ Current Tobacco or Substance Use
- ◯ Depression or Anxiety
- ◯ Teen Pregnancy (Under age 18)
- ◯ Hx of Domestic Violence or Unstable Housing
- ◯ Rh Incompatibility
- ◯ Obesity
- ◯ High Blood Pressure
- ◯ HIV/AIDS
- ◯ Cardiac Conditions
- ◯ Diabetes
- ◯ Asthma
- ◯ Neurologic Disorder
- ◯ Other: _____

Notes/Comments:

REMINDER: Please be sure to attach patient records or ACOG forms.

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Confidential Patient Information

Loss of Pregnancy/Unsuccessful Birth Referral Form

CDPHP is committed to connecting our members to resources to help them have a healthy and successful birth experience. We understand that during someone's pregnancy or during delivery, the loss of a fetus or baby may occur.

Instructions: Please complete this referral form for any patient who experienced a loss of pregnancy or unsuccessful birth outcome so that we can update our records accordingly. Submit this form using HIPAA required safeguards via fax to (518) 641-3303 or via email to pregnancy@cdphp.com.

Demographic Information

Member Name: _____

Member Identification #: _____

Member Date of Birth: _____

Referring Physician: _____

Member Phone #: _____

Physician Notification Date: _____

Referral Reason

- ◯ Miscarriage
- ◯ Fetal demise
- ◯ Stillbirth
- ◯ Failure to thrive
- ◯ Planning for adoption
- ◯ Surrogacy
- ◯ Other: _____

Please note any pre-existing mental health conditions the member has that we should be aware of:

Notes/Comments:

21-19393

Confidential Patient Information

MEDICAL POLICY

Medical Policy Title	**Hip Joint Procedures for Managed Medicaid (MMC), Health and Recovery Plan (HARP), Child Health Plus (CHP), and Essential Plan (EP) Members**
Policy Number	**7.01.121**
Current Effective Date	**January 1, 2027**
Next Review Date	**September 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

SECTION LINKS

Hip Arthroplasty

Partial

Total

Revision

Resurfacing

Osteotomy-Pediatrics

Hip Arthroscopy

Hip Arthroscopy

Hip Labral Repair

Not Medically Necessary Indications

POLICY STATEMENT(S)

Hip Arthroplasty

Partial Hip Arthroplasty

I. Partial hip replacement is **medically necessary** when **EITHER** of the following criteria are met:

   A. Traumatic hip injury; **or**

   B. **ANY** of the following conditions are present when the body mass index (BMI) is 40 kg/m² or less (if BMI is greater than 40 kg/m², there is a documented weight reduction of at least 10% before surgery):

      1. Comminuted femoral head or femoral neck fracture;
      2. Completely displaced femoral neck or femoral head fracture;
      3. Impacted femoral neck or femoral head fracture;

4. Partially displaced femoral neck or femoral head fracture;
5. Intracapsular fracture that is non-displaced for which fixation is not considered an appropriate treatment option.

Total Hip Arthroplasty

II. Total hip arthroplasty is **medically necessary** when **BOTH** the following are met:
   A. BMI of 40 kg/m² or less; **and**
   B. Presence of **any** of the following conditions when associated criteria are met:
      1. Developmental dysplasia of the hip;
      2. Displaced or comminuted femoral neck or femoral head;
      3. Post-traumatic arthritis;
      4. Malunion/non-union femoral head or proximal femur fracture;
      5. Prior fracture treated with open reduction internal fixation (ORIF) resulting in advanced joint disease;
      6. Osteonecrosis (Avascular Necrosis [AVN]) with subchondral fracture or crescent sign demonstrated on imaging;
      7. Symptomatic Osteonecrosis/AVN with stage IV collapse; **or**
      8. Osteoarthritis with **all** the following:
         a. Arthritis type is **any** of the following:
            i. Arthritis is Tonnis grade 2 or 3;
            ii. Rheumatoid arthritis;
            iii. Post-traumatic arthritis;
            iv. Inflammatory arthropathy; **and**
         b. Hip pain causing loss of function for 12 weeks or more that interferes with activities of daily living; **and**
         c. Conservative management includes **BOTH** of the following:
            i. Physical therapy (PT) meets **all** the following:
               a) Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
               b) Participation for a minimum of 6 weeks during the previous 6 months; **and**
               c) Failure to improve symptoms or functional impairments;
            ii. Pain management includes **any** of the following:
               a) Non-pharmacologic pain management such as activity modification,

modification of activity/protective weight-bearing/use of an orthotic;

b) Intra-articular corticosteroid injection;

c) Medication management (e.g., non-steroidal anti-inflammatory drugs [NSAIDS]); **and**

d. Diagnostic imaging studies (e.g., radiographs, CT, and/or MRI as clinically indicated) demonstrate **ANY** of the following findings:

i. Bone-on-bone articulation;

ii. Severe joint-space narrowing;

iii. Advanced osteoarthritis;

iv. Tönnis Grade III deformity;

v. Symptomatic Osteonecrosis/AVN with stage IV collapse; **and**

e. Documentation demonstrates **ANY** of the following symptoms:

i. Contracture;

ii. Antalgic gait or Trendelenburg gait;

iii. Pain with hip rotation;

iv. Leg-length discrepancy;

v. Reduction in range of motion.

III. Total hip arthroplasty is **not medically necessary** for **ANY** of the following contraindications:

A. Diabetes with HbA1c greater than 8%;

B. Nicotine or tobacco use, including cigars, cigarette, e-cigarette, nicotine pouch, smokeless tobacco, or vape pen, within six (6) weeks of surgery;

C. Intra-articular corticosteroid injection within 12 weeks of surgery;

D. Clinically unstable or unmanaged comorbid conditions;

E. Active infection, in treatment or is ongoing;

F. Uncontrolled hypertension;

G. Allergy to medical treatment material;

H. Drug dependency that is not being appropriately managed.

<u>Revision Hip Arthroplasty</u>

IV. Revision hip arthroplasty is **medically necessary** when **ALL** the following are met:

A. BMI is either:

1. 40 kg/m² or less, **or**

2. If BMI is greater than 40 kg/m², documented weight reduction of at least 10% before surgery;

B. Prosthesis is painful, unstable, or causing loss of function; **and**

C. **ANY** of the following:

1. Recurrent instability, dislocation, or subluxation;
2. Intolerable leg-length discrepancy;
3. Aseptic loosening;
4. Osteolysis;
5. Implant component failure;
6. Implant recall;
7. Symptomatic synovitis or metallosis; **or**
8. Prosthetic infection or failure requiring removal.

Hip Resurfacing

V. Hip resurfacing is **medically appropriate**, when **ALL** the following are met:

A. The individual is aged 55 years or less;

B. Active lifestyle;

C. Candidate for conventional total hip arthroplasty;

D. Femoral head size of greater than or equal to 46mm;

E. Adequate femoral bone stock;

F. Presurgical x-rays within 2 to six 6 months;

G. Conservative management includes **BOTH** of the following:

1. Physical therapy (PT) meets **all** the following:
   a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
   b. Participation for a minimum of 6 weeks during the previous 6 months; **and**
   c. Failure to improve symptoms or functional impairments;
2. Pain management includes **any** of the following:
   a. Non-pharmacologic pain management such as activity modification, modification of activity/protective weight-bearing/use of an orthotic;
   b. Non-steroidal anti-inflammatory drugs (NSAIDS) for a minimum of 4 weeks; **and**

VI. Hip resurfacing is **not medically necessary** for **ANY** of the following contraindications:

A. Developmental abnormalities affecting the acetabulum or femur;
B. Systemic infection or other active infectious process;
C. Immunocompromised status, including chronic corticosteroid therapy;
D. Clinically significant leg length inequality;
E. Known hypersensitivity or allergy to implant metal components;
F. Osteonecrosis/AVN affecting more than 50% of the femoral head;
G. Pregnancy;
H. Moderate-to-severe renal dysfunction, including an estimated glomerular filtration rate (eGFR) below 60 mL/min/1.73m²;
I. Severe reduction in bone quality or density, such as advanced osteopenia or osteoporosis;
J. History of slipped capital femoral epiphysis (SCFE);
K. Incomplete skeletal maturity.

Osteotomy- Pediatrics

VII. Pelvic or femoral osteotomy for the treatment of developmental dysplasia of the hip (DDH) in a pediatric individual is **medically necessary** when documentation supports **ALL** the following:

A. Preoperative imaging performed within the previous 4 weeks demonstrates DDH with residual or persistent acetabular dysplasia, or a subluxated/dislocated hip (a standard pelvic radiograph is the usual primary study in a child ≥6 months. Ultrasound for infants, MRI, CT, or arthrography is acceptable, but not required);
B. **ONE** of the following indications for osteotomy are present:
    1. Persistent or recurrent instability, subluxation, or dislocation of the hip;
    2. Residual acetabular dysplasia that is not anticipated to correct on its own (e.g., a persistently elevated age-specific acetabular index or a low center-edge angle); **or**
    3. Corresponding physical findings of DDH are present, including **any** of the following:
        a. Positive Barlow/Ortolani or Galeazzi sign in infants;
        b. Limited or asymmetric hip abduction, limb-length discrepancy; or limping or waddling gait in an ambulatory child; **or**
        c. Late presentation or older age at diagnosis in which primary open reduction with concomitant osteotomy would be the appropriate approach.

Hip Arthroscopy

Hip Arthroscopy- Diagnostic

VIII. Diagnostic hip arthroscopy is infrequently indicated, and therefore is only **medically**

necessary when **ALL** the following are met:

A. Hip pain for at least 6 months resulting in functional impairment that interferes with activities of daily living;

B. Conventional imaging has not established a diagnosis, including both MRI and plain radiographs; and

C. Conservative management includes **BOTH** the following:

1. Physical therapy (PT) meets **all** the following:
    a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
    b. Participation for a minimum of 6 weeks during the previous 6 months; **and**
    c. Failure to improve symptoms or functional impairments;
2. Pain management includes **any** of the following:
    a. Non-pharmacologic pain management such as activity modification, modification of activity/protective weight-bearing/use of an orthotic;
    b. Intra-articular corticosteroid injection;
    c. Non-steroidal anti-inflammatory drugs (NSAIDS) or analgesics.

<u>Hip Arthroscopy-Biopsy, Foreign Body Removal, Synovectomy</u>

IX. Hip arthroscopy biopsy, foreign body removal, synovectomy, or a combination of these procedures is medically necessary when **ALL** the following are met:

A. Hip pain for at least 3 months;

B. **Both** the following symptoms:

1. Pain results in functional impairment that interferes with activities of daily living; **and**
2. Is associated with mechanical symptoms such as catching, clicking, grinding, locking, **or** popping;

C. Diagnostic imaging studies (e.g., radiographs, CT, and/or MRI as clinically indicated) demonstrate **any** of the following:

1. Calcification;
2. Inflammatory changes;
3. Intra-articular loose body;
4. Nodular lesion(s);
5. Pannus formation; **or**
6. Synovial proliferation;

D. Clinical exam reveals restricted range of motion of the affected hip;

E. Conservative management includes **both** of the following:
   1. Physical therapy (PT) meets **all** the following:
      a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
      b. Participation for a minimum of 6 weeks during the previous 6 months; **and**
      c. Failure to improve symptoms or functional impairments;
   2. Pain management includes **any** of the following:
      a. Non-pharmacologic pain management such as activity modification, modification of activity/protective weight-bearing/use of an orthotic;
      b. Intra-articular corticosteroid injection; **or**
      c. Pharmacologic pain management (e.g., NSAIDS).

<u>Hip Arthroscopy- Femoroacetabular Impingement</u>

X. Arthroscopic treatment of CAM-type or Pincer-type femoroacetabular impingement is **medically necessary** when **ALL** the following criteria are met:
   A. BMI is 40kg/m² or less;
   B. Imaging confirms **both** the following:
      1. The presence of **either** of the following:
         a. CAM-type impingement, demonstrated by femoral head-neck junction abnormalities (e.g., loss of femoral head sphericity, pistol-grip deformity, or alpha angle greater than 55 degrees); **or**
         b. Pincer-type impingement, demonstrated by acetabular overcoverage findings such as acetabular retroversion, crossover sign, acetabular protrusion, posterior wall sign, prominent ischial spine sign, or center-edge angle greater than 35 degrees;

         and
      2. The absence of **either** of the following on weight-bearing radiographs:
         a. Moderate-to-severe osteoarthritis (Tönnis grade 2 or 3); or
         b. Hip dysplasia; **and**
   C. Physical exam demonstrates the following:
      1. Hip and groin pain consistent with impingement, including pain with flexion, adduction, and internal rotation; **and**
      2. Symptoms are reproducible or exacerbated by hip positioning;

         (Mechanical symptoms such as locking, catching, grinding, or popping and positive provocative maneuvers such as FABER or Fitzgerald testing may also be present);

and

D. Conservative management includes **BOTH** the following:
   1. Physical therapy (PT) meets **all** the following:
      a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
      b. Participation for a minimum of 6 weeks during the previous 6 months; **and**
      c. Failure to improve symptoms or functional impairments;
   2. Pain management includes **any** of the following:
      a. Non-pharmacologic pain management such as activity modification, modification of activity/protective weight-bearing/use of an orthotic;
      b. Intra-articular corticosteroid injection; **or**
      c. Pharmacologic pain management (e.g., NSAIDS).

Hip Labral Repair

XI. Hip labral repair is **medically necessary** when **ALL** the following are met:
   A. Imaging findings include **both** the following:
      1. Weight-bearing radiographs do not demonstrate moderate-to-severe osteoarthritis (Tönnis grade 2 or 3) or hip dysplasia;
      2. Magnetic resonance imaging confirms an acetabular labral tear;
   B. Hip pain for **at least** 6 weeks that includes **all** the following:
      1. The pain results in functional impairment that interferes with activities of daily living;
      2. The pain is accompanied by examination findings consistent with impingement, including pain with flexion, adduction, and internal rotation;

         (Mechanical symptoms such as locking, catching, grinding, or popping may also be present)
   C. Conservative management meets **either** of the following:
      1. Conservative management is not required when **any** of the following is documented:
         a. Irreparable or substantially deficient labral tissue;
         b. A labral tear identified during another medically necessary hip arthroscopic procedure;
         c. Loose bodies, foreign bodies, or synovial pathology requiring surgical removal;
         d. Advanced structural femoroacetabular impingement with clearly associated labral pathology; **or**
         e. Suspected or confirmed septic arthritis; **or**

2. For all other indications, conservative management must include **both** of the following:
    a. Physical therapy (PT) meets **all** the following:
        i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
        ii. Participation for a minimum of 6 weeks during the previous 6 months; **and**
        iii. Failure to improve symptoms or functional impairments;
    b. Pain management includes **any** of the following:
        i. Non-pharmacologic pain management such as activity modification, modification of activity/protective weight-bearing/use of an orthotic;
        ii. Intra-articular corticosteroid injection; **or**
        iii. Pharmacologic pain management (e.g., NSAIDS).

Not Medically Necessary Indications

XII. The following indications are **not medically necessary**:

A. Hip Arthroscopy for **ANY** of the following conditions:
    1. Bone marrow edema;
    2. Radiographic or clinical evidence of fracture;
    3. Intra-articular loose body or synovial pathology (see procedure specific criteria for arthroscopic removal of loose bodies and synovial pathology in Policy Statement XI);
    4. Tear involving the abductor, adductor, or hamstring tendon complex;

B. Diagnostic Hip Arthroscopy when **ANY** of the following are present:
    1. Advanced degenerative joint disease when documentation demonstrates significant arthritic changes of the affected hip, including **either** of the following:
        a. Joint space narrowing to 2 mm or less on radiographs; **or**
        b. Subchondral edema identified on MRI;
    2. Structural hip abnormalities with an established diagnosis and imaging confirms **ANY** of the following:
        a. Acetabular protrusion;
        b. Acetabular overcoverage involving the anterolateral rim;
        c. Femoroacetabular impingement (FAI);
        d. Alpha angle greater than 50 degrees;
        e. Crossover sign;
        f. Posterior wall sign;

g. Prominent ischial spine sign;
h. Abnormal femoral head contour resulting in loss of normal sphericity;
i. Prominent femoral head-neck junction (e.g., pistol-grip deformity); **or**
j. Acetabular retroversion with a center-edge angle greater than 35 degrees;

C. Hip dysplasia when imaging findings are consistent, including **ANY** of the following, when the proposed procedure does not include a periacetabular osteotomy:
1. Lateral center-edge angle less than 20 degrees;
2. Anterior center-edge angle less than 20 degrees;
3. Tönnis angle greater than 15 degrees; **or**
4. Femoral head extrusion index greater than 25%;

D. Alternative identifiable pathology that adequately explains symptoms, including **ANY** of the following:
1. Intra-articular loose body;
2. Pigmented villonodular synovitis (PVNS);
3. Synovial chondromatosis;
4. Ischiofemoral impingement;
5. Pubic edema or osteitis pubis; **or**
6. MRI-confirmed tear involving the labrum, adductor tendon, hamstring tendon, gluteus medius, or gluteus minimus.

E. Presence of active infection; **or**
F. Unmanaged substance use disorder/dependency.

RELATED POLICIES

Not Applicable

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Total Hip Arthroplasty

Total hip replacement is a surgical technique in which the femoral head and neck are removed, and the femoral canal (marrow space) is reamed out. The damaged hip joint is replaced with an artificial prosthesis composed of two or three different components: (1) the head that replaces the original

femoral head; (2) the femoral component (a metal stem placed into the femur); and (3) the acetabular component, which is implanted into the acetabulum. The stem may be secured using bone cement or press-fit for the bone to grow into it.

The Tonnis Classification System is commonly used to describe the presence of osteoarthritis in the hips, with grading as follows:

- Grade 0: No signs of osteoarthritis.
- Grade 1: Sclerosis of the joint, with slight joint space narrowing and osteophyte formation and no or slight loss of femoral head sphericity.
- Grade 2: Small cysts in the femoral head or acetabulum, with moderate joint space narrowing and moderate loss of femoral head sphericity.
- Grade 3: Large cysts in the femoral head or acetabulum, severe joint space narrowing or obliteration of the joint space, and severe deformity and loss of sphericity of the femoral head.

Revision of hip replacement (partial or total) involves surgical reconstruction or replacement due to failure or complications of previous hip replacement.

Non-surgical management regarding the treatment of hip osteoarthritis is defined as any provider-directed, non-surgical treatment that has been demonstrated in the scientific literature to be efficacious and/or is considered reasonable care in the treatment of hip pain from osteoarthritis. The types of treatment can include but are not limited to relative rest/activity modification, weight loss, supervised physiotherapy modalities and therapeutic exercises, oral prescription and non-prescription medications, assistive devices (e.g., cane, crutches, walker, wheelchair), and/or intra-articular (i.e., steroid) injections.

Hip Resurfacing

Total hip resurfacing is an alternative to watchful waiting or total hip arthroplasty (THA) for younger, active individuals less than 65 years old with hip disease such as osteoarthritis, rheumatoid arthritis, or advanced avascular necrosis.

In total hip resurfacing, the surface of the femoral head is trimmed and covered with a hollow metal hemisphere that fits into a metal acetabular cup. It is believed to optimize stress transfer to the proximal femur, and, because of the large diameter of the articulation, to offer stability and optimal range of movement. Because total hip resurfacing preserves the proximal femoral bone stock, it may not compromise future total hip replacements.

Proposed advantages of total hip resurfacing as compared with THA include preservation of the femoral neck and femoral canal, thus allowing for revision or conversion to THA, if required. In addition, the resurfaced head is more similar in size to the normal femoral head, thus increasing the stability and decreasing the risk of dislocation compared with THA.

Non-surgical management with regard to the treatment of lower extremity joint pain is defined as any provider-directed, non-surgical treatment which has been demonstrated in scientific literature to be efficacious and/or is considered reasonable care in the treatment of lower extremity joint pain.

Types of treatment may include but are not limited to relative rest/activity modification, weight loss, supervised physiotherapy modalities and therapeutic exercises, oral prescription and non-prescription medications, assistive devices (e.g., cane, crutches, walker, wheelchair), and/or intra-articular injections (e.g., steroid).

Total hip resurfacing using polyethylene components offers a promising bone-conserving alternative to total hip replacement, particularly for individuals with metal allergies or small femoral geometries (variations in the shape and size of the upper part of the femur, particularly around the hip joint). Earlier concerns with conventional polyethylene relative to wear, thickness, osteolysis, and deformation are currently being studied with the use of cross-linked polyethylene which provides a low-friction bearing surface, mimicking the natural joint's articulation and thus promoting good outcomes.

SUPPORTIVE LITERATURE

Total Hip Arthroplasty

In a meta-analysis, Smith and colleagues (2010) compared the clinical and radiological outcomes and complication rates of hip resurfacing (HRS) and total hip arthroplasty (THA). A systematic review was undertaken of all published (Medline, CINAHL, AMED, EMBASE) and unpublished or gray literature research databases up to January 2010. Clinical and radiological outcomes, as well as complications of HRS, were compared to those of THA, using risk ratio, mean difference, and standardized mean difference statistics. Studies were critically appraised using the CASP appraisal tool. A total of 46 studies were identified from 1,124 citations. These included 3,799 HRSs and 3,282 THAs. On meta-analysis, functional outcomes for subjects following HRS were better than or the same as for subjects with a THA, but there were statistically significant increases in incidence of heterotopic ossification, aseptic loosening, and revision surgery with HRS, compared to THA. The evidence base showed a number of methodological inadequacies, such as the limited use of power calculations and poor or absent blinding of both patients and assessors, possibly giving rise to assessor bias. The authors concluded that, on the basis of the current evidence base, HRS may have better functional outcomes than THA, but the increased risks of heterotopic ossification, aseptic loosening, and revision surgery following HRS indicate that THA is superior in terms of implant survival.

In a 2019 retrospective cohort study, Inoue et al compared post-operative complications and survivorship of total hip and knee arthroplasty in dialysis and renal transplantation patients. They included a total of 107 patients undergoing primary total joint arthroplasty (TJA), including 50 who were receiving dialysis and 57 who had a prior renal transplantation. The end point was defined as revision surgery secondary to post-operative complications. Researchers found a significantly higher rate of post-operative complications in the dialysis cohort (28%, n=14 of 50 joints) compared to the renal transplant cohort (7.1%, n= 4 of 57 joints). There was a higher rate of surgical site infection (SSI) and periprosthetic joint infection (PJI) in dialysis patients, compared with renal transplantation patients (18% versus 3.5%, P=0.02). In addition, there was an increased rate of revision surgery in the dialysis cohort, compared to transplant cohort (24% versus 3.5%, P=0.002). A multi-variate analysis considering demographics and comorbidities revealed that patients with renal transplantation

were less likely to have revision surgery, compared to patients on dialysis as the time of arthroplasty (95 % CI, P=0.031), and demonstrated a strong trend for lower complications (95% CI, P=0.76), although the latter was not statistically significant. Researchers concluded that transplantation was independently associated with reduced rates of revision surgery in the setting of chronic renal failure, suggesting that those who are candidates may benefit from renal transplantation before undergoing elective TJA.

Chou et al (2021) compared outcomes of TJA, including THA and total knee arthroplasty, in individuals with end-stage renal disease who were either receiving dialysis or had undergone a kidney transplant (KT). The analysis included 22 studies encompassing 9,384 patients (n = 8,921 dialysis; n = 463 KT). The overall mortality rate after TJA was 14.9%-13.8% in dialysis patients and 15.8% in KT patients. The overall surgical site complication (SSC) rate was 3.3%, with KT patients experiencing a rate of 3.6%. SSCs included hematoma, seroma, delayed wound healing, and superficial infections. The overall PJI rate was 3.9%, with dialysis patients at 4.0% and KT patients at 3.7%. Multivariate regression analysis found no statistically significant differences in outcomes between dialysis and KT patients. Both groups demonstrated elevated risks compared to the general population, with comparable outcomes between them.

Kim et al (2022) conducted a systematic review and meta-analysis of 10 retrospective studies that included 3,631,861 patients and 14,996 solid organ transplantations (SOT). They evaluate whether patients with a history of SOT experienced different outcomes after primary hip arthroplasty compared to non- SOT patients. Medical complications included cardiac complications, pneumonia, acute kidney injury, and pulmonary thromboembolism and deep vein thrombosis. The study showed that patients with a history of SOT undergoing hip arthroplasty are at higher risk for medical complications, transfusion, readmission, and short-term mortality compared to non-transplant patients. However, surgical complication rates such as infection and revision are not significantly different.

Hip Resurfacing

Evidence from numerous case series demonstrates symptomatic and functional improvements that appear to be comparable to those obtained with the current generation of total hip replacement in individuals younger than age 65 years at similar follow-up duration. In addition, hip resurfacing leaves femoral bone stock intact and therefore revision is technically similar to primary total hip replacement. Increased concentrations of metal ions have been documented after metal-on-metal hip resurfacing in some individuals. The effect of metal ion release on a fetus is also unknown.

Za and colleagues (2024) performed a systematic review and meta-analysis of eight (8) randomized control trials that compared the outcomes of hip resurfacing (HR) and total hip arthroplasty (THA) in the treatment of hip osteoarthritis in 844 patients (n=387 hip resurfacing; n=469 THA). The mean follow-up was 7.72 years. The systematic review identified no significant differences between the groups in terms of Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and University of California Los Angeles (UCLA) scores, revision rates, infection, aseptic loosening, or pseudotumor occurrence (all p>0.05). However, the dislocation rate was significantly lower in the hip resurfacing group (0.72% vs 4%; p=0.04). Some studies evaluated metal ion levels with slightly

higher chromium levels noted in THA patients postoperatively. The most common cause of revision in HR was aseptic loosening (48%), while adverse reactions to metal debris were the leading cause in THA (30.77%). The authors concluded that HR is a safe and effective alternative to THA.

In a 2019 retrospective cohort study, Inoue and colleagues compared post-operative complications and survivorship of total hip and knee arthroplasty in dialysis and renal transplantation patients. They included a total of 107 patients undergoing primary total joint arthroplasty, including 50 who were receiving dialysis and 57 who had a prior renal transplantation. The end point was defined as revision surgery secondary to post-operative complications. Researchers found a significantly higher rate of post-operative complications in the dialysis cohort (28%, n=14 of 50 joints), compared to the renal transplant cohort (7.1%, n= 4 of 57 joints). There was a higher rate of SSI and PJI in dialysis patients, compared with renal transplantation patients (18% versus 3.5%, P=0.02). In addition, there was an increased rate of revision surgery in the dialysis cohort, compared to transplant cohort (24% versus 3.5%, P=0.002). A multi-variate analysis considering demographics and comorbidities revealed that patients with renal transplantation were less likely to have revision surgery, compared to patients on dialysis as the time of arthroplasty (95 % CI, P=0.031) and demonstrated a strong trend for lower complications (95% CI, P=0.76), although the latter was not statistically significant. Researchers concluded that transplantation was independently associated with reduced rates of revision surgery in the setting of chronic renal failure, suggesting that those who are candidates may benefit from renal transplantation before undergoing elective total joint arthroplasty.

Ren and colleagues (2024) performed a retrospective review of 104 individuals who underwent 134 hip resurfacing arthroplasties with either the Birmingham Hip Resurfacing (BHR) (n=67) implant or the ReCap Magnum implant (n=67) at a single institution between 2006 and 2018. The primary aim of this study was to evaluate and compare early and midterm blood metal ion levels in hips implanted with BHR and ReCap devices as both contain cobalt-chromium (CoCr) metals. The study participants were matched 1:1 by sex, femoral head and acetabular cup sizes (±2 millimeters), age at surgery (±5 y), and year of surgery (±5 y). The ReCap group had lower median metal ion levels compared to the BHR group at 1-2 years (Co: 1.5 versus 1.9 parts per billion [ppb], P=0.018; Cr: 1.3 versus 2.8 ppb, P=0.008) and 3-5 years (Co: 1.1 versus 1.9 ppb, P=0.001; Cr: 1.2 versus 2.2 ppb, P=0.003) after surgery. Metal levels were identified in both study groups but potentially not clinically significant. Correlation analysis showed no significant associations between Co and Cr ion levels and pre- and postoperative patient-reported outcomes. Revisions for both study groups varied and included three (3) BHR hip revisions due to adverse reactions to metal debris as compared to two (2) ReCap hips revisions: one for instability and another for periprosthetic fracture. The authors concluded that the study identified that the BHR group had higher metal ion levels than the ReCap group at one to two (1-2) and three to five (3-5) years after surgery; however, these metal levels are still low and in line with prior studies.

Zuke and colleagues (2025) assessed the long-term outcomes of the Birmingham Hip Resurfacing (BHR) implant in a retrospective study of 224 male individuals under 60 years of age with osteoarthritis. The study followed the participants for an average of 14 years. Survivorship analysis revealed excellent long-term durability, with 96.0% of BHR implants remaining free from any revision and 97.4% free from aseptic revision at 15 years. Eight individuals required revision surgery,

primarily due to infection (n=3), pseudotumor formation with elevated metal ions (n=2), and femoral component loosening (n=2). Median serum cobalt and chromium levels were 1.4 ppb and 1.5 ppb, respectively, with only two (2) cases of late-onset elevated metal ions requiring revision. Study participant-reported outcomes were similar between the cohort of individuals who received the BHR implant and the study participant group who received total hip arthroplasty (THA), with no significant differences in the modified Harris Hip Score (92.65 vs. 93.56; p=0.44) or long-term activity levels. The authors concluded that this cohort study demonstrated that metal on metal hip resurfacing arthroplasty using BHR implants is safe and effective with outcomes comparable to THA surgery.

PROFESSIONAL GUIDELINE(S)

Total Hip Arthroplasty

In the 2023 American Academy of Orthopaedic Surgeons adopted the evidence-based Clinical Practice Guidelines for the Management of Osteoarthritis of the Hip that state:

- "They strongly recommend conservative measures such as physical therapy, corticosteroid or hyaluronic acid injections, pharmacological management (NSAIDs)."

In the 2008 International Cartilage Repair Society Guidelines for the Management of Hip and Knee Osteoarthritis (OA), Part II, stated:

- "Patients with hip or knee OA who are not obtaining adequate pain relief and functional improvement from a combination of non-pharmacological and pharmacological treatment should be considered for joint replacement surgery. Replacement arthroplasties are effective, and cost-effective interventions for patients with significant symptoms, and/or functional limitations associated with a reduced health-related quality of life, despite conservative therapy." (Zhang et al 2008)

Hip Resurfacing

Professional Society Name	Guideline/Version/Year	Summary of Content
Hip Society	2012 Algorithmic Approach to the Diagnosis and Management of Metal-on-Metal Arthroplasty	Awareness of adverse local tissue reactions to metal debris. All arthroplasty patients returning for follow-up should be queried for pain, discomfort, or compromiseof function. Description of ideal candidate for metal on metal arthroplasty.

		Listing of contraindications for metal on metal arthroplasty.
National Institute for Health and Care Excellence (NICE)	2014 Updated Guidance on THA and Total Hip Resurfacing for End-stage Arthritis of the Hip	NICE advised that both THA and total hip resurfacing were options for treating end-stage arthritis of the hip. NICE concluded that THA was more effective and less costly than total hip resurfacing in all analyses, that the revision rate was the most important key driver of costs and quality-adjusted life years, and that because the predicted revision rate of THA was less than 5% at 10 years in the population for whom both THA and total hip resurfacing were suitable, the revision rate standard for total hip resurfacing should be the same as that for THA. NICE recommended specific prostheses for THA and total hip resurfacing only if the prostheses have revision rates of 5% or less at 10 years.

REGULATORY STATUS

Surgeries of the hip are procedures and, therefore, not regulated by the United States Food and Drug Administration (FDA). However, devices and instruments used during the surgery are regulated as medical devices. All resurfacing devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 May 11]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 May 11]

The Birmingham Hip Resurfacing Device (BHR), a metal-on-metal system, received FDA premarket approval in May 2006. The Cormet Hip Resurfacing system, another metal-on-metal system, received FDA premarket approval in July 2007. Two additional metal-on-metal hip resurfacing systems have received approval: the Cormet Hip Resurfacing System (Corin) in 2007 and the Conserve Plus Total Hip Resurfacing System (MicroPort Orthopedics) in 2009. Both implants were approved for skeletally mature patients with either noninflammatory degenerative arthritis (e.g., osteoarthritis and avascular necrosis) or inflammatory arthritis (e.g., rheumatoid arthritis).

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
27033	Arthrotomy, hip, including exploration or removal of loose or foreign body
27050	Arthrotomy, with biopsy; sacroiliac joint
27070	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (e.g., osteomyelitis or bone abscess); superficial
27071	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (e.g., osteomyelitis or bone abscess); deep (subfascial or intramuscular)
27090	Removal of hip prosthesis; (separate procedure)
27091	Removal of hip prosthesis; complicated, including total hip prosthesis, methylmethacrylate with or without insertion of spacer
27125	Hemiarthroplasty, hip, partial (e.g., femoral stem prosthesis, bipolar arthroplasty)
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft
27140	Osteotomy and transfer of greater trochanter of femur (separate procedure)
27146	Osteotomy, iliac, acetabular or innominate bone;
27147	Osteotomy, iliac, acetabular or innominate bone; with open reduction of hip

Code	Description
27151	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy
27156	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy and with open reduction of hip
27161	Osteotomy, femoral neck (separate procedure)
27165	Osteotomy, intertrochanteric or subtrochanteric including internal or external fixation and/or cast
27170	Bone graft, femoral head, neck, intertrochanteric or subtrochanteric area (includes obtaining bone graft)
27455	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); before epiphyseal closure
29860	Arthroscopy, hip, diagnostic with or without synovial biopsy (separate procedure)
29861	Arthroscopy, hip, surgical; with removal of loose body or foreign body
29862	Arthroscopy, hip, surgical; with debridement/shaving of articular cartilage (chondroplasty), abrasion arthroplasty, and/or resection of labrum
29863	Arthroscopy, hip, surgical; with synovectomy
29914	Arthroscopy, hip, surgical; with femoroplasty (i.e., treatment of cam lesion)
29915	Arthroscopy, hip, surgical; with acetabuloplasty (i.e., treatment of pincer lesion)
29916	Arthroscopy, hip, surgical; with labral repair

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HCPCS Codes

Code	Description
S2118	Metal-on-metal total hip resurfacing, including acetabular and femoral components

ICD10 Codes

Code	Description
M05.051-M08.959	Inflammatory polyarthropathies (hip) (code range)
M12.551 - M12.559	Traumatic arthropathy, hip (code range)
M16.0 - M16.9	Osteoarthritis of hip (code range)

Code	Description
M80.051A - M80.059S, M80.851A- M80.859S, M84.451A- M84.453S, M84.459A- M84.459S, M84.551A- M84.559S, M84.651A- M84.659S	Pathologic fracture of neck of femur (hip) (code range)
M84.750A- M84.759S	Atypical femoral fracture (code range)
M87.050	Idiopathic aseptic necrosis of pelvis
M87.051- M87.059, M87.150 M87.151- M87.159, M87.250 M87.251- M87.256, M87.350 M87.351- M87.353, M87.850 M87.851- M87.859, M90.551- M90.559	Osteonecrosis of femur, pelvis and thigh (code range)
M97.01XA- M97.02XS	Periprosthetic fracture around internal prosthetic hip joint (code range)
S72.001A- S72.26XS	Fracture of head and neck of femur (code range)

REFERENCES

Abdelaal, M.S., et al. Global Perspectives on Arthroplasty of Hip and Knee Joints. The Orthopedic Clinics of North Americ. 2020;51(2):169-176.

Adeyemo, A., et al. Implant Selection for Proximal Humerus Fractures The Orthopedic Clinics of North America. 2021; 52(2):167-175.

Adib, F., et al. Gluteal compartment syndrome: A systematic review and meta-analysis. Injury. 2021; 53(3):1209-1217.

Adrados M, et al. Institutional adherence to the American Association of Hip and Knee Surgeons body mass index guidelines lowers perioperative emergency department visits in primary total knee arthroplasty. J Arthroplasty. 2023 Jun;38(6S):S88-S93.

American Academy of Orthopaedic Surgeons (AAOS) [Internet]. Appropriate use criteria: Osteoarthritis of the hip: management. Dec 2017. [accessed 2026 May 11]. Available from: https://www.orthoguidelines.org/go/auc/

American Academy of Orthopaedic Surgeons (AAOS) [Internet]. Evidence-based clinical practice guideline: Management of osteoarthritis of the hip. Dec 2023. [accessed 2026 May 11]. Available from: https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-hip/oah-cpg.pdf

Anzillotti, G., et al. Conservative vs. Surgical Management for Femoro-Acetabular Impingement: A Systematic Review of Clinical Evidence. Journal of Clinical Medicine. 2022;11(19):5852.

Ardon, A. E. Safety Considerations for Outpatient Arthroplasty. Clinics in Sports Medicine. 2022;41(2):281-289.

Azar, F. M., et al. 2021. Fractures of the Acetabulum and Pelvis. M. Beebee (Ed.). Campbell's Operative Orthopaedics (14), (pp. 2958-3030). Philadelphia, PA: Elsevier Inc.

Baal, J. D., et al. Imaging of Overuse Injuries of the Hip. Radiologic Clinics of North America. 2023; 61(2):191-201.

Bannuru RR, et al. OARSI guidelines for the non-surgical management of knee, hip, and polyarticular osteoarthritis. Osteoarthritis Cartilage. 2019 Nov;27(11):1578-1589.

Bartels S, et al. Total hip arthroplasty leads to better results after low-energy displaced femoral neck fracture in patients aged 55 to 70 years: a randomized controlled multicenter trial comparing internal

fixation and total hip arthroplasty Journal of Bone Joint Surgery. 2022.Aug;104(15):1341-1351.

Bhandari M, et al. Total hip arthroplasty or hemiarthroplasty for hip fracture. N Engl J Med. 2019 Dec 5;381(23):2199-2208.

Biundo, J. J. (2020). Bursitis, Tendinitis, and Other Periarticular Disorders and Sports Medicine. L. Goldman & A. I. Schafer (Eds.). Goldman-Cecil Medicine (26), (pp. 1703-1709.e3). Philadelphia: Elsevier, Inc.

Blankstein M, et al. What factors increase revision surgery risk when treating displaced femoral neck fractures with arthroplasty: a secondary analysis of the HEALTH Trial. J Orthop Trauma. 2020 Nov;34 Suppl 3:S49-S54.

Bostrom, M. P. & Cross, M. B. (2020). The Neuromuscular Hip. D. J. Berry & J. R. Lieberman (Eds.). Surgery of the Hip (2), (pp. 965-977). Philadelphia: Elsevier, Inc.

Browne J, et al. Peritoneal dialysis does not carry the same risk as hemodialysis in patients undergoing hip or knee arthroplasty. J Bone Joint Surg. 2019;101(14):1271-77.

Busconi, B., et al. (2020). Hip Imaging. M. D. Miller & S. R. Thompson (Eds.). DeLee, Drez, & Miller's Orthopaedic Sports Medicine (5), (pp. 935-946. e2). Philadelphia: Elsevier, Inc.

Cantrell, C. K., et al. A review on management of insufficiency fractures of the pelvis and acetabulum the orthopedic clinics of North America. 2022;53(4): 431-443.

Carek, S.M. Hip and Knee Injuries. Clinics in Office Practice. 2020;47(1):115-131.

Carlo JO, et al. Perioperative implications of end-stage renal disease in orthopaedic surgery. J Am Acad Orthop Surg. 2015 Feb;23(2):107-18.

Cavanaugh PK, et al. Complications and mortality in chronic renal failure patients undergoing total joint arthroplasty: A comparison between dialysis and renal transplant patients. J Arthroplasty. 2016 Feb;31(2):465-72.

Chalmers BP, et al. Primary total hip arthroplasty for charcot arthropathy is associated with high complications but improved clinical outcomes. J Arthroplasty. 2018 Sept;33(9):2912-2918.

Chambers, H. F. & Sakoulas, G. (2020). Staphylococcal Infections. L. Goldman & A. I. Schafer (Eds.). Goldman-Cecil Medicine, (pp. 1862-1868.e2). Philadelphia: Elsevier, Inc.

Chammout G, et al. HOPE-Trial: hemiarthroplasty compared with total hip arthroplasty for displaced femoral neck fractures in octogenarians: a randomized controlled trial. JB JS Open Access. 2019 May 1;4(2):e0059.

Chang, C., Greenspan, A. & Gershwin, M.E.(2021). Osteonecrosis. G.S. Firestein & R.C. Budd (Eds.). Firestein & Kelley's Textbook of Rheumatology (11), (pp. 1852-1875.e7). Philadelphia, PA: Elsevier, Inc.

Chang, N., and King, G. J. Elbow Hemiarthroplasty for the Treatment of Distal Humerus Fractures. The Orthopedic Clinics of North America. 2020;51(2):265-277.

Chen W, et al. Direct anterior versus posterolateral approaches for clinical outcomes after total hip arthroplasty: a systematic review and meta-analysis. J Orthop Surg Res. 2020 Jun 23;15(1):231.

Cheney, C. W., et al. Radiofrequency ablation for chronic hip pain: a comprehensive, narrative review. Pain Medicine.2021; 22(S1):S14-S19

Chou TA, et al. Dialysis patients have comparable results to patients who have received kidney transplant after total joint arthroplasty: a systematic review and meta-analysis. EFORT Open Rev. 2021 Aug 10;6(8):618-628.

Cochran, H, et al. The Removal of Total Hip Arthroplasty From the Inpatient Only List Has Improved Patient Selection and Expanded Optimization Efforts. J Arthroplasty.2023 ;38:1-18.

Cohen DA, Montgomery SJ, Khoshbin A, et al. Treatment of geriatric acetabular fractures: a concise review of the literature. Orthop Clin North Am. 2021;52(4):323-333.

Crenshaw, A. H. (2021). Tuberculosis and other Unusual Infections. F. M. Azar & J. H. Beaty (Eds.). Campbell's Operative Orthopaedics (14), (pp. 868-888.e2). Philadelphia: Elsevier, Inc.

De Paula, F. J. A., Black, D. M. & Rosen, C. J. (2020). Osteoporosis: Basic and Clinical Aspects. S. Melmed & R. J. Auchus (Eds.). Williams Textbook of Endocrinology (14), (pp. 1256-1297.e10). Philadelphia: Elsevier, Inc.

Decker S, Winkelmann M, Knipp BS, et al. Pelvic ring fractures. In: Browner BD, Jupiter JB, Krettek C, Anderson PA, editors. Skeletal trauma: basic science, management, and reconstruction. 6th ed. Philadelphia (PA): Elsevier; 2020. p. 1108-1195.

Domb BG, Bheem R, Shapira J, et al. Minimum five-year outcomes of hip resurfacing: propensity-score matched against total hip arthroplasty control groups. J Arthroplasty. 2021;36(6):2012-2015.

Douglas SJ, et al. Comparing primary total hip arthroplasty in renal transplant recipients to patients on dialysis for end-stage renal disease: a nationally matched analysis. J Bone Joint Surgery Am. 2021; 103:2215-20.

Dowsey MM, et al. Effect of bariatric surgery on risk of complications after total knee arthroplasty. JAMA Network Open. 2022 Apr;5(4):e226722.

Edelstein AI, Nassif NA, McDonald D, et al. Synovial diseases of the hip. In: Berry DJ, editor. Surgery of the hip. 2nd ed. Philadelphia (PA): Elsevier; 2020. p. 426-433.

Ekhtiari S, et al. Total hip arthroplasty versus hemiarthroplasty for displaced femoral neck fracture: a systematic review and meta-analysis of randomized controlled trials. J Bone Joint Surg Am. 2020 Sep 16;102(18):1638-1645.

Farrow L, Faulkner A, Reidy M, et al. Surgical management for developmental dysplasia of the hip. Orthop Trauma. 2020;34(6):324-331.

Ferreira GE, O'Keeffe M, Zadro JR, et al. The effectiveness of hip arthroscopic surgery for the treatment of femoroacetabular impingement syndrome: a systematic review and meta-analysis. J Sci Med Sport. 2021;24(1):21-29.

Ford, M. C. (2021). Surface Replacement Hip Arthroplasty. F. M. Azar & J. H. Beaty (Eds.). Campbell's Operative Orthopaedics (14), (pp. 334-347.e2). Philadelphia: Elsevier, Inc.

Frisch NB, Jacobs JJ. Revision for metal-on-metal or taper corrosion failures. In: Berry DJ, editor. Surgery of the hip. 2nd ed. Philadelphia (PA): Elsevier; 2020. p. 1197-1211.

Fujiwara T, Ogura K, Healey J, et al. Periacetabular reconstruction following limb-salvage surgery for pelvic sarcomas. J Bone Oncol. 2021;31:100396. doi:10.1016/j.jbo.2021.100396.

Gillespie, P., Sabri, O., . . . Amr, R. (2022). Fragility fractures of the acetabulum. Orthopaedics and Trauma, 36(2), 111-119.

Goldblum JR, Folpe AL, Weiss SW. Miscellaneous benign soft tissue tumors and pseudotumors. In: Goldblum JR, Folpe AL, editors. Enzinger and Weiss's soft tissue tumors. 7th ed. Philadelphia (PA): Elsevier; 2020. p. 1085-1106.

Guyton JL. Hip pain in the young adult and hip preservation surgery. In: Azar FM, Beaty JH, editors. Campbell's operative orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 356-404.e8.

Hankins DA, Korcek L, Richter DL, et al. Femoroacetabular impingement and management of labral tears in the athlete. Clin Sports Med. 2021;40(2):259-270.

Harkness JW, Crockarell JR. Arthroplasty of the hip. In: Azar FM, Beaty JH, editors. Campbell's operative orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 178-333.

Harris JD. Hip arthroscopy. In: Miller MD, Thompson SR, editors. DeLee, Drez, and Miller's orthopaedic sports medicine. 5th ed. Philadelphia (PA): Elsevier; 2020. p. 947-956.e3.

Harris JD, Lewis BD, Park KJ, et al. Hip dysplasia. Clin Sports Med. 2021;40(2):271-288.

Heck RK, Toy PC. General principles of tumors. In: Azar FM, Beaty JH, editors. Campbell's operative orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 890-956.

Hermans MM, Droeghaag R, Curfs I, et al. Minimally invasive sacroiliac joint fusion versus conservative treatment in patients with sacroiliac joint dysfunction: a systematic review and meta-

analysis. Brain Spine. 2021;1:100263.

Hinton ZW, Wu CJ, Lachiewicz PF, et al. Current trends in revision hip arthroplasty: indications and types of components revised. J Arthroplasty. 2022;37(Suppl):S611-S615.e7.

Inoue D, et al. Comparison of postoperative complications and survivorship of total hip and knee arthroplasty in dialysis and renal transplantation patients. J Arthroplasty. 2020;35(4):971-75.

Inoue D, et al. Outcomes of simultaneous bilateral total hip arthroplasty for 256 selected patients in a single surgeon's practice. Bone Joint J. 2021 Jul;103-B(7 supple B): 116-121.

Iorio R, et al. [Internet]. What are the absolute and relative contraindications to elective primary total joint arthroplasty (TJA), with respect to surgical site infection (SSI) and periprosthetic joint infection (PJI) risk? [Internet]. Second international consensus meeting on musculoskeletal infection 2018: hip and knee. [accessed 2026 May 11]. Available from: https://www.icmortho.org/_files/ugd/0540e9_f047ffe9ecc543279bba6b84688bc27e.pdf

Jo S, et al. Clinical outcomes of total hip arthroplasty for displaced femoral neck fractures in patients 80 years of age and older selected by clinical frailty score. Hip Pelvis. 2020 Sep;32(3):148-155.

Johns K, Mabrouk A, Tavarez MM. Slipped capital femoral epiphysis. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 [cited 2022 May]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK538302/

Jolissaint JE, Kammire MS, Springer BD, et al. An update on the management and optimization of the patient with morbid obesity undergoing hip or knee arthroplasty. Orthop Clin North Am. 2023;54(3):251-257.

Kassarjian A, Isern-Kebschull J, Tomas X, et al. Postoperative hip MR imaging. Magn Reson Imaging Clin N Am. 2022;30(4):673-688.

Keller L, Hogan C, Schocket A. The role of metal patch testing in evaluating patients for metallic prosthetic joint failure. Ann Allergy Asthma Immunol. 2021;125(5):542-547.

Kelly D. Congenital anomalies of the lower extremity. In: Azar FM, Canale T, editors. Campbell's operative orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1080-1185.e11.

Kerr DA, Rosenberg AE. Tumors and tumor-like lesions of joints and related structures. In: Firestein GS, Budd RC, editors. Firestein & Kelley's textbook of rheumatology. 11th ed. Philadelphia (PA): Elsevier; 2021. p. 2167-2188.e4.

Khakharia S, Jiranek WA. Leg length inequality: prevention/treatment. In: Berry DJ, editor. Surgery of the hip. 2nd ed. Philadelphia (PA): Elsevier; 2020. p. 1272-1280.

Khazi ZM, Cates WT, Westermann RW, et al. Arthroscopy versus open arthrotomy for treatment of native hip septic arthritis: an analysis of 30-day complications. Arthroscopy. 2020;36(4):1048-1052.

Kim CH, et al. Clinical outcomes following primary hip replacement arthroplasties in patients with

solid organ transplantation: A systematic review and meta-analysis. Hip Pelvis. 2022 Sep;34(3):127-139.

Kim HKW, Herring JA. Legg-Calvé-Perthes disease. In: Herring JA, editor. Tachdjian's pediatric orthopaedics. 6th ed. Philadelphia (PA): Elsevier; 2022. p. 527-580.e10.

Kurmis A. Implant removal in revision hip arthroplasty. In: Berry DJ, editor. Surgery of the hip. 2nd ed. Philadelphia (PA): Elsevier; 2020. p. 1050-1061.

Ladd B, Jones KE, Polly DW. Sacroiliac joint pain. In: Steinmetz MP, Berven SH, Benzel EC, editors. Benzel's spine surgery. 5th ed. Philadelphia (PA): Elsevier; 2022. p. 1205-1213.e2.

LeBrun DG, Shen TS, Su EP, et al. Hip resurfacing vs total hip arthroplasty in patients younger than 35 years: a comparison of revision rates and patient-reported outcomes. Arthroplast Today. 2021;11:229-233.

Leighton JL, Watts E, Gross AE, et al. Bone grafts in hip surgery. In: Berry DJ, editor. Surgery of the hip. 2nd ed. Philadelphia (PA): Elsevier; 2020. p. 128-143.

Li J, et al. Comparison of total joint arthroplasty outcomes between renal transplant patients and dialysis patients-a meta-analysis and systematic review. J Orthop Surg Res. 2020 Dec 9;15(1):590.

Lieu D, et al. Total hip replacement in haemodialysis or renal transplant patients. J Orthop Surg (Hong Kong). 2014 Dec;22(3):393-8.

Liu Y, et al. Comparing total hip arthroplasty and hemiarthroplasty for the treatment of displaced femoral neck fracture in the active elderly over 75 years old: a systematic review and meta-analysis of randomized control trials. J Orthop Surg Res. 2020 Jun 11;15(1):215.

Mackenzie CR, Su EP. Surgical treatment of joint diseases. In: Goldman L, Cooney KA, editors. Goldman-Cecil medicine. 27th ed. Philadelphia (PA): Elsevier; 2024. p. 1826-1830.e1.

Major NM, Anderson MW, Dussault R, et al. Hips and pelvis. In: Major NM, Dussault R, editors. Musculoskeletal MRI. 3rd ed. Philadelphia (PA): Elsevier; 2020. p. 347-375.

Mancino F, et al. Metal-on-metal hips: Ten-year clinical and radiographic outcomes of the ADEPT metal-on-metal hip resurfacing and modular total hip arthroplasty. Journal Clinical Medicine. 2023 Jan 22;12(3):889.

Martin SD, et al. Hip arthroscopy versus physical therapy for the treatment of symptomatic acetabular labral tears in patients older than 40 Years: a randomized controlled trial. The American Journal of Sport Medicine. 2021 APR;49(5):1199-1208.

Mascioli A, Park AL. Infectious arthritis. In: Azar FM, Beaty JH, editors. Campbell's operative orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 485-492.e2.

Mautner K, Pitts J, Street A, et al. Hip injection techniques. In: Frontera WR, Silver JK, Rizzo TD,

editors. Atlas of interventional orthopedics procedures. Philadelphia (PA): Elsevier; 2023. p. 323-365.

Mayer SW, Flemig AD, Pearce SS. Hip disorders in the female athlete. In: Frank RM, Matzkin EG, editors. The female athlete. Philadelphia (PA): Elsevier; 2022. p. 139-160.

McGovern RP, Bucci G, Christoforetti JJ, et al. Arthroscopic capsular management of the hip: a comparison of indications for and clinical outcomes of periportal versus interportal capsulotomy. Arthroscopy. 2021;37(1):86-94.

Mintz DN, Roberts CC, Weissman BN, et al. ACR Appropriateness Criteria® chronic hip pain. J Am Coll Radiol. 2017;14(5 Suppl):S90-S102.

Modest J, Boduch AN, Cruz AI. Slipped capital femoral epiphysis (SCFE). In: Ferri FF, editor. Ferri's clinical advisor 2022. Philadelphia (PA): Elsevier; 2022. p. 1391.e2-1391.e4.

Murugan C, Shetty AP, Rajasekaran S. An unusual case of gluteal pain: case report and review of literature. J Clin Orthop Trauma. 2021;20:101487.

Naraghi AM, Mohankumar R, White LM, et al. Bone tumors. Radiol Clin North Am. 2022;60(2):205-219.

National Institute for Health and Care Excellence (NICE) [Internet]. Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip [TA304]. Original 2014 [accessed 2026 May 11] Available from: Total hip replacement and resurfacing arthroplasty for end-stage arthritis of the hip

Novais E. Treatment options for end-stage hip disease in adolescents: to replace, fuse, or reconstruct? J Pediatr Orthop. 2021;41(Suppl 2):S14-S24.

Parcells BW. Pediatric hip and pelvis. Pediatr Clin North Am. 2020;67(1):139-152.

Patel J, Bozic K. Preoperative planning and templating for revision hip arthroplasty. In: Berry DJ, editor. Surgery of the hip. 2nd ed. Philadelphia (PA): Elsevier; 2020. p. 1035-1049.

Patel KM, Mears SC, Stronach BM, et al. Sepsis and total joint arthroplasty. Orthop Clin North Am. 2022;53(1):13-24.

Patsch JM, Krestan CR. Metabolic and endocrine skeletal disease. In: Adam A, Dixon AK, editors. Grainger & Allison's diagnostic radiology. 7th ed. Philadelphia (PA): Elsevier; 2021. p. 1087-1115.

Peck JB, Sucato DJ. Slipped capital femoral epiphysis. In: Berry DJ, editor. Surgery of the hip. 2nd ed. Philadelphia (PA): Elsevier; 2020. p. 502-517.

Phillips BB, Mihalko MJ. Arthroscopy of the lower extremity. In: Azar FM, Canale T, editors. Campbell's operative orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 2576-2662.e8.

Pisanu F, Andreozzi M, Doria C, et al. Surgical management of hip prosthetic failure in metallosis: a case series and literature review. J Orthop. 2021;28:10-20.

Planka MA, Serino J, DeFroda SF. Greater trochanteric pain syndrome: evaluation and management

of a wide spectrum of pathology. SAGE Open Med. 2021;9:1-12.

Popat R, et al. Outcomes of total hip arthroplasty in haemodialysis and renal transplant patients: systematic review. Hip Int. 2021 Mar;31(2):207-214.

Prabowo Y, Saleh I, Junaidi A, et al. Management of synovial chondromatosis of the hip by open arthrotomy debridement only vs total hip replacement: a case report. Int J Surg Case Rep. 2020;74:289-295.

Prince WB. Pediatric musculoskeletal disorders. In: Walls RM, editor. Rosen's emergency medicine: concepts and clinical practice. 10th ed. Philadelphia (PA): Elsevier; 2023. p. 2201-2218.e1.

Rees HW. Management of osteoarthritis of the hip. J Am Acad Orthop Surg. 2020;28(7):e288-e291.

Ren R, et al. Blood metal ion levels after hip resurfacing: a comparison of two different implants. Arthroplasty Today. 2024;30(101555).

Sadaniantz K, Daly L, Tracy J, et al. Prophylactic fasciotomy of the anterolateral thigh donor site in head and neck reconstruction. Am J Otolaryngol. 2022;43(1):103238.

Sahr ME, Miller TT. Pain after hip arthroplasty. Magn Reson Imaging Clin N Am. 2023;31(2):215-238.

Shane AM, Reeves CL, Calaj PM, et al. Soft tissue pathology. Clin Podiatr Med Surg. 2023;40(3):381-395.

Sheffer B. Osteochondrosis or epiphysitis and other miscellaneous affections. In: Azar FM, Beaty JH, editors. Campbell's operative orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1246-1314.e13.

Shrader MW, et al. Total hip arthroplasty in patients with renal failure: a comparison between transplant and dialysis patients. J Arthroplasty. 2006;21(3):324-329.

Smith TO, et al. The clinical and radiological outcomes of hip resurfacing versus total hip arthroplasty: a meta-analysis and systematic review. Acta Orthop. 2010;81(6):684-695.

Southgate RD, Vail TP. Resurfacing hip arthroplasty: evolution, design, indications, techniques, and results. In: Berry DJ, editor. Surgery of the hip. 2nd ed. Philadelphia (PA): Elsevier; 2020. p. 779-788.

Stanborough RO, Bestic JM, Peterson JJ, et al. Shoulder osteoarthritis. Radiol Clin North Am. 2022;60(4):593-603.

Steffner RJ, Spiguel AR, Balach T. Pathologic fractures. In: Browner BD, Jupiter JB, editors. Skeletal trauma: basic science, management, and reconstruction. 6th ed. Philadelphia (PA): Elsevier; 2021. p. 613-646.

Strait AV, Ho H, Sershon RA, et al. Outpatient total joint arthroplasty in the "unhealthy": staying safe using institutional protocols. J Arthroplasty. 2025;40(1):34-39.

Taunton MJ, Trousdale RT. Arthrodesis and resection arthroplasty of the hip. In: Berry DJ, editor.

Surgery of the hip. 2nd ed. Philadelphia (PA): Elsevier; 2020. p. 739-749.

American Academy of Orthopaedic Surgeons [Internet]. Slipped capital femoral epiphysis (SCFE). Rosemont (IL): American Academy of Orthopaedic Surgeons; 2020 [cited 2022 May]. [accessed 2026 Sept 11]. Available from: https://orthoinfo.aaos.org/en/diseases--conditions/slipped-capital-femoral-epiphysis-scfe

Thomas WC, Parvataneni HK, Gray CF, et al. Early polyethylene failure in a modern total hip prosthesis: a note of caution. J Arthroplasty. 2020;35(5):1297-1302.

Thompson A, Fleischmann KE, Williams K, et al. 2024 AHA/ACC/ACS/ASNC/HRS/SCAI/SCCT/SCMR/SVM guideline for perioperative cardiovascular management for noncardiac surgery: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2024;150(19):e351-e442.

Toy PC, Heck RK. Soft-tissue tumors. In: Azar FM, Beaty JH, editors. Campbell's operative orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1049-1078.e4.

Treacy RB, et al. Birmingham hip resurfacing: a minimum follow-up of ten years. J Bone Joint Surg Br. 2011 Jan;93(1):27-33.

United States Food and Drug Administration (FDA) [Internet]. Medical devices/ metal on metal hip implant systems [Updated 2019 Mar 15; accessed 2026 May 11] Available from: https://www.fda.gov/medical-devices/metal-metal-hip-implants/metal-metal-hip-implant-systems

Upfill-Brown A, Hsiue PP, Stavrakis AI, et al. Instability is the most common indication for revision hip arthroplasty in the United States: national trends from 2012 to 2018. Arthroplast Today. 2021;11:88-101.

Usuki KY, Milano MT, Okunieff P, et al. Metastatic disease: bone, spinal cord, brain, liver, and lung. In: Tepper JE, Foote RL, editors. Gunderson & Tepper's clinical radiation oncology. 5th ed. Philadelphia (PA): Elsevier; 2021. p. 461-477.e6.

Vahedi H, Yacovelli S, Parvizi J, et al. Surgical treatment of femoroacetabular impingement. JBJS Rev. 2021;6(4).

Van de Sande MGH, Van Vollenhoven RF. Evaluation of monoarticular and polyarticular arthritis. In: Firestein GS, Budd RC, Gabriel SE, McInnes IB, O'Dell JR, editors. Firestein & Kelley's textbook of rheumatology. 12th ed. Philadelphia (PA): Elsevier. p. 647-661.

Van Vollenhoven RF. Evaluation of monoarticular and polyarticular arthritis. In: Firestein GS, Budd RC, Gabriel SE, McInnes IB, O'Dell JR, editors. Firestein & Kelley's textbook of rheumatology. 11th ed. Philadelphia (PA): Elsevier; 2021. p. 663.

Vanaclocha V, Saiz-Sapena N. Percutaneous radiofrequency hip joint denervation. In: Saiz-Sapena N, Vanaclocha V, editors. Chronic pain: physiopathology and treatment. Norderstedt (DE): BoD - Books on Demand; 2021. p. 57-71.

Vullo PA, Moreno O, Vita DC. Haemodynamic instability during hip prosthesis removal due to metallosis: an acute chrome/cobalt intoxication? A case report. Int J Surg Case Rep. 2022;94:1-4.

Waldman SD. Percutaneous sacroiliac joint fusion. In: Waldman SD, editor. Atlas of interventional pain management. 5th ed. Philadelphia (PA): Elsevier; 2021. p. 1146.

Weber AE, Bell JA, Bolia IK. Hip abductor and peritrochanteric space conditions. Clin Sports Med. 2021;40(2):311-322.

Wilkin G. Hip arthroscopy for structural hip problems. In: Berry DJ, editor. Surgery of the hip. 2nd ed. Philadelphia (PA): Elsevier; 2020. p. 672-686.

Wong BW, Chandrashekar AS, Martin JR, et al. Should we expand outpatient total joint selection criteria? Re-exploring hard stop criteria. J Arthroplasty. 2025;40(10):2852-2858.

Za P, et al. Hip resurfacing versus total hip arthroplasty: a systematic review and meta-analysis of randomized clinical trials. Int Orthop. 2024 Oct;48(10):2589-2601.

Zavras AG, Fice MP, Colman MW, et al. Indication for proximal femoral replacement is associated with risk of failure. J Arthroplasty. 2022;37(5):917-924.

Zhang W, et al. OARSI recommendations for the management of hip and knee osteoarthritis, part I: critical appraisal of existing treatment guidelines and systematic review of current research evidence. Osteoarthritis Cartilage. 2007 Sep;15(9):981-1000.

Zhang W, et al. OARSI recommendations for the management of hip and knee osteoarthritis, part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage. 2008 Feb;16(2):137-62.

Zhang W, et al. OARSI recommendations for the management of hip and knee osteoarthritis, part III: Changes in evidence following systematic cumulative update of research published through January 2009. Osteoarthritis Cartilage 2010;18(4):476-499.

Zuke WA, et al. Long-term results of the Birmingham Hip Resurfacing Implant in the United States: an updated analysis of a single institution's experience. J Bone Joint Surg Am. 2025 Mar 19;107(6): e19.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Total Joint Arthroplasty (LCD L36039) [accessed 2026 September 10].

Total Joint Arthroplasty (LCA A57428) [accessed 2026 September 10].

Total Hip Resurfacing is not specifically addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original Effective Date

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: HIV/AIDS CLINICAL PRACTICE GUIDELINES

POLICY EFFECTIVE DATE:	10/1/2024
Policy Control #:	1370/20.000227
Next Annual Review:	November, 2026

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

DESCRIPTIONS

Clinical practice guidelines established to provide guidance relating to counseling and testing, ongoing clinical and behavioral health management, and monitoring of preventive health and long-term health maintenance regimens for all HIV/AIDS infected children, adolescents, and adults.

RELATED POLICIES/DOCUMENTS

Payment Policies:

Mandated Benefits for State Funded Programs, 1550/20.000188
Medical Counseling Services, 1550/20.000177
Outpatient Behavioral Health Services, 1550/20.000204
Preventive Services Guideline, 1550/20.000211

POSITION STATEMENT

CDPHP has adopted the Clinical Guidelines, established by the New York State Department of Health AIDS Institute, for the medical and behavioral health management of enrollees with HIV/AIDS that include:

- Standards of medical care for the adult, adolescent, and pediatric patient infected with

HIV
- Standards of care for individuals with mental health or substance use disorders infected with HIV
- Standards of care relating to HIV and pregnancy and prevention of mother-to-child transmission of HIV
- Diagnostic testing of individuals for HIV infection

Experienced HIV Care Provider

CDPHP has adopted the following criteria, established by the New York State Department of Health, AIDS Institute's HIV Quality of Care Program, for defining an experienced HIV care provider for the clinical management of enrollees with HIV/AIDS:

Scientific and clinical knowledge about the management of HIV infection and disease continues to evolve at a rapid pace, resulting in frequent changes in state-of-the-art practice. For this reason, the clinical care of persons with HIV/AIDS requires the participation of clinicians with specialized expertise, which is best gained from hands-on experience that includes the direct management of patients on antiretroviral therapy. The following criteria defines an experienced HIV care provider:

- A medical doctor, nurse practitioner or physician assistant providing ongoing direct clinical ambulatory care to at least 20 HIV-infected persons who are being treated with antiretroviral therapy, in the preceding twelve months; **or**
- Ten hours annually of continuing medical education including information on the use of antiretroviral therapy in the ambulatory care setting.

For some facilities, particularly in rural or small urban areas where there may be relatively few patients with HIV infection, referral to an experienced HIV care provider is impractical. In such cases, facilities may develop formal relationships with an experienced HIV care provider to co-manage patients.

Offering of HIV Testing/ Consent Requirements

In accordance with chapter 502 of the New York State Laws of 2016, CDPHP expects physicians to provide routine HIV testing to all enrollees age 13 and older (or younger than 13 if there is evidence or indication of risk activity) receiving hospital or primary care services as specified below:

- Inpatient hospitalization
- Emergency department
- Primary care services in the outpatient department of a hospital
- Freestanding diagnostic and treatment center
- Physician, physician assistant, nurse practitioner, or midwife providing primary care (e.g., family medicine, general pediatrician, internal medicine, obstetrics, and

gynecology).

Providers will not be required to offer HIV testing if an individual is being treated for a life-threatening emergency; or (b) has previously been offered or has been tested for HIV; or (c) lacks capacity to consent to a HIV related test.

Prior to the ordering an HIV related test during routine medical care, a provider must first, at a minimum, orally advise the individual, or, when the individual lacks capacity to consent, a person lawfully authorized to consent to health care for such individual, that an HIV test will be performed. The provider may not order the test over the objection of the individual, or person authorized to consent to health care for such individual, except as authorized or required by a state or federal law (i.e., court ordered testing). The advisement, and any objection to testing, is to be documented in the individual's medical record.

Prior to consent of an HIV related test, a provider must explain the following information to the individual being tested, or if such person lacks capacity to consent, to the person lawfully authorized to consent to health care for such person: causes of HIV/AIDS, available treatments, prevention/safe practices strategies, voluntary nature of testing, confidentiality protections, and the prohibition of discrimination.

HIV testing providers are not required to obtain written consent for an HIV test via a general medical consent form or an HIV specific consent form. New York State Public Health law allows for streamline consent for an HIV test. Providers must document each HIV test in the patient's medical record.

POLICY CONSIDERATIONS

Current policies, guidelines, regulations, and other relevant HIV/AIDS information are made available on the following web sites:

- New York State Department of Health AIDS Institute: www.hivguidelines.org
- New York State Department of Health: https://health.ny.gov/

Selected HIV/AIDS materials for providers are also available, in downloadable format, at the following web locations:

- HIV Clinical Resource website: www.hivguidelines.org
- New York State Department of Health website: www.health.state.ny.us/nysdoh/aids/index.htm

You may contact the NYS Department of Health for HIV Resources and general information at 1-800-541-2437 or 1-800-233-7432 for Spanish.

A listing of experienced HIV care providers may be identified from the following sources:

- CDPHP participating provider directories

POLICY NAME: HIV/AIDS CLINICAL PRACTICE GUIDELINES

- CDPHP Find-A-Doc feature at www.cdphp.com

HIV-related tests, or testing is defined as any laboratory test(s) or series of tests approved for the diagnosis of HIV, including rapid HIV testing. Coverage of testing for HIV is offered through the CDPHP participating laboratory network.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS: Subject to all terms and conditions noted above in the policy.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted above in the policy in addition to the following specifics:

Benefits are provided for HIV screening with the appropriate Food and Drug Administration (FDA) approved laboratory tests and point of care (HIV rapid screening tests) for Medicare Choices enrollees who meet one of the following indications:

1. A maximum of one, annual, voluntary screening for all adolescents and adults between the age of 15 and 65, without regard to perceived risk (excludes pregnant enrollees addressed below).

2. A maximum of one annual voluntary HIV screening for adolescents younger than 15 and adults older than 65, who are at increased risk for HIV infection as defined below (excludes pregnant enrollees addressed below):

- Men who have sex with men
- Men and women having unprotected vaginal or anal intercourse
- Past or present injection drug users
- Men and women who exchange sex for money or drugs, or have sex partners who do
- Individuals whose past or present sex partners were HIV-infected, bisexual, or injection drug users
- Persons who have acquired or request testing for other sexually transmitted infectious diseases
- Persons with a history of blood transfusion between 1978 and 1985
- Persons who request an HIV test despite reporting no individual risk factors, since this group is likely to include

individuals not willing to disclose high-risk behaviors

- Persons with new sexual partners
- Persons who, based on individualized physician interview and examination, are deemed to be at increased risk for HIV infection

3. A maximum of three, voluntary, HIV screenings of pregnant enrollees:

- When the diagnosis of pregnancy is known; and
- During the third trimester; and

At labor, if ordered by the enrollee's physician.

4. For individuals being assessed for or using PrEP to prevent HIV, CMS covers all the following as an additional preventive service:

a) Up to eight individual counseling visits every 12 months, that include HIV risk assessment (initial or continued assessment of risk), HIV risk reduction, and medication adherence. Counseling must be furnished by a physician or other health care practitioner. Individuals must be competent and alert at the time that counseling is provided.

b) Up to eight HIV screening tests every 12 months.

c) A single screening for hepatitis B virus (HBV).

These screening tests are covered when the appropriate FDA-approved laboratory tests and point of care tests are used consistent with FDA-approved labeling and in compliance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations.

SELECT PLAN/HARP: Subject to all terms and conditions noted above in the policy to include the following specifics:

- Benefits are provided for HIV screening with laboratory tests and point of care (HIV rapid screening) testing.
- Select Plan enrollees may obtain family planning and HIV testing and counseling services, including rapid HIV testing (86701), when part of a family planning visit from any provider in the CDPHP Select Plan network or from any provider that accepts Medicaid. No referral from the PCP nor authorization is required to access such services.
- HIV testing and counseling that are not part of a family planning visit are covered by Select Plan when services are

arranged by the enrollee's PCP or are obtained at an anonymous HIV testing and counseling site.

- HIV treatment after testing and counseling is covered by Select Plan when services are arranged by the enrollee's PCP and rendered by a Select Plan participating provider.

SOURCES

1. Regulatory Compliance.
2. NYS Department of Health AIDS Institute, www.hivguidelines.org, accessed 9/15/2014.
3. NYS Depatment of Health AIDS Institute, HIV Care Provider Definitions, 2017, https://www.hivguidelines.org/hiv-testing-acute-infection/resources-care-providers/#tab_1
4. NYS Department of Health AIDS Institute HIV Specialist Policy Provider Report, http://www.hivguidelines.org/policy/hiv-experienced-provider-report/, accessed 9/15/2014.
5. NYS Laws of 2010, Chapter 308 (Amending HIV Testing Public Health Law), https://health.ny.gov/
6. Centers for Disease Control (CDC), Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings, 9/22/06, http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm
7. CMS Decision Memo for Screening for the Human Immunodeficiency Virus (HIV) Infection (CAG-00409N), 12/8/09.
8. CMS Decision Memo for Screening for the Human Immunodeficiency Virus (HIV) Infection (CAG-00409R), April13, 2015. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=276
9. NYS Public Health Law 2014 Updates, http://www.health.ny.gov/diseases/aids/providers/testing/law/docs/updates.pdf
10. NYS Department of Health Aids Institute HIV Quality of Care Program, Section 4: Quality of Care Requirements for HIV Specialist Policy, https://www.health.ny.gov/diseases/aids/providers/standards/primarycaremedicaid/section4.htm
11. Medicaid Model Contract, effective 1/1/14.
12. United States Preventive Services Task Force (USPSTF) Final Recommendation Statement:
    Human Immunodeficiency Virus (HIV) Infection: Screening, April 2013.
13. NYS Public Health Law, Article 27-F (HIV and AIDS Related Information), §2780-2787.
14. NYS Public Health Law §2782: Confidentiality and Disclosure, accessed 9/9/19, http://public.leginfo.state.ny.us/lawssrch.cgi?NVLWO:
15. NYS Public Health Law §2781-a: Required offering of HIV related testing, accessed 9/9/19,
16. http://public.leginfo.state.ny.us/lawssrch.cgi?NVLWO:
17. NYS DOH, Section 4: Quality of Care Requirements https://www.health.ny.gov/diseases/aids/providers/testing/primarycaremedicaid/section4.htm

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POLICY NAME: HIV/AIDS CLINICAL PRACTICE GUIDELINES

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POLICY APPROVAL DATES

New:	03/00
Revised:	04/01, 04/02, 03/03, 12/03, 10/04, 06/05, 03/07, 01/08, 01/09, 01/10, 01/11, 01/12, 01/13, 11/14, 11/15, 11/16, 11/17, 05/18, 11/22, 11/23, 11/24
Reviewed:	05/06, 11/13, 11/18, 11/19, 11/20, 11/21, 11/25

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
10/1/2024	Under Medicare, updated information in regard to coverage of PrEP services.
11/1/2023	Under the Position Statement, updated criteria for HIV care provider.
12/1/2022* *No change to effective date of policy	Added the following policies under the "Related Policies" section: Mandated Benefits for State Funded Programs, 1550/20.000188 Outpatient Behavioral Health Services, 1550/20.000204 Preventive Services Guideline, 1550/20.000211

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BEHAVIORAL HEALTH
RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: HOME AND COMMUNITY BASED SERVICES FOR CHILDREN

POLICY EFFECTIVE DATE:	7/1/2026
Policy Control #:	1370/20.000503
Next Annual Review:	8/2026

DISCLAIMER

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If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

H2014, T2015, H2015, H2023, 99347, 90832, 97124, 96152, S5150, S5151

DESCRIPTION

Home and Community Based Services (HCBS) are designed to allow children and youth to participate in developmentally and culturally appropriate services. HCBS are intended to offer support and services to children/youth in non-institutionalized settings that enable them to remain at home and in the community or for children/youth being discharge from an institutional setting who require these services to safely return to their home and community. HCBS are available to Medicaid youth who meet criteria under HCBS/Level of Care Eligibility Determination, which includes those with physical health, developmental disability, and/or mental health diagnoses with related significant needs.

HCBS includes the following services:

Note: *Reference to family is broadly defined, and includes families created through birth, foster care, adoption, or self-created unit.*

Note: *While Adaptive and Assistive Equipment and Environmental and Vehicle Modifications are included in the array of HCBS services available to waiver enrolled members, the Centers of Medicare and Medicaid approved a Children's Waiver Amendment on 3/1/24 to implement Financial Management Services over these projects. Children's Health Home of Upstate New York (CHUNNY, LLC) will serve as the FMS for*

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New York State and will review and provide oversight of all EMod, VMod, and AAT project funding requests for children/youth enrolled in the Children's Waiver. This transition for children enrolled in Medicaid Managed Care occurred on 7/1/24.

***Note:** Review and oversight of all EMod, VMod, and AAT project funding requests for Child Health Plus members enrolled in the Children's Waiver will be the responsibility of CDPHP, as these services are not managed under FMS through CHHUNY.*

Adaptive and Assistive Equipment
This service provides technological aids and devices identified within the child's Plan of Care (POC) which enable him/her to accomplish daily living tasks that are necessary to support the health, welfare, and safety of the child.

***Note:** Service dogs have been removed as a service option under Adaptive and Assistive Technology.*

Caregiver/Family Advocacy and Support Services Caregiver/Family Advocacy and Support Services enhance the child's ability, regardless of disability, to function as part of a caregiver/family unit and enhance the caregiver/family's ability to care for the child in the home and/or community as well as, provides the child, family, caregivers, and collateral contacts with techniques and information not generally available so that they can better respond to the needs of the child/youth.

***Note:** This service is not the same as the Medicaid Children and Family Treatment and SupportService (CFTSS) of Family Peer Support Services, which are delivered by a certified Family Peer with lived experience.*

Community Habilitation
Community Habilitation covers face-to-face services and supports related to the child's acquisition, maintenance, and enhancement of skills necessary to perform Activities of Daily Living (ADLs), Instrumental Activities of Daily Living (IADLs), and/or Health Related Tasks delivered in the community (non-certified) settings.

Acquisition, maintenance and enhancement are defined as:

- Acquisition is described as the service available to a child who is seeking greater independence by learning to perform the task for him or herself. There should be a reasonable expectation that the individual will acquire the skills necessary to perform that task within the authorization period.
- Maintenance is described as the service available to prevent or slow regression in the child's skill level and to prevent loss of skills necessary to accomplish the identified task.
- Enhancement activities are provided to the child through training and demonstration to promote growth and independence with an already acquired skill level and to support the child's goal outside of the training environment.

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Day Habilitation
Assistance with acquisition, retention or improvement in self-help, socialization and adaptive skills including communication, and travel that regularly takes place in a non-residential setting, separate from the person's private residence or other residential arrangement. Activities and environments are designed to foster the acquisition of skills, appropriate behavior, greater independence, community inclusion, relationship building, self-advocacy and informed choice. Day Habilitation services must be provided to a child at an OPWDD certified setting typically between the daytime hours of 9 a.m.-3 p.m.

***Note: Day** Habilitation was discontinued effective 1/1/26. Participants in need of strengthening skills related to ADLs/IADLs should receive these supports through Community Habilitation, which addresses the same needs, however, does not have the added restriction to be delivered at an OPWDD certified site.*

Environmental Modifications
Provides internal and external physical adaptations to the primary residence of the enrolled child which, per the child's plan of care (POC), are identified as necessary to support the health, welfare, and safety of the child or that enable the child to function with greater independence in the home and without which the child would require an institutional and/or more restrictive living setting.

Non-Medical Transportation
Transportation to access authorized HCBS and destinations that are related to a goal included on the child/youth's plan of care.

Palliative Care
Specialized medical care focused on providing relief from the symptoms and stress of a chronic condition or life-threatening illness. Goal is to improve quality of life for both the patient and the family. Palliative care is provided by a specially trained team of doctors, nurses, social workers, and other specialists who work together with a child's doctors to provide an extra layer of support. It is appropriate at any stage of a chronic condition or life-threatening illness and can be provided along with curative treatment.

Children must meet Level of Care functional criteria and suffer from the symptoms and stress of chronic medical conditions OR illnesses that put individuals at risk for death before age 21. The Health Home Care Manager or C-YES will assist the family to obtain a doctor's written order including justification for Expressive Therapy from a Physician, Physician Assistant, Nurse Practitioner, Occupational Therapist, Physical Therapist or Psychiatrist, to be included with the child's Plan of Care and made available to the Managed care plan as needed.

Types of activities include:
- Pain and Symptom Management – relief and/or control of suffering related to illness or condition and is an important part of aiding in providing relief from pain and symptoms and/or controlling pain, symptoms, and side effects related to chronic conditions or life-threatening illness a child is enduring.

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- Counseling and Support Services (provided by HCBS providers) – help for children and their families to cope with the child's chronic medical, physical, or developmental condition or life-threatening illness and with grief/loss related to the child's passing. This service can also include Bereavement Counseling Services provided by Health Homes.
- Massage Therapy – provided to improve muscle tone, circulation, range of motion and address physical symptoms related to illness as well as provide physical and emotional comfort, pain management, and restore the idea of healthy touch for children and youth who are dealing with treatments that may involve painful interventions and ongoing and/or past trauma.
- Expressive Therapy (art, music and play) – assist child/youth to better understand and express his/her reaction through creative and kinesthetic treatment.

Prevocational Services
Designed to prepare youth (age 14 or older) to engage in paid work, volunteer work, or career exploration. Prevocational Services are not job-specific but rather are geared toward facilitating success in any work environment for youth whose disabilities do not permit them access to other prevocational services. The service will be reflected in youth's plan of care and must be directed to teaching skills rather than explicit employment objectives. In addition, PrevocationalServices assist with facilitating appropriate work habits, acceptable job behaviors, and learningjob production requirements.

Respite
Short-term assistance provided to children/youth, regardless of disability (developmental, physical and/or behavioral), because of the absence of or need for relief of the child or the child's family/caregiver. Such services can be provided in a planned mode or delivered in a crisis situation. Respite workers supervise the child/youth and engage the child/youth in activities that support his/her and/ or primary caregiver/family's constructive interests and abilities. Respite providers offer services with a level of expertise in understanding and implementing behavioral/developmental interventions required to support optimal functioning for children/youth.

Respite providers will regularly communicate the details of the child/youth's intervention plan so that there is a carryover of skill from the respite source to the caregivers and treatment providers.

Supported Employment
Designed to prepare youth with disabilities (age 14 or older) to engage in paid work. Supported Employment services provide assistance to participants with disabilities as they perform in a work setting.

Supported Employment provides ongoing supports to participants who, because of their disabilities, need intensive on-going support to obtain and maintain an individual job in competitive or customized employment, or self-employment, in an integrated work setting in the general workforce for which an individual is compensated at or above the minimum wage, but not less than the customary wage and level of benefits paid by the employer for the same or

similar work performed by individuals without disabilities. The outcome of this service is sustained paid employment at or above the minimum wage in an integrated setting in the general workforce, in a job that meets personal and career goals.

Supported Employment services are individualized and may include any combination of the following services: vocational/job-related discovery or assessment, person-centered employment planning, job placement, job development, negotiation with prospective employers, job analysis, job carving, training and systematic instruction, job coaching, benefits support, training and planning, transportation, career advancement services, and other workplace support services including services not specifically related to job skill training that enable the participant to successfully integrate into the job setting.

Supported Employment services may also include services and supports that assist the participant in achieving self-employment through the operation of a business including home-based self-employment. However, Medicaid funds are not used to defray the expenses associated with starting up or operating a business.

In addition to the need for an appropriate job match that meets the individual's skills and interests, individuals may also need long-term employment support to successfully maintain a job due to the ongoing nature of the HCBS participant's support needs, changes in life situations, or evolving and changing job responsibilities.

Vehicle Modifications
Provides physical adaptations to the primary vehicle of the enrolled child which, per the child's plan of care (POC), are identified as necessary to support the health, welfare, and safety of the child or that enable the child to function with greater independence.

The following HSBS services were added under a 4/1/26 1915(c) Children's Waiver Amendment:

Transitional Care Coordination

Transitional Care Coordination is designed to address barriers to discharge from institutional care and support safe, timely transitions to home and community settings. The service promotes continuity of care by supporting coordination across settings, timely communication among providers, and connect to appropriate follow-up services for children and families. TCC provides coordination of needed services and support to families during the transition period to maintain stability after discharge.

Transitional Care Coordination is for children and youth who:

- Are in an institutional level of care, e.g., hospital, inpatient, nursing home setting for at least one year
    - Children ages 1 up to 21 years **OR**

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POLICY NAME: HOME AND COMMUNITY BASED SERVICES FOR CHILDREN

- Infants 12 weeks under 1 year of age

- Can be medically cleared within 6 months, but the following condition(s) apply:
  - Non-medical barriers to discharge are present
  - Safety and/or continued care concerns exist

Eligible individuals are those who can be safely discharged from an acute or institutional setting within six (6) months of eligibility determination, with the support of transition care coordination.

Transitional Care Coordination Services can be provided up to 180 days prior to discharge from an acute or institutional setting and up to 60 days post-discharge. Transitional Care Coordinators are matched to specific institutions and determination of whether a child/youth would benefit from these services will be determined through a collaborative process between the TCC provider and the institution. The Transitional Care Coordinator will identify non-medical barriers to discharge and will develop the Transitional Service Plan which address barriers to discharge, a plan to address them, and the supports/services needed to transition to the community. The coordinator will also facilitate referral to DOH C-YES to determine HCBS eligibility, discuss Health Home options, and complete Freedom of Choice.

Service components include, but are not limited to the following:

- Communication with the participant/family, members of the treatment team. Identified support agencies, and community service providers
- Parent/caregiver and informal/formal supports. education/training regarding the participant's needs and condition to support entry/re-entry to home/community
- Identification and connection to needed community health services/resources
- Connection to needed care, services, equipment
- Facilitation of HCBS Transitional Service Requests
- Housing connection, support, and access
- Changes to the environment and submission of Environmental Modification requests
- Arrangements for medical equipment, medication, community specialists, doctors, therapies, and transportation
- Connection to caregiver supports and resources

TCC is carved out of Medicaid Managed Care and only billed Fee for Service

Transitional Services

Transitional Services are intended to assist a waiver participant in transitioning from a nursing home or institutional setting to living in the community. These services provide funds that can be utilized to help address the barriers preventing children/youth from returning home from an institutional setting. Transitional Care Coordinators will utilize Transitional Services to provide coordination of needed services and support to families during the transition period to maintain stability after discharge. Services include funding for various items, including, but not limited to the

following: the cost of moving furniture and other belongings; purchasing essential home furnishings; health and safety assurances, pest removal, allergen control, etc.

Transitional Services are administered by the Financial Management Service (FMS) and will be carved out of Managed Care and will be billed FFS for all participants.

RELATED POLICIES/DOCUMENTS

N/A

POSITION STATEMENT

CDPHP does not provide coverage for children home and community-based services identified above except for Select Plan members under 21, who have met HCBS/Level of Care Eligibility Determination criteria as determined by the Health Home, Children and Youth Evaluation Service (C-YES), or Developmental Disabilities Regional Office (DDRO), as described below.

Please note: Home and Community Based Services (HCBS) may be available to Child Health Plus members who do not qualify for Medicaid due to immigration or income status.

POLICY CONSIDERATIONS

FOR SELECT PLAN & CHILD HEALTH PLUS ONLY

Note: According to CMS, settings that do not meet the definition of being home and community based are:

- *A nursing facility;*
- *An institution for mental disease;*
- *An intermediate care facility for individuals with developmental disabilities;*
- *A hospital;*
- *OMH Licensed Congregate Treatment Sites (Community Residences);*
- *DOH Adult Homes; or*
- *Any other location that has qualities of an institutional setting.*

Home and Community Based Services (HCBS) are available for Select Plan and Child Health Plus (CHP) enrollees under 21 years of age when the eligibility assessment completed by the Health Home or C-YES, identifies eligibilityfor HCBS. Plans of Care and approval of HCBS shall be in accordance with the CMS final rule and any applicable state guidance.

Through a person-centered planning process, the Health Home Care Manager (HHCM), or

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Qualified Individual Identified by the State (QIIS) when enrollee elects not to enroll in a Health Home, develop and maintain a comprehensive plan of care (POC) inclusive of the enrollee and family's goals. If an enrollee elects not to participate in Health Home Care Management, the QIIS will be the MMCP in collaboration with OMH (for the SED Population) or DOH (for the Medically Fragile or Developmental Disability Populations). The MMCP will be responsible for monitoring and updating the Plan of Care and Coordinating HCBS care for participants. OMH/DOH will develop the initial Plan of Care, make referrals to HCBS providers for HCBS services, and be responsible for completing the annual HCBS eligibility determination.

This person-centered planning process includes convening a multi-disciplinary team meeting, completing a comprehensive assessment to determine services needed beyond HCBS (e.g., health, behavioral health, specialty services, other community and social supports, etc.), and the CANS-NY.

Throughout the person-centered planning process, the HHCM/ QIIS will update the POC. In addition to HCBS, the POC includes preventative services (e.g., annual physicals) and health education/promotion services. Enrollee/family's preferences (enrollee/family is not required to identify specific procedure code or provider to request service) and the presence of functional impairment is enough to support need.

CDPHP reviews the submitted POC, including the enrollee/family's identified goals, for clinical appropriateness of care based in the enrollee's current condition, effectiveness of previous treatment, environmental and family supports, and desired outcomes. In addition, the enrollee's CDPHP file is reviewed to identify eligibility, duplication of services, enrollee suitability for service(s) based on information that may not have been available to HHCM, evidence ofenrollee readiness, and regulatory requirements/criteria identified for the requested HCBS. CDPHP works with HHCM/QIIS.

CDPHP will conduct a quality review of the child/youth's POC, the HCBS service plan, as well as the Children's HCBS Authorization Form. When review is complete, CDPHP will notify Health Home, HCBS provider, and/or child/family of completed quality review and discuss any questions and/or provide feedback. CDPHP Care Managers will review the above referenced documents to ensure completion and assessment of frequency, scope, and duration, as well as assess the appropriateness of the anticipated utilization. Once youth begin to utilize services, CDPHP Care Managers will review utilization to ensure it aligns with the levels outlined on the HCBS Authorization Form and Plan of Care. See CDPHP Children HCBS Quality Review Process Guide for additional information.

Throughout the HCBS review process, the HHCM/QIIS continues to update the POC, as appropriate. If additional HCBS needs are identified during the process, an updated POC is submitted to CDPHP.

The completed POC is submitted to CDPHP for review within 90 days of completing theeligibility assessment. The POC is reviewed for compliance with CMS requirements.

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The final POC is shared with CDPHP case management and behavioral health teams who work collaboratively with the HHCM to monitor approved services, verifying approved are rendered appropriately with regard to the frequency, scope, and duration.

The HHCM/QIIS (OMH for SED eligibility and DOH for medically fragile eligibility) conducts eligibility re-assessment of HCBS needs on an annual basis, or after asignificant change in condition.

Continued service provision is provided when enrollee makes measurable progress toward goals, or there is evidence that the service plan has been modified to address the barriers in treatment progression, or continuation of services is necessary to maintain progress already achieved and/or prevent deterioration. Ongoing services can be outlined for quality review by submitting an updated Plan of Care (POC) and/or HCBS service plan to CDPHP.

Plan of care meetings involving the enrollee, Health Home/QIIS, and HCBS provider(s) are conducted, at a location, date and time convenient to the enrollee and the enrollee's chosen participants, to evaluate the plan of care and identify possible updates to the current plan of care. Enrollee specific requests made during these meetings, as well as requests agreed to by the team, are submitted to CDPHP for quality review.

See Department of Health Children Home and Community Based Services Workflow for an outline in roles and responsibilities and steps through the POC and HCBS process.

See NYS Children's Health and Behavioral Health Medicaid System Transformation: Children's Home and Community Based Services Manual for a complete outline of HCBS Service Components, Modality, Setting, Limitations/Exclusions, Certification/Provider Qualifications, Training Requirements, and Billing Details. CDPHP follows and complies with all guidance outlined in this document, as well as any other applicable NYS document outlining Children's HCBS.

EXCLUSIONS

Exclusions listed under each applicable area of coverage above.

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POLICY NAME: HOME AND COMMUNITY BASED SERVICES FOR CHILDREN

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted above in the policy. *Note: Review and oversight of all EMod, VMod, and AAT project funding requests for Child Health Plus members enrolled in the Children's Waiver will be the responsibility of CDPHP, as these services are not managed under FMS through CHHUNY.*
MEDICARE ADVANTAGE:	Medicare Choices does not provide coverage for children's HCBS.
SELECT PLAN/HARP:	HARP does not provide coverage for children's HCBS.

SOURCES

1. New York State: Children's Health and Behavioral Health Services Transformation – Home and Community Based Services (HCBS) Provider Manual, March 2023, NYS DOH OMH OASAS OCFS OPWDD https://www.health.ny.gov/health_care/medicaid/redesign/behavioral_health/children/docs/hcbs_manual.pdf
2. CMS Final Rule on HCBS: https://www.govinfo.gov/content/pkg/FR-2024-05-10/pdf/2024-08363.pdf

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Date 7/2/26
CDPHP Behavioral Health

BEHAVIORAL HEALTH
RESOURCE COORDINATION POLICY

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POLICY NAME: HOME AND COMMUNITY BASED SERVICES FOR CHILDREN

POLICY APPROVAL DATES

New: 9/19

Revised: 5/22, 8/24, 12/24, 7/26

Reviewed: 9/20, 9/21, 9/22, 9/23, 8/25

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POLICY NAME: HOME AND COMMUNITY BASED SERVICES FOR CHILDREN

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
7/1/2022	Added benefit update under "Bereavement Service" section on page 15: "Families are able to receive additional Palliative Care Bereavement Counseling for up to six (6) months following the passing of a child or youth that was enrolled in the Children's Waiver at the time of their passing, when the family has received a bereavement counseling review and bereavement counseling is stated on the Service Plan and Plan of Care, prior to the child passing."
8/1/2023	Added 96156 and 96159. Updated Caregiver/Family Advocacy and Support Services definition. Removed comprehensive service components and limitations/exclusions for services, and refer to NYS Children HCBS Manual. Updated process on CDPHP review of POC and HCBS Authorization Form.
7/1/24	Removed codes for EMods, VMods, and AAT (S5165, T2039, and T2028). Updated service array to include carve out of EMods, VMods, and AAT to FMS through CHUNNY, effective 7/1/24.

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12/24	Added explanation of coverage for Child Health Plus as per NYS mandate.
7/2/26	Added removal of day habilitation from the HCBS service array Removed codes for day habilitation (T2020) Added exclusion of service dogs as allowable under Adaptive and Assistive Technology Added Transitional Care Coordinator and Transitional Services under HCBS service array Added responsibility of the MCO to assume the care coordination role as the Qualified Individual Identified by the State (QIIS) when a member elects not to enroll in Health Home Care Management Updated links for New York State: Children's Health and Behavioral Health Services Transformation – Home and Community Based Services (HCBS) Provider Manual and CMS Final Rule on HCBS

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RESOURCE COORDINATION POLICY

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POLICY NAME: HOME CARE SERVICES: HOME HEALTH CARE/TELE-HOMECARE/PERSONAL CARE/PERSONAL EMERGENCY RESPONSE SYSTEM

POLICY EFFECTIVE DATE:	9/1/2025
Policy Control #:	1370/20.000048
Next Annual Review:	July, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

Refer to the Policy Considerations section below for procedure codes relating to specific home health care services.

DESCRIPTIONS

Home health care is an extension of hospital care afforded patients as an alternative to hospitalization or treatment in a skilled nursing facility (SNF).

Tele-homecare is technology utilized in the home by means of an audio/video/digital telecommunication system to transmit clinical information to a skilled home care agency for the management of chronic conditions. It is used as an alternative to office-based or emergency room monitoring.

Personal care services (PCS) are services that provide assistance with activities of daily living (e.g., housekeeping, meal preparation, personal hygiene) for individuals who require such support services based on a medical need.

Personal emergency response system (PERS) is the provision and maintenance of electronic communication equipment in the home of certain high-risk individuals to secure help in the event of a physical, emotional, or environmental emergency.

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RELATED POLICIES/DOCUMENTS

Payment Policy:

Telehealth/Telemedicine Services, 1550/20.000221

POSITION STATEMENT

CDPHP administers benefits for home health care and/or tele-homecare when all the conditions listed below are met.

Home Health Care

- Services are ordered by a practitioner.
- Services are in lieu of a hospitalization or placement in a SNF.
- Services are provided by a licensed or certified home health agency.
- The services are required on a part-time or intermittent basis, as defined in the Medicare Benefit Policy Manual published by the Centers for Medicare & Medicaid Services (CMS).
- Services are skilled in nature.
- Services are provided by or under the supervision of a registered nurse or qualified therapist.
- Services consist primarily of caring for the patient.
- Services are considered by CDPHP to be specific, effective, and reasonable for the treatment of the patient's diagnosis and physical condition, and the most cost-effective approach to care.

In addition, CDPHP, at the network provider's request, will provide a woman a minimum of one prenatal or postnatal home health care nurse (99500, 99501) visit when the woman may derive medical or psychosocial benefits from such visits. The visit shall identify familial and environmental factors that may produce increased risk to the woman or fetus and the relevant finding shall be incorporated into the care plan.

A minimum of one home health care visit is covered for all patients who participate in early discharge from maternity care. Requests for such service may occur any time within 48 hours of the time of delivery (96 hours for caesarean section delivery) and be provided within 24 hours after discharge from the hospital or of the time of the request, whichever is later. The request for service may come from either the patient or physician. This visit is not subject to an enrollee cost-share.

Each visit by a member of the Home Health Agency is considered one (1) visit. Each visit of up to four (4) hours by a home health aide is considered one (1) visit. Any Rehabilitation or Habilitation Services received under this benefit will not reduce the amount of services available

POLICY NAME: HOME CARE SERVICES: HOME HEALTH CARE/TELE-HOMECARE/PERSONAL CARE/PERSONAL EMERGENCY RESPONSE SYSTEM

under the Rehabilitation or Habilitation Services benefits.

Home health care services may include:

- Nursing care by or under the supervision of a registered nurse.
- Physical, occupational, or speech therapy services provided by or under the supervision of a qualified therapist.
- Home health aide services that are an adjunct to a skilled service.
- Medical supplies, drugs, and medications provided by the home health agency, and prescribed by an authorized provider.
- Laboratory services by or on behalf of the home health agency.
- Home infusion therapy.

A certified doula to help manage your pregnancy, prenatal, and postnatal care may be available. (Refer to specific member contracts for benefits, if any, relating to doula services)

Tele-Homecare

CDPHP administers benefits for tele-homecare services for enrollees who have a primary or secondary diagnosis of congestive heart failure (CHF), chronic obstructive pulmonary disease (COPD), diabetes, or coronary artery disease (CAD) when **all** the following criteria is met:

- Documentation member has had two or more inpatient hospitalizations or emergency room visits in the past 12 months.
- Services are ordered by a practitioner who agrees to review the generated data and respond in a timely fashion to the home health agency (e.g., change in orders).
- Services are provided by a home health agency.
- Services are required on a part-time intermittent basis for up to six weeks and are provided seven days per week.
- Services are provided by or under the supervision of a registered nurse.
- Services are considered by CDPHP to be specific, effective, and reasonable for the treatment of the patient's diagnosis and physical condition, and the most cost-effective approach to care.

Tele-homecare services may include monitoring and reporting of the following measurements:

- Blood pressure readings
- Blood glucose levels
- Daily weights

- Vital signs

POLICY CONSIDERATIONS

Claims for the following home health care services are to be submitted utilizing the following codes:

- Home Health Aide: S5125, S5126, S9122, T1021, G0156
- Home Infusion services: 99601, 99602
- Licensed Practical Nurse (LPN): S9124, T1003, T1031, G0300, G0494, G0496
- Medical Social Services: S9127, G0155
- Nutritional Counseling: S9470, G0270
- Occupational Therapist: S9129, G0152
- Other Home Health Services/Procedures: 99500, 99501, 99502, 99503, 99504, 99505, 99506, 99507, 99511, 99512, 99600
- Physical Therapist: S9131, G0151
- Private Duty Nursing: T1000
- Registered Nurse (RN): S9123, T1002, T1030, G0162, G0299, G0493, G0495
- Respiratory Therapy: G0237, G0238
- Speech Therapist: S9128, G0153
- Tele-homecare: S9110, T1014, G0320, G0321, G0322

Services must relate directly and specifically to an active/written treatment plan, which has been approved by the ordering physician.

Services noted will be provided to the extent that such items would have been covered under the contract if the enrollee had been hospitalized or confined in an SNF.

Benefit coverage, for up to a maximum of six visits, will be provided for the establishment of an effective therapy (e.g., physical therapy, G0159, occupational therapy, G0160, and speech therapy, G0161) maintenance program in the home setting. However, no coverage will be provided for the continuation of maintenance programs (maintenance begins when the therapeutic goals of a treatment plan have been achieved and when no further functional progress is apparent or expected to occur).

In determining the appropriateness of tele-homecare, CDPHP expects consideration be given to the complexity of the enrollee's medical condition and the probability that a hospitalization or emergency room visit would occur in the absence of tele-homecare services.

To determine whether a service requires the skill of a nurse, consideration must be given to both the complexity of the service and the condition of the patient.

POLICY NAME: HOME CARE SERVICES: HOME HEALTH CARE/TELE-HOMECARE/PERSONAL CARE/PERSONAL EMERGENCY RESPONSE SYSTEM

Tele-homecare services may be initiated in conjunction with skilled nursing care.

Supplies rendered in conjunction with covered home care services are reimbursed based upon the provider agreement contracted rate.

Laboratory testing must be processed at a lab.

EXCLUSIONS

Custodial care (99509) or rest cures and services rendered for the convenience of an enrollee or provider. Care is considered custodial when it is primarily for the purpose of helping the member with daily living or meeting personal needs and could be provided safely and reasonably by people without professional skills or training. For example, custodial care includes help with walking, getting in and out of bed, bathing, dressing, and eating.

Personal care services/consumer directed personal assistance, personal emergency response systems, private duty nursing, and UAS assessment/plan of care development services are excluded for all products other than Select Plan/HARP.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy to include the following: • Services must be provided by a certified participating home health agency (CHHA).
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted above in the policy to include the following: • Services must be provided by a Medicare participating home health care agency. • Individuals must be confined to the home as defined by Medicare. The following required criteria must be met: **Criterion One** • Enrollee must either, because of illness or injury, need the aid of supportive devices such as crutches, canes, wheelchairs, and walkers; the use of special transportation; or the assistance

	of another person in order to leave their place of residence; **OR** • Have a condition such that leaving their home is medically contraindicated. If the patient meets one of the criterion above, then the following two additional requirements defined in criterion two must be met as well: **<u>Criterion Two:</u>** • There must exist a normal inability to leave home; **AND** • Leaving the home requires a considerable and taxing effort. *Note: If the enrollee does in fact leave the home, the enrollee may be considered homebound if the absences from the home are infrequent or for periods of relatively short duration, or are attributable to the need to receive health care treatment to include, but not limited to: • Attendance at adult day centers to receive medical care; • Ongoing receipt of outpatient kidney dialysis; • The receipt of outpatient chemotherapy or radiation therapy. In accordance with guidelines from the Centers for Medicare & Medicaid (CMS), an enrollee or their designee must receive a Notice of Medicare Non-Coverage (NOMNC) no later than two days prior to termination of services. Participating agencies will provide the CDPHP NOMNC to enrollees, which includes completion of valid delivery, faxing of copy to CDPHP, and maintaining a copy in the enrollee's medical record upon completion of services.
SELECT PLAN/HARP:	Billing codes for Medicaid programs: • Personal Care Aide Level I (Homemaker/Housekeeper): S5130 (Note: Effective 9/1/25, Personal Care Aide Level I services are only billable for members granted Legacy Status, and who are therefore not subject to new Minimum Needs requirements upon reassessment. See below for additional information on the 9/1/25 Minimum Needs update) • Personal Care Aide Level II: T1019, T1020 • Consumer Directed Personal Assistant: T1019, T1020

	• Personal emergency response system: S5160, S5161 • Uniform Assessment System (UAS-NY): Service Assessment/Plan of Care Development: T2024 (Billed to Medicaid fee-for-service) • T1001: RN Supervisory Visit In accordance with New York State Public Health Law, providers must bill the universal billing codes with respective modifiers, if any, when submitting claims for payment of home care or personal care services. Subject to all terms and conditions noted above in the policy to include the following: • Home health services must be provided by a certified home health agency (CHHA), or if no CHHA available, a registered professional nurse or licensed practical nurse under the direction of the primary care physician. • Home visits for pregnant women and home visits beyond the initial visit for postpartum women are covered as medically necessary. • At least two visits to high-risk infants (newborns). • Perinatal care visits need not be in lieu of a hospitalization or placement in a SNF. • Prior authorization is required for Private Duty Nursing (PDN), Personal Care Services (PCS), Consumer Directed Personal Assistance (CDPA) & Personal Emergency Response System (PERS) as outlined below. CDPHP utilizes the New York State Medicaid Management Information System (MMIS) Home Health Manual Policy Guidelines for guidance: https://www.emedny.org/ProviderManuals/HomeHealth/index.aspx **Private Duty Nursing** Private duty nursing services, rendered by a registered professional nurse or licensed practical nurse, are covered only when determined by the attending physician to be medically necessary and prior authorized by CDPHP. Approved services are provided through a licensed home care agency or private practitioner and can be

	performed in and out of the home setting depending on the enrollee's normal life activities (e.g., for a child, full time private duty nursing would be covered in a school, an approved pre-school (both of these settings are covered by the school district of the member's residence) or a natural environment, including home and community settings). CDPHP utilizes the New York State Medicaid Management Information System (MMIS) Private Duty Nursing Manual Policy Guidelines for guidance: https://www.emedny.org/ProviderManuals/NursingServices/index.aspx **Home Telehealth Services** Benefits are provided for home telehealth services when provided by agencies approved by NYS Department of Health for enrollees who have conditions or clinical circumstances requiring frequent monitoring and when the provision of telehealth services can appropriately reduce the need for on-site or in-office visits or acute or long-term care facility admission. **Personal Care Services (PCS)/Consumer Directed Personal Assistance Program (CDPAP)** Personal care services are provided to enrollees who need additional assistance with activities of daily living (e.g., housekeeping, meal preparation, personal hygiene) to live independently at home due to the presence of a medical condition. Consumer-directed personal assistance is similar to personal care except the care is rendered by a family member or caregiver of choice, rather than a home health agency. Effective 9/1/25, members will be required to meet Minimum Needs Requirements at initial assessment and upon subsequent reassessments in order to qualify for PCS and CDPAP services. These Minimum Needs Requirements are: • Member is assessed as needing at least limited assistance with physical maneuvering with **more than two** ADL's, OR • Member has a Dementia or Alzheimer's diagnosis, and is assessed as needing at least supervision with **more than one** ADL

	○ Members with a Dementia or Alzheimer's diagnosis must provide proof of a diagnosis during the assessment process. The Alzheimer's Disease or Dementia form (DOH-5821) must be completed by the licensed health care professionals listed on the form, however, the diagnosis must be made by a physician (MD or DO) with the knowledge and expertise to confirm a diagnosis of Dementia or Alzheimer's. ○ A copy of the DOH-5821 form must be retained in the member's file. The plan must also document the date of the documentation of diagnosis in the individual's case notes and the UAS-NY "Section H: Disease Diagnoses" Prior to 9/1/25, PCS and CDPAP services were provided on two different levels depending on the needs and requirements of the individual (see outline of Level I and Level II services below). Due to the 9/1/25 Minimum Needs regulation updates, Level I will not be available on their own, and can only be received and authorized along with Level II services. • Level I are environmental and nutritional support services necessary to maintain the individual in the home when no family member or other persons are available or able to assist. Examples of such services include assistance with preparing and serving meals, making and changing beds, cleaning the kitchen, caring for laundry, and shopping for essential supplies. Benefits for level 1 (housekeeping only) services are limited to eight hours per week. • Level II includes basic personal care services, such as bathing, grooming, toileting, ambulation, turning and positioning, and assistance with taking physician-prescribed medication, in addition to household tasks. **PCS and CDPAP Legacy Status** All individuals seeking an initial assessment and authorization for PCS or CDPAS beginning on 9/1/25 must meet the Minimum Needs requirements outlined above, which will also apply to all subsequent reassessments. Both the initial assessments and reassessments to follow the information outlined below, as well as the requirements outlined above related to the Minimum Needs requirements. Individuals authorized for PCS or CDPAS before 9/1/25 will be granted

Legacy Status and will not be subject to the new Minimum Needs requirements upon subsequent reassessments.

Authorization Process

Initial assessments for adult members 18 years or older

The New York Independent Assessor – NYIA - conducts all initial assessments for adult members 18 years or older seeking PCS and/or CDPAS services.

NYIA will complete the Community Health Assessment (CHA) in UAS-NY.

The NYIA includes an Independent Practitioner Panel (IPP) to conduct the exam. During the Clinical Appointment, an IPP clinician will: review the CHA, examine the member (either in person or through a telehealth modality) and if necessary, consult with providers and others who may have insight into the member's needs; ensure that the current diagnoses and medications are documented accurately and thoroughly; attest to the member's need for assistance; indicate whether the member is self-directing, or has identified an appropriate self-directing other; indicate if the member can complete the consumer's roles and responsibilities (if they are authorized for and enroll in CDPAS); and determine if the member's medical condition is stable to receive PCS and/or CDPAS.

Once both the Initial Assessment and Clinical Appointment are completed, the member will receive a written notice from NYIA informing them of the outcome of the assessment and clinical exam.

CDPHP is responsible for developing a plan of care and authorizing services for the individual.

Reassessments for adults aged 18 and over, and initial assessments and reassessments for children aged 0-17

CDPHP conducts reassessments for adults aged 18 and over, and initial assessments and reassessment for children aged 0-17 (until further notice).

The following documentation is to be submitted for review as part of

	the initial authorization process. • A **signed physician order** certifying that the enrollee can be cared for at home. The signed order needs to identify current medical conditions, treatment regimens, medication regimen, and personal care assistance needed, and must be written within 30 calendar days of medical examination of the enrollee by the physician. Upon receipt of a completed physician order, CDPHP will arrange for a registered nurse to perform a home assessment (either in person or through a telehealth modality), which includes both nursing and social components. • A **social assessment** that documents the potential contribution of informal caregivers, such as family and friends, to the enrollee's care. • A **nursing assessment** that includes the following: a review and interpretation of the physician's order; an evaluation of the functions and tasks required by the patient and the degree of assistance required for each function and task; and the development of a plan of care recommending the appropriate amount, frequency, and duration of services. Once the process described above is complete, if documentation supports the recommended plan of care, authorization for personal care/consumer-directed personal assistance will be given. CDPHP utilizes the New York State Medicaid Management Information System (MMIS) Personal Home Care Manual Policy Guidelines for guidance: https://www.emedny.org/ProviderManuals/PersonalCare/index.aspx **Personal Emergency Response System (PERS)** A Personal Emergency Response Service (PERS) is the provision and maintenance of electronic communication equipment in the home of certain high-risk individuals to secure help in the event of a physical, emotional, or environmental emergency. A PERS has three components: a small radio transmitter, a console that is connected to a telephone, and an emergency response center that monitors the calls.

POLICY NAME: HOME CARE SERVICES: HOME HEALTH CARE/TELE-HOMECARE/PERSONAL CARE/PERSONAL EMERGENCY RESPONSE SYSTEM

	Personal Emergency Response Services are available under the following circumstances: • Only enrollees currently receiving personal care or consumer-directed personal care are eligible for personal emergency response services. • The process and procedures for the authorization of personal emergency response services are completed in accordance with and/or in coordination with the authorization process for personal care/consumer-directed personal assistance, as stated above. • Authorization for PERS services is based on a physician or nurse practitioner's order and a comprehensive assessment that must include an evaluation of the enrollee's physical disability status, the degree that they would be at risk of an emergency due to medical or functional impairments or disability and the degree of their social isolation. Qualifying for personal care services does not necessarily mean an enrollee automatically qualifies for PERS services. CDPHP utilizes the New York State Medicaid Management Information System (MMIS) Personal Emergency Response Services Manual Policy Guidelines for guidance: https://www.emedny.org/ProviderManuals/PERS/index.aspx **Recertification of Services** Requests for ongoing personal care services and/or personal emergency response services require recertification prior to the end date of the previous approved authorization period.

SOURCES

1. Center for Medicare Advocacy, Grijalva v. Shalala, http://www.medicareadvocacy.org/Litigation_Archives.htm
2. Member contract language
3. HCFA, Home Health Agency Manual Coverage of Services, Section 206.7, www.hcfa.gov/pubforms.
4. Kane, R.; Chen, Q.; Finch, M.; Blewett, L.; Burns, R.; Moskowitz, M.; Clinical Investigations:

Functional Outcomes of Posthospital Care for Stroke and Hip Fracture Patients Under Medicare. Journal of the American Geriatrics Society. Volume 46. Number 12. December 1998.

5. Medicaid Managed Care Contract, Appendix K.
6. Medicare Benefit Policy Manual, Chapter 7: Home Health Care Services, http://www.cms.hhs.gov/Manuals/IOM/list.asp
7. Medicare Managed Care Manual, Chapter 13: Medicare Managed Care Beneficiary Grievances, Organization Determinations, and Appeals Applicable to Medicare Advantage Plans, Cost Plans, and Health Prepayment Plans, Section 90.3: Notice of Medicare Non-Coverage (NOMNC), 9/21/07.
8. Medicare, Part B Answer Book, "Home Care Services," pgs.15401-15403, 2002.
9. New York State Medicaid Prenatal Care Standards, http://www.health.ny.gov/health_care/medicaid/standards/prenatal_care/
10. New York State Department of Health Standards, Part 85.40.
11. New York State Medicaid Redesign Team: Medicaid Managed Care Benefit Changes, 2011-2012, www.health.ny.gov
12. Other Payers
13. New York State Office of Health Insurance Programs Letter: Revision to Universal Billing Codes for Home Care and Adult Day Health Care Services, September 27, 2017.
14. New York State Department of Health New Minimum Needs Requirements for Personal Care Services, Consumer Directed Personal Assistance Services, and Managed Long Term Care Eligibility: https://www.health.ny.gov/health_care/managed_care/plans/min_needs.htm

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POLICY APPROVAL DATES

New:	04/89
Revised:	06/90, 10/93, 12/94, 10/95, 10/96, 11/98, 01/00, 09/00, 11/00, 04/01, 04/02, 03/03, 04/04, 01/05, 10/05, 09/07, 12/07, 07/08, 07/09, 11/10, 09/11, 05/11, 05/12, 07/12, 07/13, 07/14. 07/15, 01/16, 07/16, 01/17, 07/17, 03/18, 03/19, 7/19, 7/21, 7/22, 7/23, 9/23, 7/24, 7/25, 9/25
Reviewed:	09/97, 10/06, 07/11, 07/18, 07/20, 7/26

POLICY HISTORY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: HOME CARE SERVICES: HOME HEALTH CARE/TELE-HOMECARE/PERSONAL CARE/PERSONAL EMERGENCY RESPONSE SYSTEM

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
9/1/2025	Updated Select Plan PCS and CDPAP section to capture regulatory updates related to Minimum Needs Requirements.
8/1/2024* Effective date remains the same for this policy update	Under Home Care Section added information regarding doula services.
8/1/2024	Under Policy Considerations section added codes G0320, G0321 and G0322 to the tele-homecare section. Under Medicaid clarified information under Private Duty Nursing and Reassessments.
8/1/2023* *Effective date remains the same for this update	Clarified that T2024 should be billed to Medicaid FFS in the Select Plan/HARP section.
8/1/2023	Under Medicaid section: • Added that at least two home care visits are allowed to high-risk infants (newborns) • Removed the following services from the body of the policy and placed under the Medicaid section as these are services that are only covered under the Medicaid/HARP LOB: o Personal Care Aide Level I (Homemaker/Housekeeper): S5130 o Personal Care Aide Level II: T1019, T1020 o Consumer Directed Personal Assistant: T1019, T1020 o Personal emergency response system: S5160, S5161 o Uniform Assessment System (UAS-NY): Service Assessment/Plan of Care Development: T2024

	○ T1001: RN Supervisory Visit Removed home care limitations under CHP and Small/Individual as contracts are the source of truth for identifying contract limits.
5/16/2022	Updated PCS/CDPAP authorization process to reflect NYIA involvement in new authorizations for adult members 18 years or older in the Select Plan/HARP section. Updated Small Group/Individual section to remove information already addressed in the Position Statement.
8/1/2021	Clarified home care visit limit for small group & individual contracts. Removed the following statement as the services are no longer prior authorized: Requests for continuous home health care or tele-homecare services for a diagnosis not listed above or for continued services beyond six weeks will be reviewed on an individual case basis by a CDPHP medical director.

This Resource Coordination Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI), and Capital District Physicians' Healthcare Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

Medical Policy Title	**Home Non-Invasive Positive Pressure Ventilation (NIPPV) Devices for Respiratory Insufficiency and Failure**
Policy Number	**1.01.57**
Current Effective Date	**January 1, 2027**
Next Review Date	**June 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Neuromuscular and Thoracic Disorders

I. Bilevel positive airway pressure (BPAP) device with (HCPCS: E0471) or without (HCPCS: E0470) a backup rate is considered **medically necessary** when an individual has a neuromuscular or thoracic restrictive disease diagnosis and meets **ANY** of the following criteria:

   A. Documented decrease in forced vital capacity (FVC) to less than 80% of predicted and symptomatic (e.g., dyspnea, orthopnea or fragmented sleep) **or** less than 50% of predicted without symptoms;

   B. Maximal inspiratory pressure (MIP) of < 60 cm H_2O;

   C. Oxygen desaturations ≤ 88% for at least five (5) cumulative minutes during sleep oximetry (minimum recording time of two (2) hours) while either breathing room air or prescribed FIO_2 as applicable; **or**

   D. Arterial blood gas (ABG) showing a $PaCO_2$ ≥ 45 mm Hg done while awake and breathing either room air or prescribed FIO_2 as applicable.

II. Non-invasive home mechanical ventilation (HCPCS: E0466) is considered **medically appropriate** when an individual has a neuromuscular or thoracic restrictive disease diagnosis and meets **ALL** of the following criteria:

   A. Meets criteria for a BPAP device (See Policy Statement I); **and**

   B. **One** of the following indications:

      1. Advanced BPAP with iVAPS (Intelligent Volume Assured Pressure Support) (HCPCS: E0471) does not meet the individual's respiratory needs due to **any** of the following:

         a. Need auto-expiratory positive airway pressure (EPAP);

         b. Concomitant obstructive sleep apnea (OSA);

         c. Bulbar dysfunction; **or**

         d. Concomitant chronic obstructive pulmonary disease (COPD);

2. Daytime dyspnea at rest;
3. Non-invasive ventilation is needed for greater than 10 hours per day;
4. Extreme loss in function with vital capacity less than 30%;
5. Worsening daytime hypercapnia with need for mouthpiece ventilation; **or**
6. Daytime use (battery operated unit) is required to reduce hypercapnia or dyspnea.

III. Dual (HCPCS: E0468) or multifunction (HCPCS: E0467) non-invasive home mechanical ventilators (ventilation, oxygen, cough, suction and nebulization [VOCSN, VOCSN VC, VOCSN VC Pro]) are considered **medically necessary** when **ALL** of the following are met:

A. Meets criteria for a home mechanical ventilator; **and**

B. There is documentation supporting the need for one or more functions on the device (i.e., oxygen concentrator, cough stimulator, suction pump, nebulizer) and they have not received any one of these devices individually.

Hypoventilation Syndrome

IV. BPAP without (HCPCS: E0470) a backup rate is considered **medically appropriate** for an individual with a hypoventilation syndrome diagnosis who meets **ALL** of the following criteria:

A. An initial ABG PaCO2 greater than or equal to 45 mm Hg done while awake and breathing the patient's prescribed FIO2;

B. Spirometry shows a forced expired volume in one (1) second (FEV1)/ FVC greater than or equal to 70%; **and**

C. **One** of the following:

1. An ABG PaCO2, done when the patient is asleep or has just woken up and is breathing their prescribed FIO2, shows that PaCO2 has worsened greater than or equal to 10 mm Hg compared to the original ABG; **or**
2. A facility-based Polysomnography (PSG) or home sleep test (HST) shows oxygen saturation less than or equal to 88% for greater than or equal to five (5) cumulative minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events.

V. BPAP with (HCPCS: E0471) a backup rate is considered **medically appropriate** for an individual with a hypoventilation syndrome diagnosis who meets **ALL** of the following criteria:

A. The individual is currently using a BPAP without backup;

B. Spirometry shows an FEV1/FVC greater than or equal to 70%; **and**

C. An ABG PaCO2, done while the patient is awake and breathing their prescribed FIO2, shows the patient's PaCO2 worsens to greater than or equal to 10 mm Hg compared to the ABG result done to qualify the patient for the E0470 device.

VI. Non-invasive home mechanical ventilations devices (HCPCS: E0466) are considered **medically appropriate** for an individual with a hypoventilation syndrome diagnosis who meets **ALL** of the following criteria:

A. Meets criteria for BPAP (see Policy Statement IV); **and**

B. **One** of the following indications:

1. Advanced BPAP with iVAPS (Intelligent volume assured pressure support) (HCPCS: E0471) does not meet the needs of the individuals and requires auto-EPAP;
2. Non-invasive ventilation is needed for greater than 10 hours per day;
3. Severe hypoxemia with an FIO_2 greater than 40% or greater than 5 L/min; **or**
4. BPAP was tried and failed (documentation of attempted daily use) with persistent hypercapnia with either of the following:
   a. Awake $PaCO_2 \geq 45$ mmHg; **or**
   b. Awake venous blood gas PCO_2, end-tidal PCO_2, or transcutaneous $PCO_2 \geq 50$ mmHg.

VII. Dual (HCPCS: E0468) or multifunction (HCPCS: E0467) non-invasive home mechanical ventilators (ventilation, oxygen, cough, suction and nebulization [VOCSN, VOCSN VC, VOCSN VC Pro]) are considered **medically necessary** for an individual when **BOTH** of the following are met:

A. Meets criteria for a home mechanical ventilator; **and**

B. There is documentation supporting the need for one or more functions on the device (i.e., oxygen concentrator, cough stimulator, suction pump, nebulizer) and they have not received any one of these devices individually.

<u>Chronic Respiratory Failure (CRF) Due to Chronic Obstructive Pulmonary Disease (COPD)</u>

VIII. BPAP without (HCPCS: E0470) backup rate is considered **medically appropriate** for an individual with CRF due to COPD who meets **ALL** of the following criteria:

A. The individual cannot tolerate high intensity NIV or back up rate is not needed;

B. The individual exhibits hypercapnia as demonstrated by PaCO2 ≥ 52 mmHg by ABG during awake hours while breathing his/her prescribed FiO2; **and**

C. Sleep apnea has been ruled out as the cause of hypercapnia.

IX. BPAP with (HCPCS: E0471) a backup rate is considered **medically appropriate** for an individual with CRF due to COPD who meets **ALL** of the following criteria:

A. Meets criteria for BPAP without a backup rate (E0470) (see Policy Statement VIII);

B. Oxygen saturations ≤ 88% for at least five (5) cumulative minutes during sleep oximetry (minimum recording time of two (2) hours) while receiving oxygen at 2 LPM or prescribed FIO2, whichever is higher; **and**

C. An ABG PaCO2, done while the individual is awake and breathing their prescribed FIO2, shows that the patient's PaCO2 worsens to greater than or equal to 10 mm Hg compared to the ABG result done to qualify the patient for the E0470 device.

X. Non-invasive home mechanical ventilation devices (HCPCS: E0466) are considered **medically appropriate** for an individual with CRF due to COPD who meets **ALL** of the following criteria:

A. Meets criteria for BPAP without a backup rate (E0470) (see Policy Statement VIII); **and**

B. **One** of the following:

1. Requires oxygen therapy at an FiO2 ≥ 36% or ≥ 4L nasally;
2. Requires ventilatory support for more than 8 hours per 24-hour period;
3. Requires the alarms and internal battery, because the patient is unable to effectively breathe on their own for more than a few hours and the unrecognized interruption of ventilatory support is likely to cause a life-threatening condition if the patient or caregiver cannot be otherwise alerted; **or**
4. Advanced BPAP with iVAPS (Intelligent volume assured pressure support) (HCPCS: E0471) does not meet the needs of the individuals and requires auto-EPAP based that the individual is unable to meet **one** of the following:
   a. Normalization (< 46 mm Hg) of PaCO2;
   b. Stabilization of a rising PaCO2;
   c. 20% reduction in PaCO2 from baseline value; **or**
   d. Improvement of at least one symptom associated with chronic hypercapnia (e.g., headache, fatigue, shortness of breath, confusion, or sleep quality).

XI. Dual (HCPCS: E0468) or multifunction (HCPCS: E0467) non-Invasive home mechanical ventilators (ventilation, oxygen, cough, suction and nebulization [VOCSN, VOCSN VC, VOCSN VC Pro]) are considered **medically necessary** when **BOTH** of the following criteria are met:

A. Meets criteria for a home mechanical ventilator; **and**

B. There is documentation supporting the need for one or more functions on the device (i.e., oxygen concentrator, cough stimulator, suction pump, nebulizer) and they have not received any one of these devices individually.

<u>Obstructive Sleep Apnea (OSA)</u>

XII. BPAP with (HCPCS: E0471) or without (HCPCS: E0470) back up rate is considered **medically appropriate** for an individual with OSA who meets **ALL** of the following indications:

A. Failed or cannot tolerate CPAP;

B. Demonstration of resolution or control of respiratory events with improved tolerance using BPAP at least two (2) weeks after an acute episode; **and**

C. The individual is stable on current treatment.

Sleep Apnea - Other

XIII. BPAP with (HCPCS: E0471) or without (HCPCS: E0470) a backup rate is considered **medically appropriate** for an individual with central sleep apnea (primary or secondary to medication or substance use, heart failure or medical condition), complex sleep apnea and treatment emergent sleep apnea who meet **ONE** of the following indications:

A. Central hypopnea/apnea > 50% of the total apnea hypopnea index rate;

B. Central hypopnea/apnea rate/index > 5 (five) events per hour;

C. Documentation supporting the effectiveness of BPAP therapy during PSG; **or**

D. Symptomatic patients with excessive sleepiness, disrupted sleep or significant desaturations despite optimized CPAP therapy.

Hospital Discharge

XIV. Hospital discharge with a home mechanical ventilator (HCPCS: E0466) or a BPAP with backup (HCPCS: E0471) rate for individuals with acute on chronic respiratory failure due to COPD and meet **BOTH** of the following indications:

A. The individual required a ventilator or a BPAP device within 24 hours prior to discharge; **and**

B. The individual is at risk of rapid symptom exacerbation or rise in PaCO2 after discharge.

Continuation of Use

XV. Continuation of use of an non-invasive home mechanical ventilation device for the diagnosis of COPD, OSA and hypoventilation syndrome are considered **medically appropriate** when compliance is demonstrated by using the device for 70% of the nights for four (4) or more hours per 24-hour period during a consecutive 30-day period.

Durable Medical Equipment (DME) Repair

XVI. Repair of a medically necessary home non-invasive positive pressure ventilation (NIPPV) devices or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** the following:

1. Date of DME initiation;

2. Manufacturer warranty information, if applicable;

3. Attestation that the patient has been compliant with the use of the DME and will continue to benefit from the use of the DME;

B. The DME is no longer functioning adequately; and **BOTH** of the following criteria are met:

1. Inadequate function interferes with activities of daily living; and

2. Repair is expected to make the equipment fully functional (as defined by manufacturer).

XVII. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

DME Replacement

XVIII. Replacement of a medically necessary home non-invasive positive pressure ventilation (NIPPV) devices or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

A. The DME is no longer functioning adequately and has been determined to be non-repairable, or the cost of the repair is in excess of the replacement cost;

B. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

XIX. The replacement of a properly functioning home non-invasive positive pressure ventilation (NIPPV) devices, its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or to make the DME more aesthetically pleasing;

XX. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

XXI. Accessories or components for home non-invasive positive pressure ventilation (NIPPV) devices that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

1.01.00 Durable Medical Equipment (DME) and Devices, Standard and Non-Standard

1.01.06 Continuous Positive Airway Pressure (CPAP) and Auto-Adjusting Positive Airway Pressure (APAP)

1.01.07 Medical Management for Obstructive Sleep Apnea (OSA)

1.01.15 Airway Clearance Devices

2.01.28 Sleep Studies

7.01.41 Surgical Management of Sleep Disorders

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Individuals who do not meet the criteria for continuation of coverage during the initial 90 day trial are eligible to re-qualify for a home ventilation devices, but must have a clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to ventilation therapy (e.g., documentation of failure of symptoms to resolve or improper fit of device, and re-education of the individuals regarding proper use of the equipment or re-fitting of masks).

II. BPAP with expiratory relief are options for patients who cannot tolerate the high constant air pressure associated with CPAP but wish to continue treatment for OSA.

III. BPAP devices may or may not include a backup rate. BPAP devices with a backup rate are timed devices that supply breaths at a specific rate per minute. These devices will deliver a breath when the minimum number of breaths per minute has not been met by the user.

IV. Supplemental oxygen or humidification can be added to positive pressure devices to increase oxygen saturation and decrease vasomotor rhinitis.

V. Coverage is allowed for a one-month rental when the home ventilation device is malfunctioning and out of warranty, (and not associated with a manufacturer recall) while the device is being repaired.

VI. The monitoring feature/device, stand-alone or integrated, any type, including all accessories, components, and electronics, not otherwise classified (HCPCS: A9279) is considered inclusive to the positive airway pressure device.

VII. Devices used to clean or sanitize BPAP devices are considered a convenience item and are **ineligible for coverage** (e.g., SoClean, SoClean 2 Go).

DESCRIPTION

Bilevel Positive Airway Pressure (BPAP) (i.e. Simple BPAP)

BPAP is an airway support system, which provides two different levels of pressure delivered via a mask. There is a higher-pressure during inspiration and a lower pressure level during expiration. BPAP is an option for individuals who cannot tolerate the high constant air pressure associated with CPAP. BPAP devices with volume and/or pressure with a back-up rate feature are types of ventilators that can be used for many applications (as described below) but have not shown effectiveness for treating OSA. Bilevel positive pressure devices are used as respiratory assist devices for individuals with chronic respiratory failure in the following situations:

- At night for the management of chronic respiratory failure;
- For the long-term management of neuromuscular disorders with respiratory involvement;
- For patients with respiratory insufficiency due to severe kyphoscoliosis; or
- For the improvement of nighttime desaturation and hypoventilation in patients with chest-wall diseases.

Advanced BPAP

Advanced BPAP includes all the baseline functions of a standard BPAP but includes additional ventilation modes that automatically respond to the patient's real-time respiratory needs. The machine has adaptive volume/pressure support with backup rate. Typically, these machines are designed for:

- Complex or central sleep apnea;
- Cheyne-Stokes respiration;
- Obesity hypoventilation syndrome;
- Other irregular ventilation patterns.

Non-Invasive Positive Pressure Ventilation (NIPPV)

NIPPV involves the delivery of oxygen into the lungs via positive pressure without the need for endotracheal intubation. It is used in both acute and chronic respiratory failure but requires careful monitoring and titration to avoid complications. NIPPV is increasingly being used to treat individuals with chronic respiratory failure (e.g., neuromuscular diseases, restrictive thoracic disorders, obstructive lung diseases), and other hypoventilation conditions. NIPPV is a type of mechanical ventilation that can be used at home to assist with taking full breaths and maintaining adequate oxygen supply in the body, especially while sleeping. Intermittent positive pressure reduces the work of breathing through three different methods. By applying positive end-expiratory pressure (PEEP) through expiratory positive airway pressure (EPAP), positive pressure ventilation allows the body to overcome the dynamic intrinsic positive end expiratory pressure threshold required to initiate a breath, as well as increasing lung compliance.

Non-Invasive Dual or Multifunction Home Mechanical Ventilators (VOCSN, VOCSN VC, VOCSN VC Pro)

Non-invasive dual or multifunction home mechanical ventilators are life-support devices that combine mechanical ventilation with at least two additional respiratory functions, such as supplemental oxygen delivery, cough assistance, suction, nebulizer delivery, and oximetry in a single portable unit

Hypoventilation Syndromes

Hypoventilation syndromes are nonspecific disorders that are characterized by hypercapnia a $PaCO_2$ greater than 45 mmHg, and sometimes hypoxemia, especially during sleep with PaO_2 of less than 60 mmHg. Hypoventilation syndrome categories can be categorized as obesity hypoventilation syndrome, central sleep apnea and hypercapnic respiratory failure (not COPD).

Neuromuscular and Thoracic Restrictive Diseases

Neuromuscular disorders (muscular dystrophy, Amyotrophic Lateral Sclerosis (ALS), polio, and phrenic neuropathies) can result in weakness of the respiratory muscles, resulting in hypoventilation. Thoracic restrictive disorders can be caused by various underlying diseases that are characterized by pulmonary function testing showing patterns of restriction or respiratory muscle weakness with reductions in MIP and/or maximal expiratory pressure (MEP).

Central Apneas

Central sleep apnea is defined as the cessation of airflow through the nose and mouth for at least 10 seconds with no respiratory effort noted. The cessation in breathing can be caused by problems involving brain mechanisms, or an obstructive component. Approximately 4% of individuals undergoing PSG in a sleep laboratory are diagnosed with central sleep apnea, making this an uncommon condition.

Mixed Apneas

Mixed sleep apnea is a combination of obstructive and central sleep apnea. Not only does the patient have an obstruction in the airway, but the patient may have a neurological dysfunction or cardiopulmonary as well that contributes to the central apnea component.

Obstructive Sleep Apnea (OSA)

Obstructive sleep apnea (OSA) is a sleep-related breathing disorder caused by upper-airway obstruction, most often from relaxed throat muscles during sleep. In adults, OSA involves recurrent episodes of complete or partial upper airway blockage lasting more than 10 seconds and is commonly linked to obesity, male sex, aging, and anatomical factors. Symptoms include loud snoring, witnessed apneas, gasping, excessive daytime sleepiness, and hypertension, and diagnosis requires polysomnography or home sleep testing with evidence of clinical impairment. Untreated adult OSA increases the risk of hypertension, heart failure, atrial fibrillation, other arrhythmias, and nonalcoholic fatty liver disease.

Pediatric OSA, typically caused by enlarged tonsils and adenoids, is defined by prolonged partial obstruction or intermittent complete obstruction lasting at least two respiratory cycles and may present with snoring, breathing pauses, restless sleep, behavioral issues, or poor growth. If left untreated, children may experience growth abnormalities, neurologic problems, or cor pulmonale. Polysomnography (PSG) is the preferred diagnostic tool, although normative AHI/RDI values for children are not well established. Adenotonsillectomy is first-line therapy for pediatric OSA, while persistent cases or those with contraindications may require CPAP, observation, medications, or additional airway surgery. Obstructive hypoventilation (OH), a related condition in children, may present with normal AHI but episodes of hypercarbia indicated by elevated end-tidal CO_2.

SUPPORTIVE LITERATURE

Sarasate et al (2023) reported the results of a randomized, multicenter clinical trial evaluating whether initiating non-invasive ventilation (NIV) earlier in patients with ALS, at a FVC threshold of 75%, improves outcomes compared with standard initiation at 50%. Forty-two patients were randomized to early or standard NIV, and survival time to death or tracheostomy was the primary outcome. Although early NIV was associated with longer median survival and lower mortality incidence, these differences did not reach statistical significance. Nevertheless, early NIV demonstrated benefits in slowing respiratory muscle decline, reducing adverse events, and showing good tolerance and adherence without impairing sleep quality. Overall, while the primary survival endpoint was not met, all findings favored early NIV, supporting earlier respiratory assessment and NIV initiation around an FVC of 75% in ALS patients.

Wang et al (2019) conducted a systematic review to assess the effectiveness of home noninvasive NIPPV (home mechanical ventilation (HMV), BPAP, or CPAP devices) in adults with chronic respiratory failure. 68 studies evaluating 53,733 patients were included. In patients with COPD, home BPAP (compared to no device) was associated with lower mortality, decreased need for intubations and hospital admissions, but no change in quality of life. In patients with COPD, HMV (compared individually with BPAP, CPAP, or no device) was associated with fewer hospital admissions. In patients with thoracic restrictive diseases, HMV (compared to no device) was associated with lower mortality. In patients with neuromuscular diseases, home BPAP (compared to no device) was associated with lower mortality and better quality of life. In patients with obesity hypoventilation syndrome, home HMV/BPAP (compared to no device) was associated with lower mortality. Current evidence was not available to assess the comparative effectiveness of many device capabilities on patient outcomes. Criteria to initiate home NIPPV and home respiratory services varied and were not validated in comparative studies.

Patil et al (2019) conducted a systematic review and meta-analysis of 184 studies to evaluate the effectiveness of PAP therapy for adults with OSA. CPAP significantly reduced AHI by 23 events/hour versus no treatment—an 86% reduction from 32.7 to 4.1 events/hour. CPAP also improved daytime sleepiness by 2.4 points in symptomatic patients and showed clinically meaningful benefits for sleep-related quality of life, blood pressure, and motor vehicle crash risk. Observational evidence suggested reductions in cardiovascular events and mortality, though RCTs did not confirm these outcomes. No major differences were found among CPAP, APAP, and BPAP for individual clinical outcomes, supporting CPAP as first-line therapy unless not tolerated. Home-based versus in-lab APAP initiation showed comparable results. Education, behavioral interventions, and telemonitoring improved adherence. Nasal masks enhanced adherence and reduced AHI more effectively than oronasal masks. Humidification reduced side effects without improving adherence or outcomes. Overall, CPAP reliably reduces OSA severity, improves sleepiness, and lowers blood pressure, particularly in symptomatic or hypertensive adults. Benefits for asymptomatic individuals and long-term cardiovascular outcomes remain uncertain.

Khamankar et al (2018) reported the results of this retrospective cohort study evaluating whether earlier initiation and optimized use of NIV improves survival in patients with ALS. Among 474 patients, those who used BPAP had significantly longer survival than non-users. With survival increasing progressively when BPAP was initiated at higher FVC thresholds (< 50% (20.3 months); ≥ 50% (23.60 months); ≥ 80% (25.36 months). Longer daily BPAP use (> 8 hours/day), and combined daily use of Bi-PAP with cough assist were each associated with significant survival benefits, whereas cough assist alone had minimal impact. Higher functional status at initiation correlated with better outcomes, and time since symptom onset was not a reliable indicator for starting NIV. Overall, an optimized NIV strategy—early BPAP initiation, sustained daily use, and concurrent cough assist—was associated with markedly prolonged survival compared with standard, later initiation protocols, supporting earlier access to and combined use of NIV interventions in ALS care.

PROFESSIONAL GUIDELINE(S)

The 2025 American Academy of Sleep (AASM) reported guidelines for the treatment of central sleep

apnea (CSA) in adults, stating:

- "Suggests using continuous positive airway pressure over no continuous positive airway pressure in adults with CSA due to the following etiologies: primary CSA, CSA due to heart failure, CSA due to medication or substance use, treatment-emergent CSA, and CSA due to a medical condition or disorder." (Conditional recommendation, low certainty of evidence)
- "Suggests using bilevel positive airway pressure with a backup rate over no bilevel positive airway pressure with a backup rate in adults with CSA due to the following etiologies: primary CSA, CSA due to medication or substance use, treatment-emergent CSA, and CSA due to a medical condition or disorder." (Conditional recommendation, very low certainty of evidence)
- "Suggests against the use of bilevel positive airway pressure without a backup rate in adults with CSA due to the following etiologies: primary CSA, CSA due to heart failure, CSA due to medication or substance use, treatment-emergent CSA, and CSA due to a medical condition or disorder." (Conditional recommendation, very low certainty of evidence)
- "Suggests using adaptive servo-ventilation over no adaptive servo-ventilation in adults with CSA due to the following etiologies: primary CSA, CSA due to heart failure, CSA due to medication or substance use, treatment-emergent CSA, and CSA due to a medical condition or disorder." (Conditional recommendation, low certainty of evidence)

The 2023 American College of Chest Physicians Clinical Practice Guidelines and Expert Panel Report for the respiratory management of patients with neuromuscular weakness state:

- "Patients with neuromuscular disease (NMD) and chronic respiratory failure- they recommend using NIV for treatment with any of the following indications (indications can vary depending on age, NMD, and rate of the disease progression):
    - Any fall in FVC to < 80% of predicted with symptoms;
    - FVC to < 50% of predicted without symptoms;
    - Maximum inspiratory pressure (MIP) to < –60 cm H2O;
    - Maximum expiratory pressure (MEP) of < 40 cm H2O;
    - Based on the polysomnography results if polysomnography was indicated or the presence of hypercapnia (awake PaCO2 > 45 mm Hg)."

The American Thoracic Society released their 2020 guidelines for long-term noninvasive ventilation in chronic stable hypercapnic COPD defined as, FEV1/FVC less than 0.70; resting PaCO2 greater than 45 mm Hg; not during exacerbation. The guidelines state:

- "Suggests the use of nocturnal noninvasive ventilation (NIV) in addition to usual care for patients with chronic stable hypercapnic COPD." (conditional recommendation, moderate certainty).
- "Suggests that patients with chronic stable hypercapnic COPD undergo screening for obstructive sleep apnea before initiation of long-term NIV." (conditional recommendation, very low certainty).

- "Suggests not initiating long-term NIV during an admission for acute on-chronic hypercapnic respiratory failure, favoring instead reassessment for NIV at 2–4 weeks after resolution." (conditional recommendation, low certainty).
- "Suggests not using an in-laboratory overnight PSG to titrate NIV in patients with chronic stable hypercapnic COPD who are initiating NIV." (conditional recommendation, very low certainty).
- "Suggest NIV with targeted normalization of PaCO2 in patients with hypercapnic COPD on long-term NIV." (conditional recommendation, low certainty).

The European Respiratory Society (ERS) and the American Thoracic Society (ATS) Clinical Recommendation for Non-Invasive Ventilation (NIV) in Adults with Acute Respiratory Failure (Rochwerg 2017) state:

- "Bilevel NIV for individuals with acute respiratory failure (ARF) leading to acute or acute-on-chronic respiratory acidosis (pH < 7.35) due to COPD exacerbation." (Strong recommendation, high certainty of evidence.)
- "Either bilevel NIV or CPAP for individuals with ARF due to cardiogenic pulmonary oedema." (Strong recommendation, moderate certainty of evidence.
- "Early NIV for immunocompromised individuals ARF." (Conditional recommendation, moderate certainty of evidence.)
- "Due to the uncertainty of evidence ERS/ATS is unable to offer a recommendation on the use of NIV for de novo ARF."
- "NIV for individuals with post-operative ARF." (Conditional recommendation, moderate certainty of evidence.)
- "NIV to dyspneic individuals for palliation in the setting of terminal cancer or other terminal conditions." (Conditional recommendation, moderate certainty of evidence.)
- "NIV should not be used in the treatment of patients with established post-extubation respiratory failure." (Conditional recommendation, low certainty of evidence.

American Academy of Sleep Medicine (ASSM 2008) Clinical Guidelines for the Manual Titration of Positive Airway Pressure in Patient with OSA state:

- "Pre-Titration Preparation: All candidates should receive PAP education, hands-on demonstration, careful mask fitting, and acclimatization." (Standard)
- "Transition to BPAP: If a patient is uncomfortable or intolerant of high CPAP pressures, or obstructive respiratory events continue at 15 cm H2O, switch the patient to BPAP." (Consensus)
- "Repeat Titration Study: Consider repeating a titration if the initial titration was not optimal/good and, for split-night studies, fails to meet AASM criteria." (Consensus)

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates BPAP and home ventilators as

medical devices. All BPAP and home ventilators including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 May 26]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2026 May 26]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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HCPCS Codes

Code	Description
A7027-A7039	Accessories/supplies, code range for positive pressure airway devices (code range)
A7044-A7046	Accessories/supplies, code range for positive pressure airway devices (code range)
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified
E0466	Home ventilator, any type, used with noninvasive interface, (e.g., mask, chest shell)
E0467	Home ventilator, multi-function respiratory device, also performs any or all of the additional functions of oxygen concentration, drug nebulization, aspiration, and cough stimulation, includes all accessories, components and supplies for all functions (i.e., multi-function home ventilator)

Code	Description
E0468	Home ventilator, dual-function respiratory device, also performs additional function of cough stimulation, includes all accessories, components and supplies for all functions (i.e., dual-function home ventilator)
E0470	Respiratory assist device, bi-level pressure capability, without back-up rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device) (i.e., Simple BPAP)
E0471	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with noninvasive interface, e.g., nasal or facial mask (intermittent assist device with continuous positive airway pressure device)
E0472	Respiratory assist device, bi-level pressure capability, with backup rate feature, used with invasive interface, e.g., tracheostomy tube (intermittent assist device with continuous positive airway pressure device)
E0561	Humidifier, nonheated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device

ICD10 Codes

Code	Description
E66.2	Morbid (severe) obesity with alveolar hypoventilation
G12.0-G12.9	Spinal muscular atrophy and related syndromes (code range)
G35	Multiple sclerosis
G47.00	Insomnia, unspecified
G47.10	Hypersomnia, unspecified
G47.20	Circadian rhythm sleep disorder, unspecified type
G47.35	Congenital central alveolar hypoventilation syndrome
G47.8	Other sleep disorders
G47.9	Sleep disorder, unspecified

Code	Description
I50.9	Heart failure, unspecified
J39.8	Other specified diseases of upper respiratory tract
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.9	Chronic obstructive pulmonary disease, unspecified
J95.2	Acute pulmonary insufficiency following nonthoracic surgery
J96.00-J96.02	Acute respiratory failure (code range)
J96.10-J96.12	Chronic respiratory failure (code range)
J96.20-J96.22	Acute and chronic respiratory failure (code range)
J96.90-J96.92	Respiratory failure, unspecified, unspecified whether with hypoxia or hypercapnia (code range)
J98.4	Other disorders of lung
J98.8	Other specified respiratory disorders

REFERENCES

American Academy of Otolaryngology Head and Neck Surgery [Internet]. Position statement: Treatment of obstructive sleep apnea. [accessed 2026 May 27]. Available from: Position Statement: Treatment of Obstructive Sleep Apnea - American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)

American Academy of Pediatrics [Internet]. Clinical practice guideline: diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics 2002;109(4):704-712. [accessed 2026 May 27]. Available from: https://publications.aap.org/pediatrics/article/130/3/576/30284/Diagnosis-and-Management-of-Childhood-Obstructive?autologincheck=redirected

American Academy of Sleep Medicine. Practice parameters for the use of auto-titrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea. Sleep 2002;25(2):143-147.

American Thoracic Society. Cardiorespiratory sleep studies in children. Establishment of normative data and polysomnographic predictors of morbidity. Am J Respir Crit Care Med. 1999 Oct;160(4):1381-1387.

Badr MS, et al. Treatment of central sleep apnea in adults: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2025 Dec 1;21(12):2181-2191.

Badr MS, et al. Treatment of central sleep apnea in adults: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2025 Dec 1;21(12):2213-2236.

Berry RB, et al; American Academy of Sleep Medicine. Rules for scoring respiratory events in sleep: update of the 2007 AASM manual for the scoring of sleep and associated events. Deliberations of the Sleep Apnea Definitions Task Force of the American Academy of Sleep Medicine. J Clin Sleep Med. 2012 Oct 15;8(5):597-619.

Johnson K, Johnson D. In reference to positive airway pressure titration task force of the American Academy of Sleep Medicine. Clinical guidelines for the manual titration of positive airway pressure in patients with obstructive sleep apnea. Journal of Clinical Sleep Medicine 2008;4:157-171. J Clin Sleep Med. 2008 Dec 15;4(6):610.

Khan A, et al. Respiratory management of patients with neuromuscular weakness: An American College of Chest Physicians Clinical Practice Guideline and Expert Panel Report. Chest. 2023 Aug;164(2):394-413.

Kushida CA, et al. Positive Airway Pressure Titration Task Force; American Academy of Sleep Medicine. Clinical guidelines for the manual titration of positive airway pressure in patients with obstructive sleep apnea. J Clin Sleep Med. 2008 Apr 15;4(2):157-71.

Macrea M, et al. Long-term noninvasive ventilation in chronic stable hypercapnic chronic obstructive pulmonary disease: an official American Thoracic Society clinical practice guideline. Am J Respir Crit Care Med 2020 Aug 15;202(4):e74-e87.

Mokhlesi B, et al. Evaluation and Management of Obesity Hypoventilation Syndrome. An Official American Thoracic Society Clinical Practice Guideline. Am J Respir Crit Care Med. 2019 Aug 1;200(3):e6-e24. doi: 10.1164/rccm.201905-1071ST. Erratum in: Am J Respir Crit Care Med. 2019 Nov 15;200(10):1326.

National Institute for Health and Care Excellence. [Internet]. Obstructive sleep apnea/hypopnea syndrome and obesity hypoventilation syndrome in over 16s. Published Aug 2021. [accessed 2026 May 27]. Available from: https://www.nice.org.uk/guidance/NG202

Rochwerg B, et al. Official ERS/ATS clinical practice guidelines: noninvasive ventilation for acute respiratory failure. Eur Respir J. 2017 Aug 31;50(2):1602426.

Sarasate M, et al. Impact of early non-invasive ventilation in amyotrophic lateral sclerosis: a multicenter randomized controlled trial. J Neuromuscul Dis. 2023;10(4):627-637.

Wang Z, et al. Noninvasive positive pressure ventilation in the home. Rockville (MD): Agency for Healthcare Research and Quality (US); 2019 Mar 14. PMID: 32101390.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Respiratory Assist Devices (LCD L33800) [accessed 2026 May 27]

Durable Medical Equipment Reference List (NCD 280.1) [accessed 2026 May 27]

Noninvasive Positive Pressure Ventilation (NIPPV) in the Home for the Treatment of Chronic Respiratory Failure (CRF) Consequent to Chronic Obstructive Pulmonary Disease (COPD) (NCD 240.9) [accessed 2026 May 27]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

MEDICAL POLICY

Medical Policy Title	**Hyperbaric Oxygen Therapy (HBOT)**
Policy Number	**2.01.07**
Current Effective Date	**January 1, 2026**
Next Review Date	**July 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Topical Hyperbaric Oxygen Therapy

I. Topical hyperbaric oxygen therapy (HBOT) is considered **investigational**.

Systemic Hyperbaric Oxygen Therapy

II. Systemic HBOT in a pressurized chamber is considered **medically appropriate** for the following indications (refer to Policy Guidelines for condition-specific recommendations):

- A. Acute traumatic peripheral ischemia/insufficiency (e.g., crush injury, compartment syndrome, reperfusion injury, and suturing of severed limbs);
- B. Air or gas embolism, acute;
- C. Arterial inefficiencies: enhancement of healing in selected wounds of patients who have non-healing wounds of the lower extremities and who have **ALL** the following:
  1. A lower extremity wound due to diabetes;
  2. A wound classified as Wagner grade 3 or higher (Grade 2: ulcer penetrates to tendon, bone or joint; Grade 3: lesion has penetrated deeper than Grade 2 and there is abscess, osteomyelitis, pyarthrosis, plantar space abscess, or infection of the tendon and tendon sheaths; Grade 4: gangrene of the forefoot);
  3. No measurable signs of healing after 30 days of an adequate course of standard wound therapy; which may include **ANY** of the following:
     - a. Assessment of vascular status and correction of any vascular problems in the affected limb if possible;
     - b. Optimization of nutritional status;
     - c. Optimization of glucose control;
     - d. Debridement by any means to remove devitalized tissue;
     - e. Maintenance of clean, moist bed of granulation tissue with appropriate moist dressings;

f. Appropriate off-loading; or

g. Necessary treatment to resolve any infection that might be present.

D. Carbon monoxide poisoning, acute;

E. Central retinal artery occlusion (CRAO)

F. Cerebral edema, acute;

G. Compromised grafts and flaps (not for primary management of these wounds);

H. Cyanide poisoning, acute;

I. Decompression sickness;

J. Gas/wet gangrene (e.g., clostridial myonecrosis);

K. Idiopathic sudden sensorineural hearing loss (ISSHL)

L. Necrotizing soft tissue infections, based on location and/or organism type and/or particular host immunologic and vascular risk factors causing hypoxia resulting in necrosis;

M. Osteomyelitis, acute, refractory (has not responded to standard medical and surgical management techniques);

N. Osteomyelitis, chronic, refractory (has persisted for at least six (6) weeks or has recurred after appropriate interventions, i.e., surgical debridement and at least one appropriate course of parenteral antibiotics, have been performed);

O. Pre- and post-treatment for patients undergoing dental surgery (non-implant related) of an irradiated jaw;

P. Profound anemia with exceptional blood loss, but only when blood transfusion is impossible or must be delayed;

Q. Radiation necrosis osteoradionecrosis (ORN)/bony necrosis and soft tissue radiation necrosis, (e.g., radiation enteritis, cystitis, proctitis);

R. Refractory mycosis (mucormycosis, actinomycosis, or canidiobolus coronato).

III. Systemic HBOT in a pressurized chamber is considered **investigational** for **ALL** other indications, including, but **not limited to**, the following:

A. Acute ischemic stroke;

B. Amyotrophic Lateral Sclerosis;

C. Arterial peripheral insufficiency, acute; (outside of the other listed medically necessary indications involving arterial insufficiency)

D. Autism spectrum disorders;

E. Bell's palsy;

F. Bone grafts;

G. Breast cancer, locally advanced, as pretreatment for patients undergoing chemotherapy;
H. Brown recluse spider bites;
I. Carbon tetrachloride poisoning, acute;
J. Cardiopulmonary bypass, as pretreatment;
K. Cerebral palsy;
L. Cerebrovascular disease, acute (thrombotic or embolic) or chronic;
M. Chronic, non-healing wounds;
N. Complex regional pain syndrome;
O. COVID-19
P. Uncompromised skin grafts or flaps;
Q. Fibromyalgia syndrome;
R. Fracture healing;
S. Frostbite;
T. Head injury, traumatic (including traumatic brain injury);
U. Tinnitus;
V. Hydrogen sulfide poisoning;
W. Inflammatory bowel disease (Crohn's disease, ulcerative colitis);
X. Interstitial cystitis;
Y. Intra-abdominal and intracranial abscesses;
Z. In vitro fertilization;
AA. Lepromatous leprosy;
BB. Malignant otitis externa;
CC. Meningitis;
DD. Migraine;
EE. Myocardial infarction and acute coronary syndrome (acute myocardial infarction and unstable angina);
FF. Multiple sclerosis;
GG. Muscle soreness, delayed onset;
HH. Prevention of coronary restenosis;
II. Pseudomembranous colitis (antimicrobial agent-induced colitis);

JJ. Pyoderma gangrenosum;

KK. Radiation myelitis;

LL. Radiation therapy, for the purpose of tumor sensitization;

MM. Retinal detachment;

NN. Retinopathy, adjunct to scleral buckling procedures in patients with sickle cell peripheral retinopathy;

OO. Sickle cell crisis and/or hematuria;

PP. Soft tissue injury;

QQ. Spinal cord injury;

RR. Thermal burns, acute.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. HBOT should not be a replacement for successful standard therapeutic measures. Documentation in the medical record should support the specific condition being treated with HBOT and the medical necessity of such treatment. The following information must be documented, as applicable to the specific medical condition:

   A. Initial assessment and medical history detailing the condition requiring HBOT, and a physical exam. The history should list prior treatments, including antibiotic therapy and surgical interventions.

   B. Current adjunctive treatment that includes type of treatment and its effectiveness.

   C. Established HBOT goals.

   D. HBOT session records describing physical findings and treatment rendered (including ascent time, descent time, total compression time, oxygen dose, pressurization level, documentation of attendance, and a recording of events).

   E. Effect of treatment upon established HBOT goals.

   F. When applicable, advanced diabetic foot ulcers may require photos to avoid overuse of HBOT when the foot is not salvageable. For a Wagner 5 (or Grade D) with complete gangrene of foot, once the heel is necrotic, the patient will likely not respond to HBOT treatments.

II. HBOT treatments of diabetic wounds of the lower extremities should be discontinued when the patient heals, is unable to tolerate treatment, or fails to improve. Documentation must include an

assessment of wound healing progress; changes in the wound condition, including the precise wound length, width, and depth measurements; presence of granulation and necrotic tissue; and concurrent measures being addressed relative to wound therapy. Weekly wound measurements should be performed to document progress in wound healing. A steady decrease in wound volume should be noted from week to week.

III. Continued treatment with HBOT is **not covered** if measurable signs of healing have not been demonstrated within any 30-day period of treatment. Most patients should **NOT** require more than 40 treatments. Patients who do not respond to 40 treatments will likely not respond to 60 or 80 or 120 treatments.

IV. Below are specific recommendations on the utilization of HBOT, based upon published, peer-reviewed literature.

Condition	**Pressure (ATA*)**	**Patient Selection Criteria**	**Duration, Frequency, and/or Number of Treatments**	**Utilization review**
Air or Gas embolism, acute	High to low pressure mixed gases	Gases in the vasculature sufficient enough to interfere with the function of an organ and results in ischemia to the affected areas.	Treatment is typically one to two treatments but occasionally may be as many as five to 10; treatment continues until no additional improvement is seen.	After 10 treatments
Anemia, severe	2.0-3.0 ATA	When blood transfusion is impossible or must be delayed.	Treatments of up to three or four hours, three to four times a day. Treatment can continue with taper of time and frequency until red blood cells have been satisfactorily replaced by patient regeneration or the patient can undergo transfusion.	Daily
Arterial Inefficiencies: non-healing *diabetic wounds* of the lower	2.0-3.0 ATA	Wagner grade 3 or higher and failure of standard wound therapy for at least 30 consecutive days.	90-minute treatments, five days per week, are performed in conjunction with continuing standard wound care; may last for 30-40 treatments.	After 40 treatments

Condition	Pressure (ATA*)	Patient Selection Criteria	Duration, Frequency, and/or Number of Treatments	Utilization review
extremities				
Carbon monoxide poisoning, acute	2.5-3.0 ATA	Within six hours of patient removal from the carbon monoxide-contaminated environment.	One treatment; if patient has persistent neurologic dysfunction after the initial treatment further treatment can occur within six to eight hours and can be continued once or twice daily until there is no additional improvement in cognitive function.	After 5 treatments
Central Retinal Artery Occlusion	2-2.8 ATA	Factors which influence outcome include the length of time of occlusion, the anatomical site of the occlusion, and the presence of a patent cilioretinal artery. The diagnosis of CRAO is typically and reliably made with a fundoscopic exam.	Treat twice daily until clinical plateau plus three days (usually up to 10 days).	After 20 treatments
Compromised Grafts and Flaps	2.0-2.5 ATA	In tissue compromised by irradiation or in other cases where there is decreased perfusion (vascular compromise) or hypoxia, HBOT has been shown to be extremely useful in flap salvage. This indication is not for primary management of wounds for normal, uncompromised skin	90-120 minute treatments. It is not unusual to receive treatments twice a day. When the graft or flap appears stable, treatments are reduced to once daily. Should a graft or flap fail, HBOT may be used to prepare the already-compromised recipient site for a new graft or flap. It does not apply to the initial preparation of the body site	After 40 treatments

Condition	Pressure (ATA*)	Patient Selection Criteria	Duration, Frequency, and/or Number of Treatments	Utilization review
		grafts or flaps.	for a graft.	
Crush injury	2.0-2.4 ATA	In conjunction with standard therapeutic measures, when loss of function, limb or life is threatened, and tissue oxygen tension is below 30 mmHg.	Three 1.5-hour treatments per day for two - three days, then twice a day for two days, and then once daily for two days	After 20 treatments
Cyanide poisoning, acute	2.5-3.0 ATA	As an adjunct to infusion of sodium nitrite.	One treatment of 120 minutes.	
Decompression sickness	2.0-5.0 ATA	Gas bubbles in the tissue or blood in volumes sufficient enough to interfere with the function of an organ or cause alteration in sensation.	One treatment of 1.5 to 14 hours; patients who have residual defects after the initial treatment should receive additional treatments until clinical stability is achieved; generally, no more than five to 10 treatments.	After 10 treatments
Gas gangrene (e.g., clostridial myonecrosis)	3.0 ATA	Positive gram-stained smear or culture from tissue fluids, tissue gas visualization on X-ray, severe and sudden pain, skin changes, and edema.	Three 90-minute treatments during the first 24 hours, and then two treatments per day for the next two to five days.	After 10 treatments
Idiopathic Sudden Sensorineural Hearing Loss	2-2.5 ATA	The degree of hearing loss is typically defined as a loss of 30 decibels or more across 3 contiguous frequencies on audiogram. Treatment is	Recommend 10-20 sessions.	After 20 treatments

Condition	Pressure (ATA*)	Patient Selection Criteria	Duration, Frequency, and/or Number of Treatments	Utilization review
		recommended either: • combined with steroid therapy within 2 weeks of onset; or • combined with steroid therapy as salvage within 1 month of onset		
Necrotizing Soft Tissue Infections:	2.0-2.5 ATA	Adjunctive therapy only in patients where morbidity and mortality are expected to be high despite aggressive standard treatment.	Twice daily for 90 to 120 minutes until condition is stabilized, then once daily.	After 30 treatments
Osteomyelitis, chronic, refractory	2.0-2.5 ATA	HBOT should not be used as a primary treatment for osteomyelitis. HBOT should be considered only after surgical debridement and at least one six-week appropriate course of parenteral antibiotics have been performed.	Daily treatment for 90-120 minutes; can be continued for four to six weeks for patients who respond to initial treatment with antibiotics, surgical debridement, and HBOT.	After 30-40 sessions
Osteoradio-necrosis	2.0-2.5 ATA	As adjunctive treatment in the preoperative and postoperative management of the patient.	30 treatments, followed by only minor bony debridement. If response is adequate, an additional 10 treatments can be given. Patients who are not responding are considered stage II; they receive more extensive surgical	After 10-30 treatments

Condition	Pressure (ATA*)	Patient Selection Criteria	Duration, Frequency, and/or Number of Treatments	Utilization review
			debridement, then 10 additional treatments. Stage III patients receive 30 treatments, followed by mandibular segmental resection, and then 10 additional treatments.	
Osteoradio-necrosis, mandibular (i.e., Marx Protocol for ORN and Tooth Extraction)	2.0-2.5 ATA	Evidence of overt fracture or bony resorption. Marx Protocol: Pre-and post-treatment for patients undergoing dental surgery (non-implant-related) of an irradiated jaw.	Initial treatment for stage I patients is 30 treatments. If response is adequate, 10 additional treatments can be provided. Non-responders are considered stage II and receive more extensive surgical debridement, followed by 10 additional treatments. Patients with stage III disease can receive up to 30 treatments, followed by mandibular segmental resection, and then an additional 10 treatments.	After 10-30 treatments
Refractory mycosis (e.g., actinomycosis, mucormycosis)	2.0-2.5 ATA	In conjunction with standard treatment when the disease process is refractory to antibiotics and surgical treatment.	One to two times daily for 90-120 minutes; treatment can continue for up to 40-80 treatments.	After 10-30 treatments

*1 ATA (atmospheres absolute) = pressure of 760 mmHg, 14.7 psi, 760 torr, or 33 ft of seawater.

V. It is recommended that the Centers for Medicare and Medicaid Services (CMS) criteria for coverage be utilized in determining appropriate practitioners to render HBOT. The CMS criteria state:

   A. Qualified non-physician practitioners (NPPs) may supervise HBOT services, if such services are included within their state's scope of practice, if their required supervision or

collaborative agreement is with a physician qualified to provide HBOT services, and if the NPP meets the educational requirements identified within the coverage article.

B. Physicians supervising HBOT should be certified in Undersea and Hyperbaric Medicine by the American Board of Emergency Medicine (ABEM), the American Board of Preventive Medicine (APBM), or the American Osteopathic Conjoint Committee of Undersea and Hyperbaric Medicine (AOCUHM); or must have completed a minimum 40-hour training experience in a program such as one approved by the American College of Hyperbaric Medicine or the Undersea and Hyperbaric Medical Society.

C. Advanced Cardiac Life Support (ACLS) training and certification of supervising physicians (and NPPs) is required, for provision of HBOT services in physician offices and off-campus hospital sites; and in on-campus, provider-based departments for which provider-response time to the chamber can be expected to exceed five minutes.

D. HBOT services rendered within a hospital outpatient department are considered "incident to" a physician's or qualified NPP's services and require physician supervision. The physician supervision requirement is presumed to be met when services are performed on hospital premises (i.e., certified as part of the hospital and part of the hospital campus); however, in all instances, it is required that the physician be present during the ascent and descent portions of each treatment.

E. In order to satisfy the immediately available criterion, for HBOT performed in an on-campus outpatient hospital or in an off-campus provider-based department, the physician (or qualified NPP) must be present in the office suite or at a location with a maximum of a five-minute response time to the chamber. For HBOT services performed in a physician office, the physician (or qualified NPP) must be present in the office suite.

DESCRIPTION

HBOT is a technique of delivering highly pressurized oxygen to the tissues. Two methods of administration are available.

In systemic, or large chamber, HBOT, the patient is entirely enclosed in a pressure chamber and breathes nearly 100% oxygen intermittently at a pressure greater than one atmosphere (the pressure of O_2 at sea level). This technique relies on the systemic circulation to deliver highly oxygenated blood to the target site, typically a wound. In addition, systemic HBOT can be used to treat systemic illness such as air or gas embolism, carbon monoxide poisoning, clostridial gas gangrene, etc. Treatment may be carried out either in a mono (single person) chamber pressurized with nearly 100% O_2 or in a larger, multi-place (multi-person) chamber pressurized with compressed air, in which case the patient receives pure oxygen by mask, head hood, or endotracheal tube.

Topical HBOT describes a technique of delivering 100% oxygen directly to a wound site at a pressure slightly higher than atmospheric pressure. It is hypothesized that the high concentration of oxygen diffuses directly into the wound to increase the local cellular oxygen tension, which, in turn, promotes wound healing. Topical HBOT devices consist of an appliance to enclose the wound area and a

source of O_2; conventional O_2 tanks may be used. The appliances may be disposable and may be used without supervision in the home by well-trained patients. Topical HBOT has been investigated as a treatment for skin ulcerations due to diabetes, venous stasis, post-surgical infection, gangrenous lesion, decubitus ulcers, amputations, skin graft, and frostbite.

SUPPORTIVE LITERATURE

Topical Hyperbaric Oxygen Therapy

de Smet et al (2017) conducted a systematic review of various oxygen therapies (oxygen dressing therapy, topical oxygen therapy, HBOT, inspired oxygen therapy). Three RCTs evaluating topical oxygen therapy for chronic wound healing were identified. A total of 315 participants with stage II-IV sacral or ischial pressure ulcers (1 RCT) or refractory venous ulcers (2 RCTs) were included in the systematic review. One RCT (n=100) administered treatment for 20 minutes 3 times per day for 12 days to the treatment group and standard care to the control group. The number of patients experiencing complete wound healing, defined as complete epithelialization of the wound without drainage, was 16 in the experimental group and 1 in the control group ($p<.001$). Two of the RCTs, which had overlapping populations with refractory venous ulcers (n=83 in one and n=132 in the other) administered treatment for 180 minutes 2 times per day for 12 weeks to the treatment group and conventional compression dressing to the control group. In all trials, patients in the treatment group experienced significantly higher proportions of healed ulcers and significantly faster healing times. This systematic review is limited in two of the trials had overlapping populations, so there were not 315 unique patients. There was heterogeneity in the trial populations and treatment regimes. The data are insufficient to draw conclusions about the effect on the net health outcome.

Hu et al (2025) published a meta-analysis comparing the efficacy of 12 interventions in the treatment of diabetic foot ulcers. They included a total of 99 RCTs, involving 7,356 patients overall. Nine included studies compared topical oxygen therapy (TOT) (n=458) with standard of care (SOC) (n=421). TOT was significantly outperformed by other interventions regarding healing outcomes. Concerning percentage area reduction, TOT (18.3%) ranked lowest among the interventions.

Systemic Hyperbaric Oxygen Therapy

Sharma et al (2021) conducted a systematic review and meta-analysis of 14 studies (N=768) comparing the effect of HBOT with standard care on diabetic foot ulcers (Table 2). Study authors noted that various modalities can be considered standard care including, but not limited to, debridement, antibiotics, and blood sugar control. However, the specific standard care modality in each included study was not reported. HBOT duration ranged from 45 to 120 minutes (median, 90 minutes). All included studies had methodological limitations, including selection, performance, detection, attrition, and reporting bias. The review found those treated with standard care were less likely to have complete ulcer healing versus HBOT, based on pooled analysis of 11 studies (odds ratio [OR], 0.29; 95% confidence interval [CI], 0.14 to 0.61; I^2=62%). Results were consistent when stratified according to duration of follow up of less than 1 year (7 studies; OR, 0.63; 95% CI, 0.39 to 1.02; I^2=1%) and at 1 year (4 studies; OR, 0.16; 95% CI, 0.03 to 0.82; I^2=83%), although the risk estimate wasn't statistically significant for studies with less than one year follow up. A funnel plot

analysis for this outcome was asymmetrical, suggesting publication bias. Risk of major amputation was also significantly lower with HBOT compared to standard care based on pooled analysis of 7 studies (OR, 0.60; 95% CI, 0.39 to 0.92; I^2=24%). There were no clear differences between groups in minor amputation (9 studies; OR, 0.89; 95% CI, 0.71 to1.12) or mortality (3 studies; OR, 0.55; 95% CI, 0.25 to 1.24). Standard care was associated with an increased risk of adverse events compared with HBOT (7 studies; OR, 1.68; 95% CI, 1.07 to 2.65).

A systematic review (Hedetoft 2021) included 31 retrospective cohort studies assessing the effect of adjunctive HBOT for treating necrotizing soft-tissue infections (necrotizing fasciitis, Fournier's gangrene, and gas gangrene). Ten studies assessed to have critical (very high) risk of bias were excluded from meta-analyses. Pooled results from the remaining 21studies found HBOT associated with a reduced risk of in-hospital mortality (OR, 0.44; 95% CI, 0.33 to 0.58; I^2=8%), but the duration of follow-up for mortality was not reported. Results were consistent when studies were stratified according to moderate (5 studies; OR, 0.39; 95% CI, 0.28 to 0.55; I^2=0%) and serious (high) risk of bias (16 studies; OR, 0.51; 95% CI, 0.33 to 0.80; I^2=17%). Publication bias favoring HBOT was present for this outcome based on funnel plot analysis. For other outcomes, including major amputation and length of hospital stay, there were no statistically significant differences between HBOT use and non-use. Evidence on adjunctive HBOT and the need for surgical debridement was mixed. One study with a low/moderate risk of bias reported a higher number of debridement's with HBOT use versus non-use (mean difference, 1.8; 95% CI,1.15 to 2.45), but the mean difference between HBOT use and non-use in a pooled analysis of 5 studies with methodological flaws was not statistically significant (mean difference, 0.63; 95% CI, -0.49 to 1.75).

Cavaliere et al (2022) conducted an RCT to compare the effect of HBOT, oral steroids (OS) and a combination of both therapies (HBOT+OS) for treating sudden sensorineural hearing loss (SSNHL). One hundred and seventy-one patients with SSNHL were randomized and included in the study. Participants were evaluated by pure tone audiometry test (PTA) at baseline and 20 days after treatment. After baseline PTA, patients were randomly assigned to each group, HBOT group A, OS-group B, and HBOT+OS-group C. Patients in the HBOT+OS, and HBOT groups improved their auditory function ($p < 0.05$). HBOT was the best choice for treatment when started by seven days from SSNHL onset, while HBOT+OS in case of late treatment. Profound SNHL recovered equally by HBOT, and HBOT+OS ($p < 0.05$). Upsloping SNHL obtained better auditory results by HBOT compared to HBOT+OS ($p < 0.05$). Down sloping and flat SSNHL had the most improvement with HBOT+OS compared to HBOT only ($p < 0.05$). The authors concluded that in both early and late treatment, a combination of HBOT and OS is a valid treatment for SSNHL and had the best results. Limitations include lack of a control group.

Joshua et al (2022) conducted a systematic review and meta-analysis of RCTs to evaluate the use of HBOT with hearing outcomes in patients with SSNHL and determine if HBOT should be utilized as a single treatment or part of the combination regimen. The study included 3 RCTs, 88 patients who received HBOT in intervention groups and 62 patients who had routine treatment in the control group. The intergroup difference in mean absolute hearing gain (mean difference, 10.3 dB; 95% CI, 6.5-14.1 dB; I2 = 0%) and the odds ratio of hearing recovery (4.3; 95% CI, 1.6-11.7; I2 = 0%) favored HBOT over the control therapy. The authors suggest that HBOT as part of a combination

treatment regimen should be considered for patients with SSNHL. Limitations include small sample sizes of studies, and the secondary outcome (adverse effect of treatment) could not be assessed. The authors recommend further studies to assess the adverse effects of treatment and to determine the optimal HBOT protocol.

Rhee et al (2018) performed a systematic review and meta-analysis through February 2018 for patients comparing HBOT plus medical therapy (MT) with MT alone for ISSNHL treatment. Randomized clinical trials and nonrandomized studies were included. The main outcomes considered were complete hearing recovery, any hearing recovery, and absolute hearing gain. Nineteen studies (3 randomized and 16 nonrandomized) with a total of 2401 patients (mean age, 45.4 years; 55.3% female) were included. In the HBOT+MT group, rates of complete hearing recovery and any hearing recovery were 264/897 (29.4%) and 621/919 (67.6%), respectively, and in the MT alone group were 241/1167 (20.7%) and 585/1194 (49.0%), respectively. Pooled HBOT+MT also showed favorable pooled results from random-effects models for both complete hearing recovery (OR, 1.61; 95% CI, 1.05 to 2.44) and any hearing recovery (OR, 1.43; 95% CI, 1.20 to 1.67). The study was limited by the following: (1) differences in clinical and methodological characteristics of selected studies, (2) considerable heterogeneity, (3) the possibility of measured or unmeasured confounder effects, and (4) difficulty in evaluating the benefit of treatment due to a substantial proportion of patients experiencing spontaneous recovery.

Včeva et al (2022) published a retrospective study that included a total of 59 patients (31 males and 28 females, median age 56 years) treated for ISSNHL with HBOT in the period from January 2015 to the end of December 2019. Patients were offered various treatments, and the patients with sudden sensorineural hearing loss of idiopathic cause included in this study were those who refused corticosteroid therapy. The median time from the onset of symptoms to treatment was three days. A pure-tone audiogram was recorded in all patients during the first visit to the otorhinolaryngologist and after completion of the HBOT course. Following HBOT (90 min at 203 kPa daily for 20 days), hearing loss was significantly reduced with the median loss across all frequencies falling from 81.2 dB (IQR 70.0−95.0) to 58.1 dB (IQR 47.5−77.5) ($P < 0.001$). The difference in the median value of hearing loss before and after HBOT across all patients was 22.5 dB (IQR 12.5–33.75). Significantly lower hearing thresholds were observed at 500, 1,000, 2,000 and 4,000 Hz after treatment, with the largest difference at 1,000 Hz. There were four patients who started HBOT greater than 14 days from the onset of symptoms. The median value of hearing recovery (difference in hearing thresholds before and after HBOT) was 17.5 dB (IQR 4.1–38.4), and the median hearing threshold after HBOT was 54.3 dB (IQR 51.8–68.1) for these 'delayed' patients. There was no significant difference in recovery (difference in hearing threshold before and after HBOT) between patients who started therapy within seven days, 7–14 days, or > 14 days from the onset of symptoms ($P = 0.39$). There was no association between treatment initiation time and recovery. The principal limitation of this study is the lack of a comparator group primarily treated with corticosteroids that would allow comparison of outcomes with those obtained using HBOT. The study is also small and retrospective in design. The authors concluded the study showed HBOT is a legitimate choice as the primary treatment for ISSNHL, especially if it is readily accessible, and if there are contraindications for corticosteroid therapy.

Wu et al (2018) conducted a meta-analysis to determine the effectiveness of oxygen therapy in retinal artery occlusion patients. The primary endpoint was visual acuity (VA). Seven RCTs met inclusion criteria. Patients who received oxygen therapy exhibited probability of visual improvement about 5.61 times compared with the control group who did not receive oxygen therapy. No statistically significant difference was observed between oxygen inhalation methods, combined therapy, or RAO type. Conversely, 100% oxygen and hyperbaric oxygen significantly improved VA in RAO patients. Better effect was showed in period within three months and the most effective treatment length was over nine hours. The authors concluded that oxygen therapy had beneficial effects in improving VA in RAO patients, especially when treated with 100% hyperbaric oxygen for over nine hours.

Boyoung M et al (2025) published a retrospective clinical cohort study to describe the outcomes of HBOT for patients with central retinal artery occlusion (CRAO) at a single tertiary care center. Medical records of all patients diagnosed with CRAO who received HBOT at Mayo Clinic in Rochester, Minnesota from January 1, 2009 to December 31, 2020 were reviewed to confirm diagnosis, time from onset to presentation, exam findings, treatments, and follow-up data. Main outcome measures included final visual acuity (VA) and number of lines of improvement. There were 41 patients diagnosed with CRAO who received HBOT during the 12-year study period. Median time from symptom onset to HBOT treatment was 9.5 h (interquartile range [IQR] 6.5, 14.0 h), and patients received a median of 4 HBOT sessions (IQR 2.5, 6.0 sessions). There were 20 patients who received HBOT within 9 h, 14 (70%) of which had clinically meaningful improvement in VA of ≥ 0.3 logMAR. In comparison, of the 21 patients treated after 9 h, 6 (28.6%) had VA improvement of ≥ 0.3 logMAR ($P = .008$). For all patients, the median logMAR VA at presentation was 2.00 (IQR 1.70, 2.30) and the median logMAR VA at follow-up was 1.94 (IQR 1.00, 2.00) ($P < .001$), with median lines of improvement of 3.0 (IQR 0.0, 7.0). For patients treated within 9 h, the median logMAR VA at presentation was 2.00 (IQR 1.93, 2.30) and the median logMAR VA at follow-up was 1.70 (IQR 0.54, 2.00). Patients treated within 9 h had statistically significant greater median lines of VA improvement than cases that were treated after > 9 h from symptom onset at 5.9 (IQR 3.0, 10.0) and 0.0 (IQR 0.0, 3.0), respectively ($P < .001$). There was no difference in VA recovery associated with specific retinal exam findings such as cherry-red spot ($P = .22$) and cilioretinal artery perfusion ($P = .36$) compared to patients without those findings. Limitations of the study include the retrospective design and the small cohort of patients. There was a statistically significant improvement in VA after HBOT treatment in CRAO patients among patients that received early HBOT, with patients receiving the most benefit when receiving treatment within 9 h.

Maldonado et al (2024) published a retrospective study to report the visual acuity outcomes in all patients with CRAO and symptoms lasting for less than 24 hours who were prescribed HBOT in the Hyperbaric Medicine Unit of a Portuguese hospital from March 2009 to February 2023. All patients were subjected to 90-minute HBOT sessions with 100% oxygen at 2.4 ATA. The primary outcome was VA change (dif-logMAR) before and after treatment. A clinically significant visual improvement was defined as a dif-logMAR≥0.3. A total of 114 patients were included in this study; 68% (n=77) were male, with a mean age of 69 years, and were subjected to a median number of seven HBOT sessions. No serious adverse effects from HBOT were reported. The mean time delay from symptoms

to treatment was 12 hours, and best-corrected visual acuity (BCVA) at baseline was counting fingers or worse in 84% (n=96) of the patients. A dif-logMAR≥0.3 occurred in 46% (n=52) of the patients, and 58% (n=66) reported subjective VA improvement after the treatment. A significant improvement between BCVA before HBOT (2.12±0.74) and after HBOT (1.67±0.74) was observed. The VA outcome was found to be related to the total number of sessions, age, obesity, supplementary treatments, and cherry-red spot (CRS) at presentation. There were no significant effects of the time delay from symptoms to treatment in the explanation of the VA outcome. Limitations of the study included the retrospective design and absence of a control group for ethical reasons. The authors concluded HBOT appears to be safe and has a beneficial effect on VA outcomes in patients with non-arteritic CRAO, particularly depending on the number of sessions. Patient factors such as age, obesity, and the presence of CRSs also appear to influence the VA outcome.

Bagli BS et al (2018) aimed to investigate efficacy of HBO2 treatment in CRAO patients that were referred to their Hyperbaric Oxygen Treatment Unit. Patient demographics, their systemic diseases, best-corrected visual acuity (BCVA) and the time of visual loss were recorded. Oral acetazolamide and topical beta blocker treatments as well as HBO2 treatments were administered to patients as soon as possible. Patients received 20 treatments as standard. Visual acuity was examined and recorded following each HBO2 treatment administration. 10 eyes (five right, five left) of 10 patients) were included in the study. While average visual acuity was LogMAR 3 before the treatment, it was measured as LogMAR 1.8 on average after treatment (P ⟨ 0.05). None of the patients were observed to have neovascular glaucoma. The authors concluded their study showed HBO2 treatment is an efficacious method with few side effects and can be used in the treatment of CRAO patients. During acute and subacute periods, a certain number of HBO2 treatment sessions may be beneficial. Stopping treatments before eight completed HBO2 sessions for a patient who did not show improvement until that time may miss a patient who would have benefited from HBO2 treatment.

Kim YS et al (2020) published a registry-based observational study which included adult patients who presented to the emergency department or ophthalmology outpatient department within 24 hours of the onset of CRAO symptoms. Data of patients from October 2016 to February 2019 were analyzed. The patients were categorized into two groups according to the use of adjunctive HBO2: no HBO2 and HBO2. During the study period, 34 consecutive patients were enrolled, of which 19 were included in the study. In the total cohort, 10 patients (52.6%) were treated with adjunctive HBO2. There were no statistically significant differences in terms of age, sex, comorbidities, duration from symptoms onset to hospital visit, presence of the cilioretinal artery, and use of anterior chamber paracentesis between the two groups. The HBO2 group showed significantly higher change in best-corrected visual acuity than the no HBO2 group (p=0.043). The authors concluded the study showed patients with CRAO in the HBO2 group showed significantly greater visual improvement than those in the no-HBO2 group.

A 2016 Cochrane review identified one randomized, controlled trial (RCT) evaluating systemic HBOT for people with autism spectrum disorder who met reviewers' eligibility criteria, and that trial did not find significantly improved outcomes with HBOT versus sham (Xiong 2016). The authors concluded that there is no evidence that HBOT improves core symptoms and associated symptoms of ASD, adding that it is important to note that adverse effects (minor-grade ear barotrauma events) can

occur. Given the absence of evidence of effectiveness, the limited biological plausibility, and possible adverse effects, the need for future RCTs of HBOT must be carefully considered.

Published clinical trials have not provided evidence to support the efficacy and safety of HBOT over current treatment options for the indications listed as investigational in this policy.

PROFESSIONAL GUIDELINE(S)

The Undersea and Hyperbaric Medical Society (UHMS) (2023) published recommended indications for systemic hyperbaric oxygen therapy which include the following:

- Air or gas embolism
- Arterial insufficiencies
    - Central retinal artery occlusions
    - Selected problem wounds-diabetic ulcers (microvascular insufficiency)
- Carbon monoxide poisoning/ carbon monoxide poisoning complicated by cyanide poisoning
- Clostridial myositis and myonecrosis (gas gangrene)
- Crush injury, compartment syndrome, and other acute traumatic ischemias
- Decompression sickness
- Severe anemia
- Intracranial abscesses
- Necrotizing infections
- Osteomyelitis (refractory)
- Delayed radiation injury (soft tissue and bony necrosis)
- Compromised skin grafts and flaps
- Acute thermal burn injury
- Idiopathic sudden sensorineural hearing loss
- Avascular necrosis (aseptic osteonecrosis)

In 2015, the Undersea and Hyperbaric Medical Society (UHMS) published guidelines on the use of HBOT for treating diabetic foot ulcers (Huang 2015). Recommendations in the current version include:

- Suggest against using HBOT in patients with "Wagner Grade 2 or lower diabetic foot ulcers..."
- Suggest adding HBOT in patients with "Wagner Grade 3 or higher diabetic foot ulcers that have not shown significant improvement after 30 days of [standard of care] therapy..."
- Suggest "adding acute post-operative hyperbaric oxygen therapy to the standard of care" in patients with "Wagner Grade 3 or higher diabetic foot ulcers" who have just had foot surgery

related to their diabetic ulcers.

In December 2009, the Undersea and Hyperbaric Medical Society issued a position paper stating that the society does not recommend routine treatment of autism with HBOT, as there is very little evidence to support an effect of pressure alone or that oxygen has differing effects whether given by increasing ambient pressure or increasing the inspired fraction.

In 2019, the American Academy of Otolaryngology-Head and Neck Surgery updated clinical guidelines on the treatment of sudden sensorineural hearing loss (SSNHL) (Chandrasekhar 2019). They give the following options regarding HBOT:

- Clinicians may offer, or refer to a physician who can offer, hyperbaric oxygen therapy (HBOT) combined with steroid therapy within 2 weeks of onset of SSNHL.
- Clinicians may offer, or refer to a physician who can offer, hyperbaric oxygen therapy (HBOT) combined with steroid therapy as salvage within 1 months of onset of SSNHL."

The guideline provided a comprehensive list of evidence gaps and future research needs on the use of HBOT for SSNHL. These included, among others, the need for a standardized, evidence-based definition of SSNHL, the assessment of the prevalence of SSNHL, and the need for the development of standardized HBOT treatment protocols and standardized outcome assessments.

In 2025, The American Academy of Ophthalmology (AAO) published a Preferred Practice Pattern for Retinal and Ophthalmic Artery Occlusions (Kovach 2025). They state the use of hyperbaric oxygen therapy (100% oxygen over 9 hours) has demonstrated efficacy over observation alone in several small retrospective studies (Wu 2018, Chiabo 2024). However, a Cochrane review concluded that evidence is uncertain regarding interventions and well-designed randomized controlled trials are needed (Lin 2023).

In 2024, the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines published a Guideline for the Management of Lower Extremity PAD. The Guideline was developed in collaboration with and endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Podiatric Medical Association, Association of Black Cardiologists, Society for Cardiovascular Angiography and Interventions, Society for Vascular Medicine, Society for Vascular Nursing, Society for Vascular Surgery, Society of Interventional Radiology, and Vascular & Endovascular Surgery Society. The Guideline included the following statements relevant to this evidence review:

- Beyond wound care, hyperbaric oxygen therapy has been studied in the context of wound healing for CLTI as an adjunctive therapy to revascularization and may have a limited role in this population.
- Hyperbaric oxygen therapy may be considered as an adjunctive therapy to revascularization for wound healing in the context of CLTI (chronic limb threatening ischemia) and diabetic foot ulcers.

In 2019 the American Heart Association and American Stroke Association updated the guidelines for early management of acute ischemic stroke (Powers 2019). The guidelines were endorsed by the

Society for Academic Emergency Medicine, the Neurocritical Care Society, the American Association of Neurological Surgeons, and the Congress of Neurological Surgeons. The Guideline included the following statements relevant to this evidence review:

"The limited data available on the utility of HBO therapy for acute ischemic stroke (not related to cerebral air embolism) show no benefit. HBO therapy is associated with claustrophobia and middle ear barotrauma, as well as an increased risk of seizures. Given the confines of HBO chambers, the ability to closely/adequately monitor patients may also be compromised. HBO thus should be offered only in the context of a clinical trial or to individuals with cerebral air embolism."

In 2016, the Society of Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine published guidelines on the management of the diabetic foot (Hingorani 2016). According to the guidelines, for diabetic foot ulcers that fail to demonstrate improvement (> 50% wound area reduction) after a minimum of 4 weeks of standard wound therapy, adjunctive therapy such as HBOT is recommended (grade 1B). Also, for diabetic foot ulcers with adequate perfusion that fail to respond to 4 to 6 weeks of conservative management, HBOT is suggested (grade 2B).

REGULATORY STATUS

Since 1979, the U.S. Food and Drug Administration (FDA) has cleared multiple topical and systemic hyperbaric oxygen administration devices through the 510(k) pathway. Last updated in 2021, the FDA has cleared hyperbaric chambers for the following disorders:

- Air and gas bubbles in blood vessels
- Anemia (severe anemia when blood transfusions cannot be used)
- Burns (severe and large burns treated at a specialized burn center)
- Carbon monoxide poisoning
- Crush injury
- Decompression sickness (diving risk)
- Gas gangrene
- Hearing loss (complete hearing loss that occurs suddenly and without any known cause)
- Infection of the skin and bone (severe)
- Radiation injury
- Skin graft flap at risk of tissue death
- Vision loss (when sudden and painless in one eye due to blockage of blood flow)
- Wounds (non-healing, diabetic foot ulcers)

HBOT is being studied for other conditions, including COVID-19. However, at this time, the FDA has not cleared or authorized the use of any HBOT device to treat COVID-19 or any conditions beyond

those listed above.

In 2013, the FDA published a statement warning that non-FDA approved uses of HBOT may endanger the health of patients. If patients mistakenly believe that HBOT devices have been proven safe for uses not cleared by the FDA, they may delay or forgo proven medical therapies. Patients receiving HBOT are at risk of suffering an injury that can be mild (such as sinus pain, ear pressure, painful joints) or serious (such as paralysis, air embolism). Since hyper baric chambers are oxygen rich environments, there is also a risk of fire.

The FDA states the safety and effectiveness of HBOT has not been established for these diseases and conditions, including:

- AIDS/HIV
- Alzheimer's Disease
- Asthma
- Bell's Palsy
- Brain Injury
- Cerebral Palsy
- Depression
- Heart Disease
- Hepatitis
- Migraine
- Multiple Sclerosis
- Parkinson's Disease
- Spinal Cord Injury
- Sport's Injury
- Stroke

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session

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HCPCS Codes

Code	Description
A4575 (E/I)	Topical hyperbaric oxygen chamber, disposable
E0446 (E/I)	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval

ICD10 Codes

Code	Description
A18.01	Tuberculosis of spine
A18.03	Tuberculosis of other bones
A42.0-A42.2	Actinomycosis (code range)
A42.81-A42.89	Other forms of actinomycosis (code range)
A42.9	Actinomycosis, unspecified
A43.0-A43.9	Nocardiosis (code range)
A48.0	Gas gangrene
A50.01-A50.09	Early congenital syphilis, symptomatic (code range)
A52.77	Syphilis of bone and joint
B36.0-B36.9	Other superficial mycoses (code range)
B47.1	Actinomycetoma
B47.9	Mycetoma, unspecified
B48.3	Geotrichosis
B48.8	Other specified mycoses

Code	Description
B49	Unspecified mycosis
D62	Acute posthemorrhagic anemia
E08.52	Diabetes mellitus due to underlying condition with diabetic peripheral angiopathy with gangrene
E09.52	Drug or chemical induced diabetes mellitus with diabetic peripheral angiopathy with gangrene
E10.52	Type 1 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E10.618-E10.69	Type 1 diabetes mellitus with other specified complications (code range)
E11.52	Type 2 diabetes mellitus with diabetic peripheral angiopathy with gangrene
E11.618-E11.69	Type 2 diabetes mellitus with other specified complication
E13.52-E13.69	Other specified diabetes mellitus (code range)
G93.6	Cerebral edema
H05.021-H05.029	Osteomyelitis of orbit (code range)
H90.3	Sensorineural hearing loss, bilateral
H90.5	Unspecified sensorineural hearing loss
H90.A2-H90.A22	Sensorineural hearing loss, unilateral, with restricted hearing on the contralateral side (code range)
H91.2-H91.23	Sudden idiopathic hearing loss (code range)
H34.1-H34.13	Central retinal artery occlusion (code range)
I70.361-I70.369	Atherosclerosis of bypass graft(s) of the extremities with gangrene (code range)
I70.461-I70.469	Atherosclerosis of autologous vein bypass graft(s) of the extremities with gangrene (code range)
I73.01	Raynaud's syndrome with gangrene

Code	Description
I96	Gangrene, not elsewhere classified
K12.2	Cellulitis and abscess of mouth
L02.01-L02.93	Cutaneous abscess, furuncle, and carbuncle (code range)
L03.111-L03.119	Cellulitis of other parts of limb (code range)
L03.121-L03.129	Acute lymphangitis (code range)
L03.211-L03.91	Cellulitis and acute lymphangitis (code range)
L08.1	Erythrasma
L59.9	Disorder of the skin and subcutaneous tissue related to radiation, unspecified
L98.3	Eosinophilic cellulitis (Wells)
M27.2	Inflammatory conditions of jaws
M27.8	Other specified diseases of jaws
M46.20-M46.28	Osteomyelitis of vertebra (code range)
M46.30-M46.39	Infection of intervertebral disc (pyogenic) (code range)
M86.00-M86.09	Acute hematogenous osteomyelitis (code range)
M86.10-M86.19	Other acute osteomyelitis (code range)
M86.20-M86.29	Subacute osteomyelitis (code range)
M86.30-M86.69	Chronic osteomyelitis (code range)
M86.8x0-M86.9	Other and unspecified osteomyelitis (code range)
M90.80-M90.89	Osteopathy in diseases classified elsewhere (code range)

Code	Description
P11.0	Cerebral edema due to birth injury
S06.1x0A-S06.1x9A	Traumatic cerebral edema (code range)
S07.0xxA, S17.9xxA,	Crushing injury (code range)
T57.3x1A-T57.3x4A	Toxic effect of hydrogen cyanide (code range)
T58.01xA-T58.94xA	Toxic effect of carbon monoxide (code range)
T65.0x1A-T65.0x4A	Toxic effect of cyanides (code range)
T66.xxxA-T66.xxxS	Radiation sickness, unspecified (code range)
T70.3xxA-T70.3xxS	Caisson disease (decompression sickness) (code range)
T79.0xxA-T79.0xxS	Air embolism (traumatic) (code range)
T86.820-T86.822	Complications of skin graft (allograft) (autograft) (code range)
T86.828-T86.829	Other and unspecified complications of skin graft (allograft) (autograft) (code range)

REFERENCES

American College of Emergency Physicians Clinical Policies Subcommittee (Writing Committee) on Critical Issues in the Management of Adult Patients Presenting to the Emergency Department with Carbon Monoxide Poisoning. Clinical policy: critical issues in the management of adult patients presenting to the emergency department with acute carbon monoxide poisoning. Ann Emerg Med 2008 Feb;51(2):138-52.

Bagli BS, et al. Effect of hyperbaric oxygen treatment in central retinal artery occlusion. Undersea Hyperb Med. 2018 Jul-Aug;45(4):421-425.

Bennett MH, et al. Hyperbaric oxygen therapy for acute ischemic stroke. Cochrane Database Syst Rev. 2014 Nov 12;11:CD004954.

Bennett M, et al. Hyperbaric oxygen therapy for the adjunctive treatment of traumatic brain injury.

Cochrane Database Syst Rev. 2012 Dec 12;(12):CD004609.

Bennett M, et al. Hyperbaric oxygen therapy for delayed onset muscle soreness and closed soft tissue injury. Cochrane Database Syst Rev. 2005 Oct 19;(4):CD004713.

Bennett MH, et al. Hyperbaric oxygen for idiopathic sudden sensorineural hearing loss and tinnitus. Cochrane Database Syst Rev. 2012 Oct 17;10:CD004739.

Bennett MH, et al. Hyperbaric oxygen therapy for late radiation tissue injury. Cochrane Database Syst Rev. 2012 May 16;5:CD005005.

Bennett MH, et al. Hyperbaric oxygen therapy for multiple sclerosis. Cochrane Database Syst Rev. 2004, Issue 1. Art. No.: CD003057.

Bennett MH, et al. Hyperbaric oxygen therapy for promoting fracture healing and treating fracture non-union. Cochrane Database Syst Rev. 2012 Nov 14;11:CD004712.

Bennett MH, et al. Hyperbaric oxygen for tumour sensitisation to radiotherapy. Cochrane Database Syst Rev. 2012 Apr 18;4:CD005007.

Bennett MH, et al. Normobaric and hyperbaric oxygen therapy for migraine and cluster headache. Cochrane Database Syst Rev. 2015 Dec 28;12:CD005219.

Bennett M, et al. The treatment of autism spectrum disorder with hyperbaric oxygen therapy. UHMS position paper [Internet]. 2009 Dec 5 [accessed 2026 Jun 11]. Available from: https://www.uhms.org/images/Position-Statements/autism_position_paper.pdf

Boudreau R, et al. Canadian Agency for Drugs and Technologies in Health [Internet]. Ottawa, CA. Hyperbaric oxygen therapy for difficult wound healing: systematic review of clinical effectiveness and cost-effectiveness. 2010 Jun [accessed 2026 Jun 11]. Available from https://cadth.ca/sites/default/files/pdf/M0016_HBOT_L3_e.pdf

Boyoung M, et al. Outcomes of hyperbaric oxygen treatment for central retinal artery occlusion: a single center experience. Am Jour of Ophthalmol. 2025 Jan;269:393-401.

Buckley NA, et al. Hyperbaric oxygen for carbon monoxide poisoning. Cochrane Database Syst Rev. 2011 Apr 13;4:CD002041.

Cavaliere M, et al. Combination of hyperbaric oxygen therapy and oral steroids for the treatment of sudden sensorineural hearing loss: early or late? Medicina (Kaunas). 2022 Oct 10;58(10).

Chandrasekhar SS, et al. Clinical Practice Guideline: Sudden Hearing Loss (Update). Otolaryngol Head Neck Surg. 2019 Aug;161(1_suppl):S1-S45.

Chiabo J, et al. Efficacy and safety of hyperbaric oxygen therapy monitored by fluorescein angiography in patients with retinal artery occlusion. Br J Ophthalmol 2024;108:956-62.

de Smet GHJ, et al. Oxygen therapies and their effects on wound healing. Wound Repair Regen. 2017 Aug;25(4):591-608.

Eskes A, et al. Hyperbaric oxygen therapy for treating acute surgical and traumatic wounds. Cochrane Database Syst Rev. 2013 Dec;12:CD008059.

Eskes AM, et al. Hyperbaric oxygen therapy: solution for difficult to heal acute wounds? Systematic review. World J Surg. 2011 Mar;35(3):535-42.

Esposito M, et al. Interventions for replacing missing teeth: hyperbaric oxygen therapy for irradiated patients who require dental implants. Cochrane Database Syst Rev. 2013 Sep 30;9:CD003603.

Fakkert RA, et al. Early hyperbaric oxygen therapy is associated with favorable outcome in patients with iatrogenic cerebral arterial gas embolism: systematic review and individual patient data meta-analysis of observational studies. Crit Care. 2023 Jul;27(1):282.

Gornik et al. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/SVN/SVS/SIR/VESS Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2024 Jun 11;149(24):e1313-e1410.

Hadanny A, et al. Hyperbaric oxygen therapy improves neurocognitive functions of post-stroke patients – a retrospective analysis. Restorative Neurology and Neuroscience. 2020;38:93–107.

Harch PG, et al. Hyperbaric oxygen therapy for mild traumatic brain injury persistent post-concussion syndrome: a randomized controlled trial. Medical Gas Research. 2020 Mar;10(1).

Hedetoft M, et al. Adjunctive hyperbaric oxygen treatment for necrotising soft-tissue infections: A systematic review and meta-analysis. Diving Hyperb Med. 2021 Mar 31;51(1): 34-43.

Hingorani A, et al. The management of diabetic foot: A clinical practice guideline by the Society for Vascular Surgery in collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine. Jour of Vasc Surg. 2016 Feb;63(2):3S-21S.

Holland NJ, et al. Hyperbaric oxygen therapy for Bell's palsy. Cochrane Database Syst Rev. 2012 Feb 15;2:CD007288.

Hu X, et al. Comparison of the efficacy of 12 interventions in the treatment of diabetic foot ulcers: a network meta-analysis. PeerJ. 2025 Aug 11;13:e19809.

Huang ET, et al; UHMS CPG Oversight Committee. A clinical practice guideline for the use of hyperbaric oxygen therapy in the treatment of diabetic foot ulcers. Undersea Hyperb Med. 2015 May-Jun;42(3):205-47.

Joshua TG, et al. Hyperbaric oxygen therapy for patients with sudden sensorineural hearing loss: a systematic review and meta-analysis. JAMA Otolaryngol Head Neck Surg. 2022 Jan 01; 148(1):5-11.

Juurlink DN, et al. Hyperbaric oxygen for carbon monoxide poisoning. Cochrane Database Syst Rev 2005 Jan 25;1:CD002041.

Kaspryzyk-Kucewicz T, et al. Thermal effects of topical hyperbaric oxygen therapy in hard-to-heal wounds- A pilot study. Int J Environ Res Public Health. 2021 Jun 23;18(13):6737.

Kjellberg A, et al. Hyperbaric oxygen therapy for long COVID (HOT-LoCO), an interim safety report from a randomised controlled trial. BMC Infect Dis. 2023 Jan 20;23(1):33.

Kim YS, et al. The effect of adjunctive hyperbaric oxygen therapy in patients with central retinal

artery occlusion. Undersea Hyperb Med. 2020 First Quarter;47(1):57-64.

Kovach JL, et al; American Academy of Ophthalmology Preferred Practice Pattern Retina/Vitreous Committee. Retinal and Ophthalmic Artery Occlusions Preferred Practice Pattern. Ophthalmology. 2025 Apr;132(4):P270-P302.

Kranke P, et al. Hyperbaric oxygen therapy for chronic wounds. Cochrane Database Syst Rev. 2015 Jun 24;6:CD004123.

Levett D, et al. Adjunctive hyperbaric oxygen for necrotizing fasciitis. Cochrane Database of Systematic Reviews 2015 Jan 15;1:CD007937.

Lin JC, Song S, Ng SM, et al. Interventions for acute non-arteritic central retinal artery occlusion. Cochrane Database Syst Rev. 2023;1:CD001989.

Maldonado F, et al. Effects of hyperbaric oxygen therapy in the treatment of patients with central retinal artery occlusion: a retrospective study. Cureus. 2024 Aug 5;16(8):e66196.

Nakajima M, et al. Hyperbaric oxygen therapy and mortality from carbon monoxide poisoning: A nationwide observational study. American Journal of Emergency Medicine. 2020;38:225-230.

Oliaei S, et al. The effects of hyperbaric oxygen therapy (HBOT) on coronavirus disease -2019 (COVID-19): a systematic review. Eur J Med Res. 2021 Aug;26(1):96.

Powers WJ, et al. Guidelines for the early management of patients with acute ischemic stroke: 2019 update to the 2018 guidelines for the early management of acute ischemic stroke: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2019 Dec; 50(12):e344-e418.

Rhee TM, et al. Addition of hyperbaric oxygen therapy vs medical therapy alone for idiopathic sudden sensorineural hearing loss: a systematic review and meta-analysis. JAMA Otolaryngol Head Neck Surg. 2018 Dec 01; 144(12):1153-1161.

Secil A, et al. Is salvage hyperbaric oxygen therapy effective for sudden sensorineural hearing loss in patients with non-response to corticosteroid treatment? Cureus. 2020;12(1):e6560.

Sharma R, et al. Efficacy of hyperbaric oxygen therapy for diabetic foot ulcer, a systematic review and meta-analysis of controlled clinical trials. Sci Rep. 2021 Jan 26;11(1):2189.

U.S. Food and Drug Administration. Consumer Health Information [Internet]. Hyperbaric oxygen therapy: don't be misled. 2013 August [accessed 2026 Jun 11]. Available from: https://www.talkingaboutthescience.com/studies/FDA2013.pdf

Včeva A, et al. Pretreatment hearing grades and hearing recovery outcomes after primary hyperbaric oxygen treatment in patients with idiopathic sudden sensorineural hearing loss. Diving Hyperb Med. 2022 Sep 30;52(3):191-196.

Villanueva E, et al. Hyperbaric oxygen therapy for thermal burns. Cochrane Database Syst Rev. 2004 Apr 19;2:CD004727.

Villeirs L, et al. Hyperbaric oxygen therapy for radiation cystitis after pelvic radiotherapy: Systematic

review of the recent literature. International Journal of Urology. 2020;27:98-107.

Wu X, et al. Oxygen therapy in patients with retinal artery occlusion: A meta-analysis. PLoS One 2018;13:e0202154.

Xiao Y, et al. Hyperbaric oxygen therapy for vascular dementia. Cochrane Database Syst Rev 2012 Jul 11;7:CD009425.

Xiong T, et al. Hyperbaric oxygen therapy for people with autism spectrum disorder (ASD). Cochrane Database Syst Rev. 2016 Oct 13;10:CD010922.

SEARCH TERMS

Topical hyperbaric oxygen pressurization, Topical oxygen wound therapy, TOWT.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Hyperbaric Oxygen Therapy (NCD 20.29) [accessed 2026 Jun 11]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New:02/99

Revised:10/99, 12/00, 09/03, 12/04, 09/05, 11/06, 09/08, 07/09, 09/11, 09/14, 01/15, 09/15, 09/17, 09/20, 9/21, 11/23, 5/24, 11/25

Reviewed:01/01, 12/02, 07/04, 10/07, 09/10, 09/12, 09/13, 09/16, 09/18, 09/19, 9/22, 9/23, 9/24, 9/25, 9/26

Date	Summary of Changes
1/1/2026	• Transitioned Hyperbaric Oxygen Therapy policy, 1370/20.000203 to Lifetime Healthcare Companies policy template.
6/1/2024	• Added examples of soft tissue radionecrosis.

12/1/2023	• Added the following additional covered indications: • Central retinal artery occlusion (CRAO) • Idiopathic sudden sensorineural hearing loss (SSHL)
1/1/2022	• Removed indication for HBOT as an adjunct treatment for burns and added skin burns (thermal) to the exclusions. • Under Medicaid: To clarify criteria, added verbiage from the MMIS DME Manual for topical oxygen wound therapy. Also removed code E0446 as this code is no longer on the MMIS DME Manual.
1/1/2021	• Added Lyme disease to the Exclusions section.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Policy/Procedure Name: Immune Thrombocytopenia (ITP) Policy **Control Number: 1350/20.000329**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care for enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Immune thrombocytopenia (ITP) is a rare autoimmune bleeding disorder defined as thrombocytopenia (platelet count < 100,000 x 10^9/L) without anemia or leukocytopenia and without another apparent cause of thrombocytopenia. Patients may appear asymptomatic, in which thrombocytopenia is detected through CBC, or symptomatic with signs of bleeding, such as petechiae, purpura, epistaxis, and rarely, major or clinical hemorrhages. ITP can be further categorized based on duration: newly diagnosed (within 3 months), persistent (3-12 months), and chronic ITP (> 12 months).

ITP can affect both children and adults. First line treatment is corticosteroids. For adults with persistent ITP, who are dependent on or unresponsive to corticosteroids, it is recommended to initiate thrombopoietin (TPO) receptor agonists: Nplate (romiplostim), Promacta (eltrombopag olamine), Alvaiz (eltrombopag choline), and Doptelet (avatrombopag). For adults with chronic ITP, who are dependent on or unresponsive to corticosteroids, recommended treatment options include TPO receptor agonists or splenectomy.

For children with persistent ITP, who are unresponsive to corticosteroids or intravenous immune globulin (IVIG), recommended treatment options include TPO receptor agonists and splenectomy.

Intravenous immune globulin (IVIG) is a potent immunomodulating agent that consists of concentrated human immunoglobulin, prepared from pooled plasma collected from human donors. IVIG is indicated for providing antibodies to patients who are susceptible to diseases where there is no immunization available and to treat certain immunodeficiencies. IVIG is recommended for patients who require a rapid increase in platelet count in those unresponsive to corticosteroid. In ITP, IVIG increases platelet count by blocking the Fc receptors on macrophages in the spleen and liver, preventing the uptake of autoantibody-coated platelets.

This policy contains coverage requirements for the following drugs: Nplate (romiplostim), Promacta (eltrombopag olamine), Alvaiz (eltrombopag choline), Doptelet (avatrombopag), Tavalisse (fostamatinib), and Wayrilz (rilzabrutinib). IVIG is addressed in a separate policy (Intravenous Immune Globulin (IVIG) & Subcutaneous Immune Globulin (SCIG) Therapy, 1350/20.000143).

TPO receptor agonists for the treatment of ITP include **Nplate (romiplostim)**, **Promacta (eltrombopag olamine)**, **Alvaiz (eltrombopag choline)**, and **Doptelet (avatrombopag)** which are all indicated after insufficient response to corticosteroids, immunoglobulin, or splenectomy. Nplate is also indicated for increasing the survival in adults and pediatric patients (including term neonates) with hematopoietic syndrome of acute radiation syndrome. Promacta and Alvaiz are also indicated for thrombocytopenia due to chronic hepatitis C and severe aplastic anemia. Doptelet is also indicated for chronic liver disease who are scheduled to undergo a procedure.

Tavalisse (fostamatinib) is a spleen tyrosine kinase (SYK) inhibitor that is only indicated for the treatment of chronic ITP after insufficient response to previous therapies.

Wayrilz (rilzabrutinib) is a Bruton's tyrosine kinase (BTK) inhibitor that is only indicated for the treatment of adults with persistent or chronic ITP who have had insufficient response to previous treatments.

Summary

Effective date of policy:	2/12/2026
Indications	Per product
ICD10 diagnosis codes	D69.5, D69.3, T66
Availability	*See individual formulary for covered product(s)*
HCPCS Code	Nplate – J2802
Duration	Thrombocytopenia in adults with chronic liver disease: 14 days Chronic immune thrombocytopenia: • Initial: 6 months • Continuation: 12 months

Required Criteria for Approval

Alvaiz (eltrombopag) - Rx	
Indication	**Criteria**
Immune thrombocytopenia (FDA approval) ICD10: D69.3	• Must be prescribed by or in consultation with a hematologist • Must have a diagnosis of immune thrombocytopenia/idiopathic thrombocytopenia purpura • Must have a current (within 30 days) platelet count of either: o less than 30 x 10^9/L o less than 50 x 10^9 with significant bleeding symptoms • Must have had an insufficient response (defined as a platelet count of < 30 x 109/L, or ≥ 30 x 109/L but with bleeding symptoms) to corticosteroids OR immunoglobulins (IVIG) • Initial approval will be provided for 6 months. • Recertification for 12 months at a time will require the following: o First recertification (after initial approval) will require documentation of the following: ▪ Positive response to treatment as documented by one of the following: • Platelet count ≥ 50 x 10^9/L OR • Platelet count ≥ 30 x 10^9/L without evidence of bleeding o Subsequent recertifications (after first recertification) will require documentation of the following: ▪ Maintenance of increased platelet count from baseline (platelet count ≥ 50 x 109/L OR platelet count ≥ 30 x 10^9/L without evidence of bleeding) AND ▪ Provider attests continuation of treatment is required to maintain a platelet count sufficient to avoid clinically important bleeding and will not be used to normalize platelet counts • Quantity limit is 30 tablets per 30 days o Approved requests for FDA approved indications that require 108 mg dosing will be approved with a quantity authorization to allow two 54 mg tablets per day o Requests above the quantity limit will be reviewed for medical necessity **AND** reviewed to require the most cost-efficient dose available for the quantity requested
Chronic Hepatitis C-Associated Thrombocytopenia (FDA approval) ICD 10: D69.59	• Must have a diagnosis of hepatitis C-associated thrombocytopenia • Must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hepatology or hematology • Must have a platelet level < 75 x 10^9 within previous 4 weeks • Eltrombopag is being prescribed to increase platelet count sufficiently to allow the initiation (or maintenance) of interferon-based therapy • Initial approval will be provided for 6 months. • Recertification for 6 months at a time will require documentation of the following: o Documentation of platelet count ≥ 90 x 10^9/L OR platelet count has increased sufficiently to initiate or maintain interferon therapy **AND** o Patient is continuing to receive interferon-based therapy. Eltrombopag should be discontinued when interferon therapy is discontinued • Quantity limit is 30 tablets per 30 days o Approved requests for FDA approved indications that require 108 mg dosing will be approved with a quantity authorization to allow two 54 mg tablets per day o Requests above the quantity limit will be reviewed for medical necessity **AND** reviewed to require the most cost-efficient dose available for the quantity requested
Severe Aplastic Anemia (FDA approval) ICD 10: D61.2	• Must have a diagnosis of severe aplastic anemia • Must be prescribed by or in consultation with a hematologist • Diagnosis of severe aplastic anemia must be documented by BOTH: o One of the following: ▪ A marrow biopsy showing < 25% of normal cellularity ▪ A marrow biopsy showing < 50% normal cellularity in which < 30% of cells are hematopoietic

	○ At least 2 of the following are present at the time of diagnosis ▪ Absolute reticulocyte count < 60,000microL ▪ Absolute neutrophil count < 500/microL ▪ Platelet count < 20,000/microL • Baseline hemoglobin and documentation of RBC transfusion status must be submitted • Must have had an insufficient response to immunosuppressive therapy • Alvaiz should not be used to normalize platelet counts. • Initial approval will be provided for 6 months. • Recertification for 12 months at a time requires the following: ○ First recertification (after initial approval) will require documentation of positive hematologic response as evidenced by any of the following: ▪ Platelet count ≥ 50 x 109/L ▪ Platelet count increases to 20 x 109/L above baseline ▪ Stable platelet counts with transfusion independence for a minimum of 8 weeks ▪ Hemoglobin increase by greater than 1.5 g/dL ▪ Reduction in greater than or equal to 4 units of RBC transfusions for 8 consecutive weeks ▪ An ANC increase of 100% ▪ An ANC increase greater than 0.5 x 10^9/L ○ Subsequent recertifications (after first recertification) will require documentation of maintenance of positive hematologic response. • Quantity limit is 30 tablets per 30 days ○ Approved requests for FDA approved indications that require 108 mg dosing will be approved with a quantity authorization to allow two 54 mg tablets per day ○ Requests above the quantity limit will be reviewed for medical necessity **AND** reviewed to require the most cost-efficient dose available for the quantity requested
Doptelet and Doptelet Sprinkle (avatrombopag) - Rx	
Thrombocytopenia in adults with chronic liver disease (FDA approval) ICD10: D69.5	• Member must have a diagnosis of chronic liver disease and be scheduled to undergo a procedure with date of the procedure provided **AND** ○ Must be 18 years of age or older ○ Must also have a diagnosis of thrombocytopenia defined as a platelet count of less than 50 x 10^9/L within 30 days prior to procedure ○ Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or hematologist ○ Must be prescribed for the appropriate dose based on platelet count prior to the scheduled procedure: ▪ For patients with a platelet count between 40 and 50 x 10^9/L, Doptelet can be approved at a dose of 40 mg (2 tablets) per day for 5 days ▪ For patients with a platelet count less than 40 x 10^9/L, Doptelet can be approved at a dose of 60 mg (3 tablets) per day for 5 days ○ Patients should begin dosing 10-13 days prior to their procedure and undergo their procedure within 5-8 days after their last dose ○ Approval will be for 14 days ○ Reauthorizations for future peri-procedural treatment must meet initial authorization criteria. ○ Documentation of prior response to therapy is required. Patients will not be eligible for retreatment if considered a non-responder to the initial course of therapy (non-responder defined as requiring a platelet transfusion following avatrombopag therapy) ○ Quantity limit: Tablets: 15 tablets per 30 days.
Chronic immune thrombocytopenia (ITP) (FDA approval) ICD10: D69.3	• Member must have a diagnosis of Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura (ITP) **AND** ○ An adult patient with thrombocytopenia lasting more than 12 months (chronic ITP) **OR** ○ Pediatric patient 1 year of age or older with thrombocytopenia lasting 6 months or greater (persistent or chronic ITP) **AND** ○ Must be prescribed by or in consultation with a hematologist **AND** ○ Member has one of the following within the previous 30 days:

	▪ Platelet count < 30 x 10^9/L **OR** ▪ Platelet count < 50 x 10^9/L with significant bleeding symptoms o Must have had an insufficient response (defined as a platelet count of < 30 x 10^9/L, or ≥ 30 x 10^9/L but with bleeding symptoms) to corticosteroids **OR** immunoglobulins (IVIG) o Initial approval will be provided for 6 months. o Recertification for 12 months at a time will require the following: ▪ First recertification (after initial approval) will require documentation of the following: • Positive clinical response to treatment as documented by one of the following: ▪ Platelet count ≥ 50 x 10^9/L OR ▪ Platelet count ≥ 30 x 10^9/L without evidence of bleeding • Subsequent recertifications (after first recertification) will require documentation of the following: ▪ Maintenance of increased platelet count from baseline (platelet count ≥ 50 x 10^9/L or platelet count ≥ 30 x 10^9/L without evidence of bleeding) **AND** ▪ Provider attests continuation of treatment is required to maintain a platelet count sufficient to avoid clinically important bleeding and will not be used to normalize platelet counts • Doptelet should not be used to normalize platelet counts • Quantity limit: o **Tablets:** 15 tablets per 30 days. ▪ For adult and pediatric patients with a diagnosis of ITP, a quantity of 60 tablets per 30 days will be allowed o **Sprinkle capsules** are only approved for children aged 1 to less than 6 years old with a quantity limit of 60 capsules per 30-day supply for a maximum of 20 mg/day.
Mulpleta (lusutrombopag) - Rx	
Thrombocytopenia in adults with chronic liver disease (FDA approval) ICD10: D69.5	• Must be at least 18 years old • Must be prescribed by or in consultation with a hepatologist, gastroenterologist, or hematologist • Must have a diagnosis of chronic liver disease and be scheduled to undergo an invasive procedure that has a high risk of bleeding associated, as described in Table 1 (below)[3], OR is undergoing a low-bleeding-risk procedure with a personal history of clinically relevant bleeding requiring intervention o Date of procedure must be provided • Must have a platelet count below 50 x 10^9/L obtained within four weeks prior to procedure • Doptelet is started 10 to 13 days prior to scheduled procedure, and members should undergo procedure five to eight days after last dose • Quantity limit is 15 tablets per 30 days • Reauthorizations for future peri-procedural treatment must meet initial authorization criteria. Documentation of prior response to therapy is required. Patients will not be eligible for retreatment if considered a non-responder to the initial course of therapy (non-responder defined as requiring a platelet transfusion following avatrombopag therapy) • Mulpleta therapy is initiated 8 to 14 days prior to scheduled procedure, and member should undergo procedure 2-8 days after last dose of drug o Quantity limit is 7 tablets per 30 days • Reauthorizations for future peri-procedural treatment must meet initial authorization criteria. Documentation of prior response to therapy is required. Patients will not be eligible for retreatment if considered a non-responder to the initial course of therapy (non-responder defined as requiring a platelet transfusion following lusutrombopag therapy)

Nplate (romiplostim) - Medical	
Immune thrombocytopenia (ITP) (FDA approval) ICD10: D69.3	• Must be prescribed by or in consultation with a hematologist • Must have a diagnosis of immune thrombocytopenia/idiopathic thrombocytopenia purpura • Must have a current (within 30 days) platelet count of either: o less than 30 x 10^9/L o less than 50 x 10^9 with significant bleeding symptoms • Must have had an insufficient response (defined as a platelet count of <30 x 109/L, or ≥ 30 x 109/L but with bleeding symptoms) to corticosteroids OR immunoglobulins (IVIG) • Initial approval will be provided for 6 months. • Recertification for 12 months at a time will require the following: o First recertification (after initial approval) will require documentation of the following: ▪ 1. Positive response to treatment as documented by one of the following (A OR B): • A. Platelet count ≥ 50 x 10^9/L OR • B. Platelet count ≥ 30 x 10^9/L without evidence of bleeding o Subsequent recertifications (after first recertification) will require documentation of the following: ▪ Maintenance of increased platelet count from baseline (platelet count ≥ 50 x 10^9/L or platelet count ≥ 30 x 10^9/L without evidence of bleeding) AND ▪ Provider attests continuation of treatment is required to maintain platelet count sufficient to avoid clinically important bleeding and will not be used to normalize platelet counts. • Nplate may be used in combination with other medical ITP therapies such as, corticosteroids, danazol, azathioprine, intravenous immunoglobulin (IVIG), and anti-D immunoglobulin. • The approved dose is 1 mcg/kg once weekly (subcutaneously). The dose may be adjusted in increments of 1 mcg/kg to achieve platelet counts of ≥ 50 x 10^9/L. Max weekly dose of 10 mcg/kg.
Hematopoietic subsyndrome of acute radiation syndrome (HSARS) (FDA approval) ICD10: T66	• The medication must be used to treat hematopoietic subsyndrome of acute radiation syndrome to increase survival in adults and in pediatric patients (including term neonates) acutely exposed to myelosuppressive doses of radiation o The medication must be given as a single dose of 10 mcg/kg o Approval will be provided for 1 month and may not be renewed
Promacta and eltrombopag tablet and powder for suspension - Rx	
Immune Thrombocytopenia (ITP) (FDA approval) ICD10: D69.3	• Must be at least 18 years of age • Must be prescribed by or in consultation with a hematologist • Must have a diagnosis of immune thrombocytopenia/idiopathic thrombocytopenia purpura • Must have a current (within 30 days) platelet count of either: o less than 30 x 10^9/L o less than 50 x 10^9 with significant bleeding symptoms • Must have had an insufficient response (defined as a platelet count of less than 30 x 10^9/L, or ≥ 30 x 10^9/L but with bleeding symptoms) to corticosteroids OR immunoglobulins (IVIG) • Initial approval will be for 6 months. • Recertification for 12 months at a time will require the following: o First recertification (after initial approval) will require documentation of the following: ▪ Positive response to treatment as documented by one of the following: • Platelet count ≥ 50 x 10^9/L **OR** • Platelet count ≥ 30 x 10^9/L without evidence of bleeding o Subsequent recertifications (after first recertification) will require documentation of the following: ▪ Maintenance of increased platelet count from baseline (platelet count ≥ 50 x 109/L or platelet count ≥ 30 x 10^9/L without evidence of bleeding) AND ▪ Provider attests continuation of treatment is required to maintain a platelet count sufficient to avoid clinically important bleeding and will not be used to normalize platelet counts • Quantity limit is 30 tablets or packets per 30 days

	○ Approved requests for FDA approved indications that require 150 mg dosing will be approved with a quantity authorization to allow two 75 mg tablets per day ○ Requests above the quantity limit will be reviewed for medical necessity AND reviewed to require the most cost-efficient dose available for the quantity requested
Chronic Hepatitis C-Associated Thrombocytopenia (FDA approval) ICD 10: D69.59	• Must have a diagnosis of hepatitis C-associated thrombocytopenia • Must be prescribed by or in consultation with a prescriber specializing in infectious disease, gastroenterology, hepatology or hematology • Must have a platelet level < 75 x 10^9 within previous 4 weeks • Eltrombopag is being prescribed to increase platelet count sufficiently to allow the initiation (or maintenance) of interferon-based therapy • Recertification for 6 months at a time will require documentation of the following: ○ Documentation of platelet count ≥ 90 x 10^9/L OR platelet count has increased sufficiently to initiate or maintain interferon therapy **AND** • Patient is continuing to receive interferon-based therapy. Eltrombopag should be discontinued when interferon therapy is discontinued • Quantity limit is 30 tablets or packets per 30 days ○ Approved requests for FDA approved indications that require 150 mg dosing will be approved with a quantity authorization to allow two 75 mg tablets per day ○ Requests above the quantity limit will be reviewed for medical necessity AND reviewed to require the most cost-efficient dose available for the quantity requested
Severe Aplastic Anemia (FDA approval) ICD 10: D61.2	• Must have a diagnosis of severe aplastic anemia • Must be prescribed by or in consultation with a hematologist • Diagnosis of severe aplastic anemia must be documented by BOTH: ○ One of the following: ▪ A marrow biopsy showing < 25% of normal cellularity ▪ A marrow biopsy showing < 50% normal cellularity in which < 30% of cells are hematopoietic ○ At least 2 of the following are present at the time of diagnosis ▪ Absolute reticulocyte count < 60,000microL ▪ Absolute neutrophil count < 500/microL ▪ Platelet count < 20,000/microL • Baseline hemoglobin and documentation of RBC transfusion status must be submitted • Promacta will be prescribed for one of the following: ○ As first-line therapy in combination with standard immunosuppressive therapy ○ For refractory or second-line treatment as a single agenet following insufficient response to immunosuppressive therapy • Eltrombopag should not be used to normalize platelet counts • Initial response will be provided for 6 months • Recertification for 12 months requires the following: ○ First recertification (after initial approval) will require documentation of positive hematologic response as evidenced by any of the following: ▪ Platelet count ≥ 50 x 109/L ▪ Platelet count increases to 20 x 109/L above baseline or ▪ Stable platelet counts with transfusion independence for a minimum of 8 weeks or ▪ Hemoglobin increase by greater than 1.5 g/dL or ▪ Reduction in greater than or equal to 4 units of RBC transfusions for 8 consecutive weeks or ▪ An ANC increase of 100 % or ▪ An ANC increase greater than 0.5 x 109/L • Subsequent recertifications will require documentation of maintenance of positive hematologic response

	• Quantity limit is 30 tablets or packets per 30 days o Approved requests for FDA approved indications that require 150 mg dosing will be approved with a quantity authorization to allow two 75 mg tablets per day o Requests above the quantity limit will be reviewed for medical necessity AND reviewed to require the most cost-efficient dose available for the quantity requested
Tavalisse (fostamatinib) - Rx	
Immune thrombocytopenia (ITP) (FDA approval) ICD10: D69.3	• Must be at least 18 years of age • Must be prescribed by or in consultation with a hematologist • Must have a diagnosis of chronic immune thrombocytopenia/idiopathic thrombocytopenia purpura (thrombocytopenia lasting more than 12 months) • Must have a current (within 30 days) platelet count of either: o less than 30 x 10^9/L o less than 50 x 10^9 with significant bleeding symptoms • Must have had an insufficient response (defined as a platelet count of less than 30 x 109/L, or ≥ 30 x 10^9/L but with bleeding symptoms) to corticosteroids OR immunoglobulins (IVIG) • Tavalisse should not be used to normalize platelet counts • Initial approval will be provided for 6 months. • Recertification for 12 months at a time requires the following: o First recertification (after initial approval) will require documentation of positive response as evidenced by one of the following: ▪ Platelet count ≥ 50 x 10^9/L OR ▪ Platelet count ≥ 30 x 10^9/L without evidence of bleeding o Subsequent recertifications (after first recertification) will require documentation of the following: ▪ Maintenance of increased platelet count from baseline (platelet count ≥ 50 x 109/L or platelet count ≥ 30 x 10^9/L without evidence of bleeding) AND ▪ Prescriber attests continuation of treatment is required to maintain a platelet count sufficient to avoid clinically important bleeding and will not be used to normalize platelet counts. • The starting dose of Tavalisse is 100 mg twice daily. After 4 weeks, the dose can be increased to 150 mg twice daily to achieve a platelet count of at least 50 x 10^9/L to reduce the risk of bleeding. • Quantity limit of 60 per 30 days
Wayrilz (rilzabrutinib) - Rx	
Immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment (FDA approval) ICD10: D69.3	• Must be prescribed by or in consultation with a hematologist AND • Must be 18 years of age or older AND • Member must have a diagnosis of persistent or chronic Immune Thrombocytopenia/Idiopathic Thrombocytopenia Purpura (ITP) AND • Member has one of the following within the previous 30 days: o Platelet count <30 x 10^9/L OR o Platelet count < 50 x 10^9/L with significant bleeding symptoms • Must have had an insufficient response (defined as a platelet count of less than 30 x 10^9/L, or ≥ 30 x 10^9/L but with bleeding symptoms) to corticosteroids OR immunoglobulins (IVIG) AND • Must have had serious side effects or drug failure with eltrombopag • Initial approval will be provided for 6 months. • Recertification for 12 months at a time will require the following: o First recertification (after initial approval) will require documentation of positive response as evidenced by one of the following: ▪ Platelet count ≥ 50 x 10^9/L OR ▪ Platelet count ≥ 30 x 10^9/L without evidence of bleeding o Subsequent recertifications (after first recertification) will require documentation of the following:

	▪ Maintenance of increased platelet count from baseline (platelet count ≥ 50 x 109/L or platelet count ≥ 30 x 10^9/L without evidence of bleeding) AND ▪ Provider attests continuation of treatment is required to maintain a platelet count sufficient to avoid clinically important bleeding • Recommended dosage of Wayrilz is 400 mg twice daily. • Quantity limit is 60 tablets per 30-day supply

Exclusion Criteria

Exclusion Criteria for therapy in the treatment of Thrombocytopenia in adults with chronic liver disease (CLD):

- Members undergoing procedures that have a low risk of bleeding associated, including paracentesis, thoracentesis, gastrointestinal endoscopy with or without plans for biopsy, colonoscopy, polypectomy, or variceal banding. See Table 2 below for other procedures that are considered to have a low risk of bleeding, and will not be covered.
- Members undergoing procedures including laparotomy, thoracotomy, open-heart surgery, craniotomy, or organ resection.
- Mulpleta has been investigated only when used in a single seven-day once-daily dosing regimen in those with CLD undergoing a procedure, and should not be given to those with CLD in an attempt to normalize platelet count.
- Doptelet had been approved for use for five days only, and should not be given to those with CLD in an attempt to normalize platelet count.
- Doptelet use in members with thrombotic or thromboembolic complications (arterial or venous).
- Members will not be eligible for future re-treatment if considered a non-responder to the initial course of therapy (non-responder defined as requiring platelet transfusion following TPO receptor agonist therapy).
- Members with history of splenectomy, partial splenic embolization, or thrombosis; and those with Child-Pugh class C liver disease, absence of hepatopetal blood flow, or a prothrombotic condition other than CLD.

Considerations

- Patient must have prescription drug coverage administered by CDPHP.
- Prior authorization is obtained through the CDPHP pharmacy department.
- Members who have received therapy for thrombocytopenia with chronic liver disease (undergoing a procedure) should have repeat platelet count obtained no more than two days prior to procedure.
- Guideline suggested treatment regimens –
    - Corticosteroids - prednisone 0.5-2 mg/kg/per day for 2-3 weeks (tapered by 6-8 weeks) OR dexamethasone 40 mg per day for four days
    - IVIG - 1 g/kg/day for 1–2 days (high-dose) or 0.4 g/kg/day for up to five days (low-dose)

Table 1[3]

Risk of bleeding associated with procedure	Procedure
Low risk	Catheter exchanges (gastrostomy, biliary, nephrostomy, abscess, including gastrostomy/gastrojejunostomy conversions)
	Diagnostic arteriography and arterial interventions: peripheral, sheath < 6 F, embolotherapy
	Diagnostic venography and select venous interventions: pelvis and extremities
	Dialysis access interventions
	Facet joint injections and medial branch nerve blocks (thoracic and lumbar spine)
	IVC filter placement and removal
	Lumbar puncture
	Non tunneled chest tube placement for pleural effusion
	Non tunneled venous access and removal (including PICC placement)
	Paracentesis
	Peripheral nerve blocks, joint, and musculoskeletal injections
	Sacroiliac joint injection and sacral lateral branch blocks
	Superficial abscess drainage or biopsy (palpable lesion, lymph node, soft tissue, breast, thyroid, superficial bone, e.g., extremities and bone marrow aspiration)
	Thoracentesis
	Transjugular liver biopsy
	Trigger point injections including piriformis

	Tunneled drainage catheter placement
	Tunneled venous catheter placement/removal (including ports)
	Gastrointestinal endoscopy with or without plans for biopsy, colonoscopy, polypectomy, or variceal banding
High risk	Ablations: solid organs, bone, soft tissue, lung
	Arterial interventions: > 7-F sheath, aortic, pelvic, mesenteric, CNS
	Biliary interventions (including cholecystostomy tube placement)
	Catheter directed thrombolysis (DVT, PE, portal vein)
	Deep abscess drainage (e.g., lung parenchyma, abdominal, pelvic, retroperitoneal)
	Deep nonorgan biopsies (e.g., spine, soft tissue in intraabdominal, retroperitoneal, pelvic compartments)
	Gastrostomy/gastrojejunostomy placement
	IVC filter removal complex
	Portal vein interventions
	Solid organ biopsies
	Spine procedures with risk of spinal or epidural hematoma (e.g., kyphoplasty, vertebroplasty, epidural injections, facet blocks cervical spine)
	Transjugular intrahepatic portosystemic shunt
	Urinary tract interventions (including nephrostomy tube placement, ureteral dilation, stone removal)
	Venous interventions: intrathoracic and CNS interventions

References

		Updated	Accessed
1	Mulpleta prescribing information, Shionogi Inc., Florham Park, NJ 07932.	4/2020	9/2023
2	Doptelet prescribing information. AkaRx, Inc., Durham, NC 27707	7/2021	9/2023
3	Patel, I. J., Rahim, S., Davidson, J. C., Hanks, S. E., Tam, A. L., Walker, T. G., Wilkins, L. R., Sarode, R., & Weinberg, I. (2019). Society of Interventional Radiology Consensus Guidelines for the Periprocedural Management of Thrombotic and Bleeding Risk in Patients Undergoing Percutaneous Image-Guided Interventions-Part II: Recommendations: Endorsed by the Canadian Association for Interventional Radiology and the Cardiovascular and Interventional Radiological Society of Europe. *Journal of vascular and interventional radiology: JVIR*, *30*(8), 1168–1184.e1. https://doi.org/10.1016/j.jvir.2019.04.017	8/2019	9/2023
4	Terrault N, Chen YC, Izumi N, et al. Avatrombopag Before Procedures Reduces Need for Platelet Transfusion in Patients with Chronic Liver Disease and Thrombocytopenia. Gastroenterology 2018; 155(3):705-718.	9/2018	9/2023
5	Terrault N, Chen YC, Izumi N, et al. Avatrombopag Before Procedures Reduces Need for Platelet Transfusion in Patients with Chronic Liver Disease and Thrombocytopenia. Gastroenterology 2018; 155(3):705-718. (Study Protocol)	12/ 2016	10/2018, 8/2019
6	Jurczak W, et al. Phase 3 randomised study of avatrombopag, a novel thrombopoietin receptor agonist for the treatment of chronic immune thrombocytopenia. Br J Haematol. 2018 Nov;183(3):479-490.	7/2018	9/2023
7	Neunert C, et al. American Society of Hematology 2019 guidelines for immune thrombocytopenia. Blood Adv 2019; 3(23): 3829-3866.	12/2019	9/2023
8	Provan D, Arnold DM, Bussel JB, et al. Updated international consensus report on the investigation and management of primary immune thrombocytopenia. Blood Adv. 2019;3:3780–817. doi: 10.1182/bloodadvances.2019000812.	11/2019	9/2023
9	Kim DS. Recent advances in treatments of adult immune thrombocytopenia. Blood Res. 2022 Apr 30;57(S1):112-119. doi: 10.5045/br.2022.2022038. PMID: 35483935; PMCID: PMC9057657.	4/2022	9/2023

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application if administered under the medical benefit.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application if administered under the medical benefit.

Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program

CDPHP Pharmacy Services 2/12/2026

New: 09/2018

Revised	Reviewed
12/18, 4/20, 4/21, 6/22, 12/22, 6/25, 12/25, 2/26	12/19, 12/23, 12/24

Revision Date	Changes Made
6/2022	Updated risk of bleeding associated with procedure categories to align with updated guidelines (removed "moderate risk" category), updated inclusion criteria for the indication of thrombocytopenia in adults with chronic liver disease (CLD) to align with the updated bleeding risk categories.
12/2022	Clarified and described guideline suggested dosage and duration for corticosteroid and IVIG regimens under criteria for chronic ITP
6/2025	Addition of Promacta, Alvaiz, Tavalisse, and Nplate to policy with criteria consistent across ITP and other shared diagnoses
12/2025	Updated Doptelet to say "Refer to Clinical Review Prior Authorization (CRPA) Rx policy 1350/20.000554 for criteria."
2/2026	Doptelet was moved from Clinical Review Prior Authorization (CRPA) Rx, 1350/20.000554 Reformatted policy Age removed from Alvaiz for diagnosis of ITP Changed insufficient response to either steroids or IVIG instead of both for ITP diagnosis Removed splenectomy with an inadequate response **AND** had an insufficient response or is intolerant to post-splenectomy corticosteroids Added Doptelet Sprinkle, eltrombopag tablet and powder for suspension, and Wayrilz

This Pharmacy Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI), and Capital District Physicians' Healthcare Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

MEDICAL POLICY

Medical Policy Title	**Implantable and Invasive Neuromodulation Systems**
Policy Number	**1.01.60**
Current Effective Date	**August 1, 2026**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

This policy does not address Sacral, Spinal Cord/Dorsal Column Stimulation or Tibial Nerve Stimulation.

POLICY STATEMENT(S)

I. The following implantable and invasive neuromodulation systems are **investigational**:
   A. Peripheral Nerve Stimulation (PNS)- Permanent Systems;
   B. Peripheral Nerve Stimulation (PNS)-Temporary Systems (e.g., SPRINT);
   C. Restorative Neurostimulation (e.g., ReActiv8);
   D. Percutaneous Electrical Nerve Stimulation/Percutaneous Neuromodulation Therapy.

RELATED POLICIES

Corporate Medical Policy

1.01.58 Cranial and Auricular Neuromodulation

01.01 59 Electromagnetic and Pulsed Field Stimulation

1.01.61 Non-Invasive Surface Electrical Stimulation for Pain and Rehabilitation

1.01.62 Specialized Neuromodulation for Specific Conditions

7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

7.01.10 Sacral Nerve Stimulation

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Peripheral Nerve Stimulation (PNS)- Permanent Systems

PNS is a similar concept to transcutaneous electrical nerve stimulation (TENS) but different in that

electrodes are implanted around or adjacent to the nerve serving the painful stimuli and then stimulated using a pulse generator and remote control. A trial of treatment is typically required prior to permanent implant of the generator and/or electrodes. Success of the trial is defined as > 50% reduction in pain response. PNS is generally reserved for patients who fail to get pain relief from TENS, medications, physical therapy or injection therapy.

The Moventis PNS (Micron Medical Corporation) received U.S. Food and Drug Administration (FDA) approval based upon substantial equivalence to The Freedom Spinal Cord Stimulator (SCS) System (Curonix) and an implanted peripheral nerve stimulator (StimQ PNS, Stimwave Technologies) for pain management. All of the devices are intended to treat adults who have severe intractable chronic pain of peripheral origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach and are not intended to treat pain in the craniofacial region of the body.

The Nalu neurostimulation (Nalu Medical, Inc.) system involves a 3-step process: wear experience, therapy trial, and permanent implantation. The treatment involves the initial use of adhesive clips and nonfunctioning Therapy Discs to determine future stimulation location and comfort level, followed by a temporary trial of the implanted leads, prior to permanent implantation. It is used for the management of chronic pain.

Peripheral Nerve Stimulation- Temporary Systems

The SPRINT peripheral nerve stimulation system (SPR Therapeutics, Inc.) is considered a temporary device, SPRINT uses a percutaneous electrode placed via an introducer needle near target peripheral motor or sensory nerves. The insertion of the implant does not require incisions or anesthesia, and the indwelling leads are left in place for up to 60 days. The device utilizes 300-micron diameter leads (one quarter the size of conventional neurostimulation leads) to provide safe lead withdrawal at the completion of the treatment. The device is intended to provide symptomatic relief of chronic, intractable pain, post-surgical and post-traumatic acute pain. It is not intended to treat pain in the craniofacial region of the body.

Restorative Neurostimulation Therapy

The ReActiv8 (Mainstay Medical) device is a permanent implant indicated for adults with intractable chronic low back pain associated with multifidus dysfunction who have failed pain medications and physical therapy and are not candidates for spine surgery. The device components consist of an implantable pulse generator, stimulation leads, software and programmer wand, activator, and magnet. ReActiv8 is marketed as the first and only restorative neurostimulation therapy to treat mechanical chronic low back pain and is full body MRI conditional.

Percutaneous Electrical Nerve Stimulation (PENS)/Percutaneous Neuromodulation Therapy (PNT)

PENS and PNT are terms often used interchangeably in the literature. This form of stimulation utilizes very fine needle-like electrode arrays placed near the painful area to stimulate peripheral sensory nerves in the soft tissue. PENS and PNT are also not to be confused with acupuncture using electrical stimulation. In electrical acupuncture, needle electrodes are inserted below the skin, but not necessarily at the site of pain. They are placed according to acupuncture meridians, which are a concept of Chinese medicine.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

SUPPORTIVE LITERATURE

Peripheral Nerve Stimulation- Permanent Systems

Lin et al (2024) conducted a systematic review and meta-analysis of randomized controlled trials. The authors investigated the effectiveness of peripheral nerve stimulation (PNS) has on pain and improvement in function on post operative lower-limb orthopedic patients. Data was used from eight randomized controlled trials involving 633 patients. While PNS did not significantly reduce pain intensity or improve functional outcomes such as range of motion and length of hospitalization, it did lead to a marginally significant reduction in analgesic consumption. These findings suggest that although PNS may offer some benefit in reducing the need for pain medication, its overall clinical efficacy remains uncertain. The authors recommend future research with larger sample sizes, longer follow-up periods, and varied stimulation parameters to better assess its potential.

Peripheral Nerve Stimulation- Temporary Systems

Gilmore et al (2021) performed a prospective multi-center study aimed at characterizing the responses of percutaneous medial branch peripheral nerve stimulation (PNS) to see if results from earlier, smaller single-center studies and reports were generalizable when performed on a larger number of patients refractory to nonsurgical treatments. Participants (n=89) with chronic lower axial backpain, a pain score greater than or equal to four, had failed at least two different categories of treatments and had at least four weeks of stable analgesic medication usage were enrolled, eight of which were later to be found ineligible because they did not meet the predefined criteria at the baseline. Authors report enrollment stopped short due to COVID-19. Exclusions included history of lumbar surgery, however, 10 of the patients with a history of lumbar surgery were included as part of a prospectively designed sub study with revised exclusion criteria. Participants were implanted with percutaneous PNS leads from the SPRINT PNS System under ultrasound and/or fluoroscopic guidance and were left in place for up to 60-days, when leads were removed. Follow up was planned for 12 months after the two-month PNS treatment. The study was not completed, and follow-up beyond 8 months is on-going. Clinically and statistically significant reductions in pain intensity, disability, and pain interference were reported by a majority of participants. 73% of participants were successful for the primary end point, reporting clinically significant (≥ 30%) reductions in back pain intensity after the 2-month percutaneous PNS treatment (n = 54/74). Whereas prospective follow-up is ongoing, among those who had already completed the long-term follow-up visits (n = 51), reductions in pain intensity, disability, and pain interference were sustained in a majority of participants through 14 months after the start of treatment. Limitations of the study include lack of randomization and control group.

Restorative Neurostimulation Therapy

ReActiv8 system FDA approval was based on a 2020 randomized control trial by Gilligan and colleagues (ReActiv8-B, NCT02577354). The authors have since published two-year and three-year durability studies on the same participants (Gilligan et al 2021, 2023). The pivotal trial was a multicenter sham controlled RCT enrolling 204 individuals with chronic, refractory low back pain. All participants were permanently implanted with the system. Therapeutic group participants (n=102)

received active treatment of the medial branch of the dorsal ramus nerve for 30-minutes twice daily. The control group (n=102) received low level sham stimulation. The primary endpoint was the difference in proportions of responders in the treatment and control groups. Response was defined as having a 30% or greater reduction in visual analog scale (VAS) and no increase in pain medications, assessed at 120 days. Following the 120-day randomized phase, participants in the control group were given the option to cross over to the intervention group and were followed along with the participants from the intervention group for up to three years. At 120 days, there was no difference between groups on the primary endpoint of treatment response (57.1% intervention vs 46.6% sham; p =.1377) or the individual components of the primary endpoint.

The study investigators conducted prespecified secondary analyses of the primary outcome data, including the between-group difference in VAS at 120 days, a review of participants with increased pain medications, and a cumulative-proportion-of-responders analysis, which graphically displays the proportion of responders across the range of all possible cutoffs and is described as having greater statistical power than the comparison of proportions of the dichotomized primary outcome. The VAS mean change from baseline to 120 days favored the intervention group (-3.3 vs -2.4; p =.032), but it is unclear if the difference between groups (0.9 points) was clinically meaningful. The cumulative proportion-of-responders analysis similarly favored the intervention group (p =.0499). Nine participants in both the intervention and control groups had an increase in pain medication at 120 days, but the increase was unrelated to low back pain in 6 of 9 participants in the treatment group versus 0 of 9 in the control group. Most importantly, the controlled phase was only 120 days. In the longer-term, uncontrolled follow-up phase of the trial, there was continued improvement in VAS scores over time in those who were assessed. Data was available for 176 of 204 participants at 1 year (86.3%), 156 of 204 participants (79%) at two years, and 130 of 204 (63.7%) at three years. The limitations of the studies, including a lack of a control group and high attrition limits drawing conclusions from these results. Additional evidence from longer-term sham controlled RCTs is needed.

Percutaneous Electrical Nerve Stimulation (PENS)/Percutaneous Neuromodulation Therapy (PNT)

PENS has been investigated for the treatment of headache, diabetic neuropathy, chronic neck pain, chronic low back pain, chronic surface hyperalgesia, and musculoskeletal pain. A systematic review conducted by Plaza-Manzano and colleagues (2020) concluded that PENS could decrease the level of pain intensity, but not related disability, in musculoskeletal pain disorders. The overall level of evidence, however, was low and there was heterogeneity in the application methods.

Beltran-Alacreu et al (2022) evaluated the effectiveness of PENS compared to TENS on the reduction of musculoskeletal pain. This systematic review and meta-analysis included a total of nine RCTs in the qualitative analysis, with seven in the quantitative analysis. Overall, there was low-quality evidence for increased pain intensity reduction with PENS over TENS, but the difference found was not deemed to be clinically significant. When only studies with low risk of bias were meta-analyzed, there was a moderate quality of evidence that there is no difference between TENS and PENS for pain intensity. Six out of the nine studies presented high risk for the blinding of participants, and seven out of nine were high risk for blinding of personnel. Beyond these two items, the risk of bias in the included trials was either low or unclear. Protocols and parameters for the application of PENS

and TENS were heterogenous across all trials, leading to the conclusion that there is still high uncertainty regarding the effectiveness of PENS for musculoskeletal pain.

There are no well-designed randomized controlled studies in the medical literature comparing PNS to established treatment options or a sham procedure; and studies on larger populations with longer follow-up are needed to permit scientific conclusions regarding the benefit and improved health outcomes for the use of PNS.

PROFESSIONAL GUIDELINE(S)

The American Society of Pain and Neuroscience 2022 Clinical Guidelines for the Use of Implantable Peripheral Nerve Stimulation in the Treatment of Chronic Pain stated:

Facial Pain

- "Stimulation of occipital nerves may be offered to patients with chronic migraine headache when conservative treatments have failed. The average effect size for relief of migraine symptoms is modest to moderate." (Level I, Grade B)
- "There is insufficient evidence to recommend stimulation of supraorbital and infraorbital nerves for neuropathic craniofacial pain." (Level II-3, Grade C)

Upper Extremities

- "PNS may offer modest and short-term pain relief, improved physical function, and better quality of life for chronic hemiplegic shoulder pain." (Level I, Grade B)
- "PNS for mononeuropathies of the upper extremity may be offered following a positive diagnostic ultrasound-guided nerve block of the targeted nerve and is associated with modest to moderate pain relief." (Level II-2, Grade B)

Lower Back and Trunk

- "Subcutaneous peripheral field stimulation combined with optimal medication management may offer moderate improvement in pain intensity for failed back surgery syndrome compared to optimal medication management alone." (Level I, Grade B)
- "There is evidence that PNS of medial branch nerves may improve pain intensity, physical function, and pain interference in patients with axial, mechanical low back pain." (Level II-2, Grade B)
- "There is limited evidence that PNS alleviates pain in neuropathic pain syndrome involving the trunk and back, including radiculopathy and post-herpetic neuralgia." (Level III, Grade C)

Lower Extremities

- "PNS may be considered for lower extremity neuropathic pain following failure of conservative treatment options and is associated with modest pain relief." (Level I, Grade B)

- "PNS may be considered for lower extremity post-amputation pain following failure of conservative treatment options and is associated with modest to moderate pain relief." (Level I, Grade B) (Strand 2022)

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates electrical stimulation devices as medical devices. All electrical stimulation devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Mar 13]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Mar 13]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
64555 (E/I)	Percutaneous implantation of neurostimulator electrode-electrode array; peripheral nerve (excludes sacral nerve)
64575 (E/)	Open implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)
64585 (E/I)	Revision or removal of peripheral neurostimulator electrode array
64590 (*E/I)	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver (*E/I when services include the use of systems addressed within this policy.)
64596 (E/I)	Insertion or replacement of percutaneous electrode array, peripheral nerve, with integrated neurostimulator, including imaging guidance, when performed; initial electrode array
64999 (E/I)	Unlisted procedure, nervous system (PNS or PNT using needle[s] or needle electrode[s])

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HCPCS Codes

Code	Description
C9807	Nerve stimulator, percutaneous, peripheral (e.g., sprint peripheral nerve stimulation system), including electrode and all disposable system components, nonopioid medical device (must be a qualifying Medicare nonopioid medical device for postsurgical pain relief in accordance with Section 4135 of the CAA, 2023)

ICD10 Codes

Code	Description
G89.2-G89.4	Chronic pain (code range)
G62.89	Other specified polyneuropathies
M53.86	Other specified dorsopathies, lumbar region
M53.87	Other specified dorsopathies, lumbosacral region
M54.51	Vertebrogenic low back pain
M62.85	Dysfunction of the multifidus muscles, lumbar region
M79.10	Myalgia, unspecified site

REFERENCES

Beltran-Alacreu H, et al. Percutaneous versus transcutaneous electrical nerve stimulation for the treatment of musculoskeletal pain. A systematic review and meta-analysis. Pain Med. 2022 Aug 01; 23(8):1387-1400.

Gilligan C, et al. An implantable restorative-neurostimulator for refractory mechanical chronic low back pain: a randomized sham-controlled clinical trial. Pain. 2021 Oct 21;162(10):2486-2498.

Gilligan C, et al. Long-term outcomes of restorative neurostimulation in patients with refractory chronic low back pain secondary to multifidus dysfunction: two-year results of the ReActiv8-B pivotal trial. Neuromodulation. 2023 Jan; 26(1):87-97.

Gilligan C, et al. Three-year durability of restorative neurostimulation effectiveness in patients with chronic low back pain and multifidus muscle dysfunction. Neuromodulation 2023 Jan;26(1):98-108.

Gilmore CA, et al. Treatment of chronic axial back pain with 60-day percutaneous medial branch PNS: Primary end point results from a prospective, multicenter study. Pain Practice. 2021;21:877-889.

Lin J, et al. Peripheral nerve stimulation for lower-limb postoperative recovery: A systematic review

and meta-analysis of randomized controlled trials. Psych J. 2025 Feb;14(1):15-27.

Plaza-Manzano G, et al. Effectiveness of percutaneous electrical nerve stimulation for musculoskeletal pain: A systematic review and meta-analysis. Eur J Pain. Jul 2020;24(6):1023-1044.

Strand N, et al. Evidence-based clinical guidelines from the American Society of Pain and Neuroscience for the use of implantable peripheral nerve stimulation in the treatment of chronic pain. Journal of Pain Research. 2022 Aug;15:2483-2504.

Weiner DK, et al. Efficacy of percutaneous electrical nerve stimulation and therapeutic exercise for older adults with chronic low back pain: a randomized controlled trial. Pain. 2008 Nov;140(2):344-357.

White PF, et al. Percutaneous Neuromodulation therapy: does the location of electrical stimulation effect the acute analgesic response? Anesth Analg. 2000 Oct;91:949-954.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD-Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (160.7.1) [accessed 2026 Mar 16]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 7/26

Revised:

Reviewed:

Date	Summary of Changes

8/1/2026	• New policy in conjunction with other new policies 1.01.58, 1.01.59, 1.01.61, & 1.01.62, which will replace Neuromuscular/Functional Electrical Stimulation policy 1370/20.000073 which is being made obsolete.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

MEDICAL POLICY

Medical Policy Title	**Implantable Bone Conduction Hearing Aids**
Policy Number	**7.01.77**
Current Effective Date	**January 1, 2026**
Next Review Date	**April 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

This policy addresses implantable bone conduction hearing aids only. It does not address middle ear implants (partial or full) (e.g., Maxum System, Vibrant Soundbridge, or Esteem Implanted Hearing System) or nonsurgical bone-conduction hearing aids (e.g., Baha Headband, Baha Softband).

POLICY STATEMENT(S)

I. When used according to U.S. Food and Drug Administration (FDA) labeled indications, unilateral or bilateral implantable bone conduction (bone-anchored) hearing aid(s) are **medically appropriate** as an alternative to an air-conduction hearing aid when **ALL** of the following criteria are met:

   A. Individual is five (5) years of age or older;

   B. Individual has conductive or mixed-hearing loss;

   C. Speech discrimination scores are at least 60% at elevated sound pressure levels during standardized tests;

   D. A pure-tone average (PTA) bone-conduction threshold (measured at 0.5, 1, 2, and 3 kilohertz [kHz]) up to 70 decibels (dB) in the affected ear; **and**

   E. **ONE** of the following conditions are present:

      1. Congenital or surgically induced malformations (e.g., atresia) of the external ear canal or middle ear;

      2. Chronic external otitis or otitis media (e.g., recurring, or persistent infection or inflammation that precludes the wearing of a conventional air conduction hearing aid); **or**

      3. Other acquired malformations of the middle or external ear canals that preclude the wearing of a conventional air conduction hearing aid (e.g., tumor of the external canal or tympanic cavity, dermatitis of the external canal).

II. When used according to FDA labeled indications, implantable bone conduction (bone-anchored) hearing aids are **medically appropriate** as an alternative to an air-conduction contralateral routing of signal (CROS) hearing aid when **BOTH** of the following criteria are met:

A. Individual is five (5) years of age or older; **and**

B. Individual has single-sided sensorineural deafness in one ear and normal hearing in the contralateral ear.

III. Implantable bone conduction (bone-anchored) hearing aids are **not medically necessary** for individuals with **ANY** of the following contraindications:

A. Individual is under five (5) years of age;

B. Individual has insufficient bone volume and bone quality to support successful implant placement;

C. Individuals who are unable, and have no caregiver who is able, to perform the hygienic activities necessary to maintain the abutment/skin interface of the bone conduction hearing aid.

IV. All other uses of bone conduction (bone-anchored) hearing aids (e.g., use in patients with bilateral sensorineural hearing loss) are **investigational**.

Device Repair

V. Repair of a medically necessary bone conduction hearing aid or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** of the following:

1. date of device implantation/initiation;
2. manufacturer warranty information, if applicable;
3. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device;

B. The device is no longer functioning adequately; and **BOTH** of the following criteria are met:

1. inadequate function interferes with activities of daily living; **and**
2. repair is expected to make the equipment fully functional (as defined by manufacturer).

C. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

Device Replacement

VI. Replacement of a medically necessary bone conduction hearing aid or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

A. The device is no longer functioning adequately and has been determined to be non-repairable or the cost of the repair is in excess of the replacement cost;

B. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

VII. The replacement of a properly functioning bone conduction hearing aid, its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing;

VIII. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

IX. Accessories or components for bone conduction hearing aids that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

7.01.26 Cochlear Implants and Auditory Brainstem Implants

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Coverage for implantable bone conduction (bone-anchored) hearing aids, is provided under the member's prosthetic benefit.

DESCRIPTION

The American Speech-Language-Hearing Association (ASHA, n.d.) defines hearing loss (HL) within its practice portal available from: Hearing Loss in Adults [accessed 2026 Mar 02].

HL refers to an audiologic diagnosis of hearing thresholds outside the range of typical hearing, and can be described by variation in type, degree, and configuration. The three basic types of HL are:

- Sensorineural hearing loss (SNHL): cochlear (sensory) or vestibulocochlear nerve/CN VIII (neural) auditory dysfunction.
- Conductive hearing loss: a problem conducting sound waves through the outer ear canal, tympanic membrane, or middle ear (ossicles).
- Mixed hearing loss is the result of damage to conductive pathways of the outer or middle ear and to the nerves or sensory hair cells of the inner ear.

HL can be bilateral or unilateral, symmetrical (degree and configuration of HL are the same in each ear) or asymmetrical, progressive, or sudden in onset, fluctuating or stable, and present at birth or acquired. The degree of HL refers to level of severity, and is measured in decibels in hearing level, or dB HL. The degree of HL can have significant implications for an individual (e.g., limiting the ability to

understand speech in background noise, decreasing the enjoyment of music, impacting overall quality of life).

The most widely accepted degree of hearing loss system in the audiology field (ASHA, n.d.) defines HL severity levels as the following:

- Normal: -10 to 15 dB HL
- Slight: 16 to 25 dB HL
- Mild: 26 to 40 dB HL
- Moderate: 41 to 55 dB HL
- Moderately severe: 56 to 70 dB HL
- Severe: 71 to 90 dB HL
- Profound: ≥ 91 dB HL

The World Health Organization (2024) identifies several causes of HL that span across the lifespan, and often occur during critical periods of life, including the following:

Prenatal Period

- Genetic factors including hereditary and non-hereditary HL
- Intrauterine infections, such as rubella and cytomegalovirus infection

Perinatal Period

- Birth asphyxia
- Hyperbilirubinemia
- Low-birth weight
- Other perinatal morbidities and their management

Childhood and Adolescence

- Chronic suppurative otitis media
- Chronic nonsuppurative otitis media
- Meningitis and other infections

Adulthood and Older Age

- Chronic diseases
- Smoking
- Otosclerosis
- Age-related sensorineural degeneration
- Sudden SNHL

Factors Across the Life Span

- Cerumen impaction

- Trauma to the ear or head
- Loud noise/loud sounds
- Ototoxic medicines
- Work related ototoxic chemicals
- Nutritional deficiencies
- Viral infections and other ear conditions
- Delayed onset or progressive genetic HL

Technologies for the treatment of HL are dependent on the cause and severity and include hearing aids (external or implanted), cochlear implants, and middle ear implants.

Conventional external hearing aids are subdivided into air conduction hearing aids and bone conduction hearing aids. Air conduction hearing aids require the use of ear molds, which may be problematic in patients with chronic middle ear and ear canal infections, atresia of the external canal, or an ear canal that cannot accommodate an ear mold. In these patients, bone conduction hearing aids may be an alternative.

Bone conduction devices for hearing were first utilized in the early 1900's with the invention of the carbon microphone. The devices were made to convert sound into a mechanical signal that vibrated the mastoid bone. They were held in place with a headband or eyeglasses, were cumbersome, inefficient for sound transmission, however, were found to be beneficial. Modern bone-anchored hearing aids (BAHA) are osseointegrated bone conduction prostheses, meaning they are surgically implanted into the temporal bone.

A BAHA combines a sound processor with a small titanium fixture implanted into the bone behind the ear. The sound processor is connected to the implant and abutment by means of coupling. The device is placed on the deaf side behind the ear and transmits sound through bone conduction, stimulating the cochlea from the normal hearing ear. Bahas are classified as percutaneous and transcutaneous devices dependent on whether or not the abutment penetrates the skin.

Several implantable BAHAs have been developed and are available to treat patients with conductive or mixed hearing loss, including the following:

A percutaneous or direct-drive is a device coupled to the skull bone by a skin-penetrating abutment (e.g., Baha device and Ponto system).

A transcutaneous or transcutaneous passive or skin-driven BAHA device is coupled with an implanted subcutaneous magnet (Sophono device and Baha Attract).

An active transcutaneous device is a system with an implanted actuator, which communicates wirelessly with the external sound processor over the skin by an inductive link using radiofrequency transmission (e.g., Bonebridge or Osia device) (Maier 2022).

According to the American Speech-Language-Hearing Association (ASHA), a pure tone average (PTA) air conduction hearing threshold (measured at 0.5, 1, 2, and 3 kHz) of 71 - 90 dbHL (dB HL) is considered a severe hearing loss, and above 90 is considered a profound hearing loss. A normal

hearing range is up to 15 dB HL (ASHA, n.d.).

SUPPORTIVE LITERATURE

Published data have suggested that the BAHA device is associated with improved hearing outcomes compared to external bone conduction hearing aids, and equivalent outcomes compared to a conventional air conduction hearing aid.

Gawecki et al (2022) performed a small, randomized study that compared patients who received the Osia system (n=4) or the Baha Attract system (n=4) for bilateral mixed hearing loss. After implantation, the mean gain in PTA was 42.8 ± 4.9 dB in the Osia group and 38.8 ± 8.5 dB in the BAHA group. Patient ratings of hearing quality were better in the Osia group based on subjective Likert scores of sound loudness, sound distinctness, and hearing of own voice. Patient reported voice quality scores for reverberation were similar in the Osia and BAHA groups. Both groups reported improved quality of life based on global Abbreviated Profile of Hearing Aid Benefit scores but there was a numerically larger improvement in the Osia group. Results for the Speech, Spatial and Qualities of Hearing Scale improved in both groups and were slightly better in the BAHA group. The authors concluded that larger studies with longer follow-up are needed to evaluate differences in outcomes between these 2 systems.

Kim et al (2022) compared the effects of the Osia system with the Baha Attract and Bonebridge systems in 67 patients with conductive hearing loss (CHL) or mixed hearing loss (MHL) or single-sided deafness (SSD). Patients who received the Osia system (n=17) were prospectively recruited and retrospectively compared with patients who received the Baha Attract or Bonebridge systems (n=50). Effective gains in bone conduction threshold at 2 kHz were 11.1 ± 14.9 dB in the Osia group compared to -2.7 ± 12.6 dB in the Baha Attract and Bonebridge group (combined) among patients with CHL or mixed hearing loss (p=.01). Among patients with SSD, average functional gains at 4 kHz were 37.5 ± 8.9 dB in the Osia group, 21.7 ± 15.7 dB in the BAHA Attract group, and 29.0 ± 13.0 dB in the Bonebridge group.

Schwab et al (2020) completed a systematic review of adverse events associated with bone-conduction and middle-ear implants. The ten most frequently reported adverse events for bone conduction hearing implants included skin reactions (Holgers grade 1 to 3), skin revision surgery due to overgrowth or cellulitis, minor soft tissue/skin overgrowth, skin infection, surgical revision, preimplantation, failure to osseointegrate, and minor skin complications.

Verheij et al (2016) published a systematic review on complications of tissue preservation surgical techniques with percutaneous BAHA devices, including 18 studies with 381 devices. The implantation techniques reported in the studies were as follows: punch method, four studies (81 implants); linear incision technique without soft tissue reduction, 13 studies (288 implants); and Weber technique, one study (12 implants). Indications for surgery were SSD (n=68), sensorineural hearing loss (n=4), mixed hearing loss (n=65), or CHL (n=66). The Holgers classification was used to grade soft tissue reactions (grade 0, no reaction; grade 2, red and moist tissue; grade 3, granulation tissue; grade 4, removal of skin-penetrating implant necessary due to infection). The incidence of Holgers 3 was 2.5% with the punch technique, 5.9% with the linear incision technique, and 0% with the Weber

technique. Holgers 4 was reported in one patient implanted with the linear incision technique.

Dimitriadis et al (2016) reported a systematic review of observational studies of the BAHA Attract device, including 10 studies (total N=89 patients; range, 1-27 patients). Seventeen (19%) of the patients were children, of whom five had unilateral sensorineural hearing loss and four had CHL. Of the 27 (45%) adults, 22 had unilateral sensorineural hearing loss and 11 (18%) had bilateral mixed hearing loss. Audiologic and functional outcome measures and the timing of testing varied greatly in the studies. Summary measures were not reported. In general, audiologic and functional outcomes measured pre- and post-implantation showed improvement, although statistical comparisons were lacking in some studies.

Use of bilateral devices has been evaluated in patients with conductive or mixed hearing losses. A number of studies, published over several years, have demonstrated a consistent improvement in speech recognition in noise and in sound localization with bilateral devices.

PROFESSIONAL GUIDELINE(S)

In 2021, the American Academy of Otolaryngology - Head and Neck Surgery revised the position statement on bone conduction hearing devices (BCHD), indicating the devices are appropriate, and in some cases preferred for the treatment of conductive and mixed hearing loss. BCHD may also be indicated in select patients with single-sided deafness. BCHDs include semi-implantable bone conduction devices utilizing either a percutaneous or transcutaneous attachment, as well as bone conduction oral appliances and scalp-worn devices. The recommendation for BCHD should be determined by a qualified otolaryngology-head and neck surgeon. These devices are approved by the Food and Drug Administration (FDA) for these indications, and their use should adhere to the restrictions and guidelines specified by the appropriate governing agency, such as the FDA in the United States and the respective regulatory agencies in countries other than the United States.

REGULATORY STATUS

BAHAs have received U.S. Food and Drug Administration (FDA) clearance as Class II devices. The following table is provided for convenience and may not be all inclusive. Visit Devices@fda.gov for updates and device specific indications regarding age and degree of HL. Additionally, the FDA maintains a list of recent device recalls. [accessed 2026 Feb 16] Available from: Medical Device Safety | FDA.

Implantable Bone-Conduction Hearing Systems			
Device	**Manufacturer**	**Date Cleared**	**510(k) No.**
Baha 7 Sound Processor	Cochlear Americas	May 2025	K250215
Baha 6 System	Cochlear Americas	Sept 2021	K212136

BA310 Abutment, BIA310 Implant/Abutment	Cochlear Americas	Dec 2018	K182116
Baha 5 Power Sound Processor	Cochlear Americas	May 2016	K161123
Baha 5 Superpower Sound Processor	Cochlear Americas	Mar 2016	K153245
Baha 5 Sound Processor	Cochlear Americas	Mar 2015	K142907
Baha Attract System	Cochlear Americas	Nov 2013	K131240
Baha Cordelle II	Cochlear Americas	Jul 2015 Apr 2008	K150751 K080363
Baha Divino	Cochlear Americas	Aug 2004	K042017
Baha Intenso (digital signal processing)	Cochlear Americas	Aug 2008	K081606
Baha 4 (upgraded from the BP100)	Cochlear Americas	Sep 2013	K132278
Cochlear Osia 2 System	Cochlear Americas	Dec 2019	K191921
OBC Bone-Anchored Hearing Aid System	Oticon Medical	Nov 2011	K112053
Ponto Bone-Anchored Hearing System	Oticon Medical	Sep 2012	K121228
Ponto 5 SuperPower	Oticon Medical	Dec 2021	K213733
Ponto 4	Oticon Medical	May 2019	K190540
Ponto 3, Ponto 3 Power, Ponto 3 SuperPower	Oticon Medical	Sep 2016	K161671
Sentio System	Oticon	July 2024	K240614
Bonebridge	MED-EL	Mar 2019	K183373
Otomag Bone-Conduction Hearing System	Medtronic (Formerly Sophono)	Nov 2013	K132189

Cochlear Baha 4 Sound Processor	Cochlear Americas	Oct 2012	K121317
Ponto 3, Ponto 3 Power, Ponto 3 SuperPower	Cochlear Americas	Sep 2016	K161671

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
69710	Implantation or replacement of electromagnetic bone conduction hearing device in temporal bone
69711	Removal or repair of electromagnetic bone conduction hearing device in temporal bone
69714	Implantation, osseointegrated implant, skull; with percutaneous attachment to external speech processor
69716	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or resulting in removal of less than 100 sq mm surface area of bone deep to the outer cranial cortex
69717	Replacement (including removal of existing device), osseointegrated implant; skull; with percutaneous attachment to external speech processor
69719	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex
69726	Removal, entire osseointegrated implant, skull; with percutaneous attachment to external speech processor

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Code	Description
69727	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, within the mastoid and/or involving a bony defect less than 100 sq mm surface area of bone deep to the outer cranial cortex
69728	Removal, entire osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
69729	Implantation, osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside of the mastoid and resulting in removal of greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
69730	Replacement (including removal of existing device), osseointegrated implant, skull; with magnetic transcutaneous attachment to external speech processor, outside the mastoid and involving a bony defect greater than or equal to 100 sq mm surface area of bone deep to the outer cranial cortex
92622	Diagnostic analysis, programming, and verification of an auditory osseointegrated sound processor, any type; first 60 minutes
92623	each additional 15 minutes (List separately in addition to code for primary procedure)

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HCPCS Codes

Code	Description
L8690	Auditory osseointegrated device, includes all internal and external components
L8691	Auditory osseointegrated device, external sound processor, excludes transducer/actuator, replacement only, each
L8693	Auditory osseointegrated device, abutment, any length, replacement only
L8694	Auditory osseointegrated device, transducer/actuator, replacement only, each

ICD10 Codes

Code	Description
H60.391-H60.399	Other infective otitis externa (code range)
H60.60 - H60.93	Other or unspecified otitis externa (code range)
H61.391 - H61.399	Other acquired stenosis of external ear canal (code range)
H62.8x1 - H62.8x9	Other disorders of external ear in diseases classified elsewhere (code range)
H65.20 - H65.499	Chronic otitis media (code range)
H66.001 - H66.019	Acute suppurative otitis media with or without spontaneous rupture of ear drum (code range)
H66.10 - H66.43	Suppurative otitis media (code range)
H66.90 - H66.93	Otitis media, unspecified (code range)
H67.1 - H67.9	Otitis media in diseases classified elsewhere (code range)
H90.0 - H90.2	Conductive hearing loss (code range)
H90.41 - H90.42	Sensorineural hearing loss, unilateral, with unrestricted hearing on the contralateral side
H90.6 - H90.8	Mixed conductive and sensorineural hearing loss
Q16.1	Congenital absence, atresia, and stricture of auditory canal (external)
Q16.3	Congenital malformation of ear ossicles
Q16.4	Other congenital malformations of middle ear

REFERENCES

American Academy of Otolaryngology – Head and Neck Surgery [Internet]. Position Statement: bone conduction hearing devices. Drafted 2016. [revised 2021 Apr 13; accessed 2026 Mar 03]. Available from: https://www.entnet.org/resource/position-statement-bone-conduction-hearing-devices/

American Speech-Language-Hearing Association (ASHA) [Internet]. Clinical topics: cochlear implants, hearing loss adults, and hearing loss in childhood. [accessed 2026 Mar 03]. Available from: https://www.asha.org/practice-portal/clinical-topics/

American Speech-Language-Hearing Association (ASHA) [Internet]. The audiogram. [accessed 2026 Mar 03]. Available from: https://www.asha.org/public/hearing/Audiogram/

Carnevale C, et al. Bonebridge bone conduction implant. Hearing outcomes and quality of life in patients with conductive/mixed hearing loss. Eur Arch Otorhinolaryngol. 2022 Sep 05. PMID 36063211

Dimitriadis PA, et al. Three-year experience with the cochlear BAHA attract implant: a systematic review of the literature. BMC Ear Nose Throat Disord. 2016;16:12.

Ellsperman SE, et al. Review of Bone Conduction Hearing Devices. Audiol Res. 2021 May 18;11(2):207-219.

Gawecki W, et al. The evaluation of a surgery and the short-term benefits of a new active bone conduction hearing implant-the Osia. Braz J Otorhinolaryngol. 2022 May-Jun;88(3):289-295.

Goldstein MR, et al. Early Osia 2 bone conduction hearing implant experience: Nationwide controlled-market release data and single-center outcomes. Am J Otolaryngol. 2021 Jan-Feb;42(1):102828.

Hampton T, et al. Association of bone conduction devices for single sided sensorineural deafness with quality of life: a systematic review and meta-analysis. JAMA Otolaryngol Head Neck Surg. 2022 Jan 1;148(1)35-42.

Heath E, et al. The outcomes of bilateral bone conduction hearing devices (BCHD) implantation in the treatment of hearing loss: A systematic review. Cochlear Implants Int. 2022 Mar;23(2):95-108. PMID 34852723

Kim Y, et al. A comparative study of audiological outcomes and compliance between the Osia system and other bone conduction hearing implants. Eur Arch Otorhinolaryngol. 2023 May;280(5):2217-2224. Epub 2022 Nov 01. PMID 36318324

Kruyt IJ, et al. The efficacy of bone-anchored hearing implant surgery in children: A systematic review. Int J Pediatr Otorhinolaryngol. 2020 Jan 28;132:109906.

Lin J, et al. Application of implantable hearing aids and bone conduction implant system in patients with bilateral congenital deformation of the external and middle ear. Int J Pediatr Otorhinolaryngol. 2019 Apr;119:89-95.

Maier H, et al. Consensus Statement on Bone Conduction Devices and Active Middle Ear Implants in Conductive and Mixed Hearing Loss. Otology & Neurotology. 2022 Jun;43(5):513-529.

Ontario Health (Quality) [Internet]. Implantable devices for single-sided deafness and conductive or

mixed hearing loss: a health technology assessment. 2020 Mar. [accessed 2026 Mar 05]. Available from: https://www.hqontario.ca/evidence-to-improve-care/health-technology-assessment/reviews-and-recommendations/implantable-devices-for-single-sided-deafness-and-conductive-or-mixed-hearing-loss

Peters JPM, et al. Short-term outcomes of cochlear implantation for single-sided deafness compared to bone conduction devices and contralateral routing of sound hearing aids-results of a randomized controlled trial (CINGLE-trial). PLoS One. 2021;Oct 13;16(10).

Pla-Gil I, et al., Clinical performance assessment of a new active osseointegrated implant system in mixed hearing loss: results from a prospective clinical investigation. Otol Neurotol. 2021;42:1-6.

Sanchez-Perez J, et al. Osseointegrated bone-conducting hearing protheses. StatPearls [Internet]. [updated 2023 Apr 03; accessed 2026 Mar 05]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK564385/

Schwab B, et al. Adverse events associated with bone-conduction and middle-ear implants: a systematic review. Eur Arch Otorhinolaryngol. 2020 Feb;277(2):423-438. PMID 31749056

U.S. Food & Drug Administration. 510(k) premarket notification. Search database. [updated 2025 Feb 17; accessed 2026 Mar 05]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

Verheij E, et al. A systematic review on complications of tissue preservation surgical techniques in percutaneous bone conduction hearing devices. Otol Neurotol. Aug 2016;37(7):829-837. PMID 27273402

SEARCH TERMS

Unilateral percutaneous bone anchored hearing device (unilateral and bilateral), transcutaneous bone conduction hearing device (unilateral and bilateral).

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Implantable bone conduction hearing aids are not addressed in National or Regional Medicare coverage determinations or policies.

However, osseointegrated hearing aids are addressed under Chapter 16, Section 100 of the Medicare Benefit Policy Manual. Please refer to the following website for Medicare Members [updated 2014 Nov 06; accessed 2026 Feb 16]. Available from: Medicare Benefit Policy Manual- Chapter 16: General Exclusions from Coverage

PRODUCT DISCLAIMER

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- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New:03/10 **Revised**:03/11, 09/11, 9/13, 03/14, 9/16, 03/17, 01/18, 03/19, 11/19, 3/21, 3/22, 1/23, 3/25, 11/25 **Reviewed:** 03/12, 03/13, 03/15, 03/16, 03/18, 3/20, 3/23, 3/24, 7/26	
Date	**Summary of Changes**
7/1/2026	Annual review; policy intent unchanged.
1/1/2026	Transitioned Bone Anchored Hearing Aid (BAHA)/Auditory Osseointegrated Device policy, 1370/20.000466 to Lifetime Healthcare Companies policy template.
3/1/2025	No changes to criteria. Removed examples of the types of models available as some are no longer available and listed models are not all inclusive.
1/1/2023	Added the following to the procedure codes section: 69716, 69717, 69719, 69726, 69727, 69728, 69729, and 69730.
3/1/2022	Removed deleted code 69715 (deleted code effective 1/1/2022).
7/1/2021	Removed Small Group Individual Plans from the Product Variations section.
1/1/2020	Added coverage criteria for Small Group Individual Plans to CDPHP Product Variations section.

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Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to healthcare practitioners how to provide appropriate healthcare to their patients. Healthcare practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing healthcare services. CDPHP reserves the right to review this policy at any time and change it without notice.

Policy Guidelines

Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, and imaging.

Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition.

Dose and frequency should be in accordance with the FDA label or recognized compendia (for off label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.

Supportive documentation of previous drug use must be submitted for any criterion that requires the trial of a preferred agent if the preferred drug is not found in claims history.

Dose and frequency should be in accordance with the FDA label or recognized compendia (for off label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.

Summary

Inborn errors of metabolism (IEMs) comprise a wide array of genetic diseases including disorders of protein, carbohydrate, and fat metabolism, lysosomal storage disorders, fatty acid oxidation defects, and mitochondrial and peroxisomal disorders. Although errors of metabolism are more common in infancy and childhood, presentation can occur at any time, even in adulthood. In many of the disorders, problems arise secondary to the accumulation of substances which are toxic or interfere with normal functions of the body. Or patients are unable to synthesize essential compounds necessary for adequate growth and maintenance of health. Enzyme replacement has become a beneficial treatment strategy for many of these previously untreatable disorders. IEMs are often treated with FDA approved replacement enzymes that may be designated as orphan drugs or investigational agents. Prompt institution of therapy is important because delay in the recognition and treatment of IEMs may result in long-term neurologic impairment or even death. Drug therapies to treat various rare diseases due to genetic mutations are also included within this policy.

Effective Date of Policy:	10/8/2026

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy

Indication	Inclusion Criteria	Recommended Dosing Regimen
Avlayah (tividenofusp alfa-eknm) **Medical Benefit** Treatment of neurologic manifestations of Hunter syndrome (Mucopolysaccharidosis type II, MPS II) when initiated in presymptomatic or symptomatic pediatric patients weighing at	**Initial: 6 month approval** 1. Patient must be followed by a physician experienced in metabolic disorders, AND 2. Must have a diagnosis of neuronopathic (severe) Hunter Syndrome (mucopolysaccharidosis [MPS] II) confirmed by: a. Enzyme and molecular testing i. Biochemical enzyme analysis for iduronate sulfatase deficiency in white blood cells or cultured skin fibroblasts AND ii. Documented pathogenic or likely pathogenic mutation in the iduronate 2-sulfatase (IDS) gene 1. For patients with clinical suspicion of MPS II and at least one IDS variant of uncertain	Week 1 to 4: 3 mg/kg once weekly Week 5 to 8: 7.5 mg/kg once weekly Week 9 and beyond: 15 mg/kg once weekly (maintenance dosage)

least 5 kg prior to advanced neurologic impairment ICD10: E76.1 HCPCS: No specific code yet	significance (VUS) documentation the following must be submitted: a. Biochemical enzyme analysis for iduronate sulfatase deficiency in white blood cells or cultured skin fibroblasts b. Documentation that alternative diagnoses have been excluded, such as other MPS types, based on biochemical enzyme analysis b. Documentation of severe disease, confirmed by meeting at least ONE of the following age-stratified criteria i. Cognitive standard score or developmental quotient (DQ) ≤ 85 on a validated instrument appropriate for the patient's age ii. Documented decline of ≥ 7.5 points in cognitive standard score or DQ on serial testing with the same instrument within the preceding 6-18 months iii. Complete IDS gene deletion, large gene rearrangement, or IDS-IDS2 recombination, which are invariably associated with neuronopathic phenotype iv. Documentation of a sibling's concordant IDS variant AND documented cognitive standard score or DQ ≤ 85 or documented cognitive regression in the sibling v. Elevated CSF heparan sulfate ≥ 4,000 ng/mL by validated LC-MS/MS assay, obtained via lumbar puncture vi. Documentation of a neurodevelopmental assessment by a pediatric neurologist or developmental specialist documenting at least 3 of the following behavioral markers of CNS involvement: sleep disturbance, hyperactivity/impulsivity, aggressive behavior, perseverative chewing, inability to achieve bowel training, inability to achieve bladder training, seizure-like episodes. 3. Must be ≥ 3 months of age and weigh ≥ 5 kg 4. Must have documentation of the following baseline values within the past 30 days: a. Hemoglobin b. Serum creatinine c. Urine or blood glycosaminoglycans (GAG) d. Cognitive ability standard score appropriate for enrollee age: i. Bayley Scales of Infant and Toddler Development (BSID) II or III ii. Nonverbal Index (NVI) of the Kaufman Assessment Battery for Children (KABC)-II iii. Differential Ability Scales (DAS)-II 5. Exclusion criteria: a. Has received gene therapy or stem cell therapy for MPS II b. Documented loss of activity of sulfatases other than IDS, indicating multiple sulfatase deficiency	

	6. If switching from Elaprase (idursulfase): Must have documentation of neuronopathic MPS II with progressive neurological symptoms 7. Avlayah will not be used in combination with other enzyme replacement therapies for MPS II 8. Initial approval will be for 6 months to assess response to treatment and adverse events **Continuation: 6 month approval** **1.** Recertification will require documentation of a reduction of urine or blood glycosaminoglycans (GAG) from baseline AND provider attestation of stable or improved clinical symptoms, such as stable or improved cognitive function Current body weight and requested dose regimen must be submitted for initial review and each recertification request	
Brineura (cerliponase alfa) **Medical Benefit** Slow the loss of ambulation in pediatric patients with neuronal ceroid lipofuscinosis type 2 (CLN2 disease), also known as tripeptidyl peptidase 1 (TPP1) deficiency ICD10: E75.4 HCPCS: J0567	**Initial: 6 month approval** • Enrollee is ≥ 3 years of age • Therapy is prescribed by or in consultation with a provider that specializes in the treatment of neuromuscular disorders and/or late infantile neuronal ceroid lipofuscinosis type 2 (CLN2) disease, also known as tripeptidyl peptidase 1 (TPP1) deficiency and is knowledgeable in intraventricular administration • Enrollee has a diagnosis of late infantile CLN2 disease confirmed by deficient TPP1 enzyme activity (in leukocytes, fibroblasts, or dried blood spots); or detection of two pathogenic mutations in trans in the TPP1/CLN2 gene • Enrollee has a score of ≥ 1 and < 6 on the CLN2 clinical rating scale for motor and language function (see below for CLN2 rating scale) **Continuation: 2 year approval** • Documentation of positive response to therapy defined as no decline or decline of one category decline and a score > 0 o Decline was defined as having an unreversed (sustained) 2 category decline or an unreversed score of 0 in the motor domain of the CLN2 Clinical Rating Scale Brineura is contraindicated in patients with ventriculoperitoneal shunts (used to drain extra fluid around the brain) and those with acute intraventricular access device-related complications (e.g., leakage, device failure, device-related infection). CLN2 Clinical Rating Scale Score | Motor Function 3 | Walks normally 2 | Intermittent falls, clumsiness, obvious instability 1 | No unaided walking OR crawling only 0 | Immobile, mostly bedridden	Recommended Dosing: • Birth to < 6 months: 100 mg every other week • 5 months to < 1 year: 150 mg every other week • 1 year to < 2 years: 200 mg (first 4 doses) every other week followed by 300 mg every other week • 2 years and older: 300 mg every other week
Carbaglu and generic carglumic acid **Rx Benefit** Adjunctive therapy to	**Initial: 1 year approval** • Enrollee must be followed by a physician experienced in metabolic disorders • Enrollee must have a diagnosis of acute or chronic hyperammonemia due to the deficiency of the hepatic enzyme, N-acetylglutamate synthase	Recommended Dosing: • Dosage for acute hyperammonemia is 100-250mg/kg/day. Dose should be divided to 2-4 times per

standard of care for the treatment of acute hyperammonemia due to N-acetylglutamate synthase (NAGS) deficiency Maintenance therapy for the treatment of chronic hyperammonemia due to NAGS deficiency Adjunctive therapy to standard of care for the treatment of acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA) ICD10: E72.2	(NAGs) confirmed via genetic testing or enzyme analysis alone or in combination with laboratory tests specific for this diagnosis including measurement of ammonia, plasma citrulline, plasma arginine, orotic acid • For acute hyperammonemia due to the deficiency of the hepatic enzyme, N-acetylglutamate synthase (NAGs), enrollee must be receiving concomitant ammonia lowering therapies such as alternate pathway medications, hemodialysis, and dietary protein restriction • For acute hyperammonemia due to propionic acidemia or methylmalonic acidemia, enrollee must be receiving standard therapies including a combination of protein restriction, intravenous (IV) glucose, insulin, and/or L-carnitine **Continuation: 2 year approval** • Documentation of normalization of plasma ammonia levels, improvement in any clinical symptoms and stability on the requested therapy • Current body weight and requested dose regimen must be submitted for initial review and each recertification request • All requests for brand Carbaglu (initial and recertification) will require documentation of severe intolerance to generic carglumic acid	day and rounded to the nearest 100 mg (1/2 tablet) • Dosage for maintenance should be targeted for normal plasma ammonia level for age (usually less than 100 mg/kg/day) • Dosage in patients with acute hyperammonemia due to propionic acidemia or methylmalonic acidemia is 150 mg/kg/day for patients ≤ 15 kg and 3.3 g/m^2/day for patients > 15 kg. Divide the daily dosage into two equal doses, round up to the next multiple of 50 mg (i.e., one-quarter of a Carbaglu tablet), and administer doses 12 hours apart
Cerdelga (eliglustat) **Rx Benefit** Long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test ICD10: E75.22	**Initial: 1 year approval** • Enrollee is ≥ 18 years of age • Prescribed by or in consultation with a physician knowledgeable in the management of Gaucher disease • Must have a confirmed diagnosis of Type 1 Gaucher disease (see Diagnosis section below for requirements) o Adults: Type 1 (nonneuronopathic) Gaucher disease confirmed by: ▪ Biochemical assay of glucocerebrosidase activity in white blood cells (WBCs) or skin fibroblasts less than or equal to 30% OR ▪ Genotype mutation of two mutant alleles of the glucocerebrosidase gene AND ▪ Symptomatic manifestations of the disease • Skeletal disease as demonstrated by radiological evidence of joint deterioration, pathological fracture, osteopenia, avascular necrosis, osteosclerosis, marrow infiltration, lytic lesions, or Erlenmeyer flask deformity) OR • Hemoglobin ≤ 11.5 for females and ≤ 12.5 g/dl for males (or 1.0 g/dL below the lower limit of normal for age and sex), platelet count <= 60,000 mm3, spleen > 15 times normal size, liver > 2.5 times normal size o Children: Type 1 (nonneuronopathic): less than 18 years of age with Type 1 Gaucher disease confirmed by: ▪ Biochemical assay of glucocerebrosidase activity in WBC's or skin fibroblasts is less than or equal to 30%. OR	Recommended Dosing: • CYP2D6 EMs or IMs: approved dose is 84 mg orally twice daily • CYP2D6 PMs: approved dose is 84 mg orally once daily • CYP2D6 ultra-rapid metabolizers (URM) and CYP2D6 indeterminate metabolizers are excluded from coverage. o CYP2D6 URMs may not achieve adequate concentrations of CERDELGA to achieve a therapeutic effect o A specific dosage cannot be recommended for those patients whose CYP2D6 indeterminate • The following drug interactions result in contraindication to Cerdelga and will not be covered: o CYP2D6 EMs or IMs taking a strong or

	▪ Genotype mutation of two mutant alleles of the glucocerebrosidase gene AND ▪ Symptomatic manifestations of the disease o Abdominal or bone pain, delayed growth, impaired psychomotor development, fatigue, exertional limitations, marrow infiltration, organomegaly, weakness and cachexia. • Not covered in patients with pre-existing cardiac disease, long QT syndrome, and concomitant use of Class IA and Class III antiarrhythmics, AND • Cerdelga will not be approved in combination with enzyme replacement therapy (taliglucerase alfa, imiglucerase, or velaglucerase alfa) as this is considered investigational, AND • Must be designated as a CYP2D6 extensive metabolizer (EM), intermediate metabolizer (IM), or poor metabolizer (PM) as detected by an FDA-cleared test to determine appropriate dosing **Continuation: 2 year approval** • Enrollee is not on strong or moderate CYP2D6/3A inhibitors which results in contraindications to Cerdelga • Documentation of improvement in any clinical symptoms and stability on the requested therapy	moderate CYP2D6 inhibitor concomitantly with a strong or moderate CYP3A inhibitor. o CYP2D6 IMs or PMs taking a strong CYP3A inhibitor. • Specific dosing information is listed in the Cerdelga package insert.
Cerezyme (imiglucerase) **Medical Benefit** Treatment of adults and pediatric patients 2 years of age and older with Type 1 Gaucher disease that results in one or more of the following conditions: anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly ICD10: E75.22 HCPCS: J1786	**Initial: 2 year approval** • Enrollee is ≥ 2 years of age • Prescribed by or in consultation with a physician knowledgeable in the management of Gaucher disease, AND • Enrollee must have a confirmed diagnosis of Gaucher disease (see Diagnosis section below for requirements), AND o Adults: Type 1 (nonneuronopathic) Gaucher disease confirmed by: ▪ Biochemical assay of glucocerebrosidase activity in white blood cells (WBCs) or skin fibroblasts less than or equal to 30% OR ▪ Genotype mutation of two mutant alleles of the glucocerebrosidase gene AND ▪ Symptomatic manifestations of the disease • Skeletal disease as demonstrated by radiological evidence of joint deterioration, pathological fracture, osteopenia, avascular necrosis, osteosclerosis, marrow infiltration, lytic lesions, or Erlenmeyer flask deformity) OR • Hemoglobin ≤ 11.5 for females and ≤ 12.5 g/dl for males (or 1.0 g/dL below the lower limit of normal for age and sex), platelet count <= 60,000 mm3, spleen > 15 times normal size, liver > 2.5 times normal size o Children Type 1 (nonneuronopathic): less than 18 years of age with Type 1 Gaucher disease confirmed by:	• Recommended Dosing: Based upon disease severity ranges from 2.5 units/kg three times a week to 60 units/kg once every two weeks

	▪ Biochemical assay of glucocerebrosidase activity in WBC's or skin fibroblasts is less than or equal to 30%. OR ▪ Genotype mutation of two mutant alleles of the glucocerebrosidase gene AND ▪ Symptomatic manifestations of the disease: • Abdominal or bone pain, delayed growth, impaired psychomotor development, fatigue, exertional limitations, marrow infiltration, organomegaly, weakness and cachexia o Adults and Children Type III (neuronopathic): Enzyme replacement therapy is considered off label for this diagnosis; however, consideration will be given for the following scenarios in which ERT has been shown to be beneficial for hematological and visceral disease ▪ Individuals with chronic (not acute) neuronopathic Gaucher disease type 3 ▪ Siblings of individuals with chronic neuronopathic Gaucher disease who have proven diagnosis ▪ Individuals with high-risk genotypes: L444P/L444P (c.1448T>C homozygote), D409H/D409H (c.1342G>C homozygote), L444P/D409H (c.1448T>C/c.1342G>C heterozygote) • Cerezyme is administered by intravenous infusion by a healthcare professional and is covered under the medical benefit, AND • All requests for Cerezyme will be required to use Elelyso (taliglucerase alfa) except in the following situation: o Cerezyme (imiglucerase) will be approved for children between age 2 and less than 4 years of age. Requests for Cerezyme as continued therapy for children at 4 years of age or older will be required to use Elelyso or document serious side effects or drug failure to Elelyso, AND • Cerezyme will not be approved in combination with any other enzyme replacement therapy for Gaucher disease • Current body weight and requested dose regimen must be submitted for initial review and each recertification request **Continuation: 2 year approval** • Documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition	
Cholbam (cholic acid) **Rx Benefit** Treatment of bile acid synthesis disorders due to single enzyme defects (SEDs) Adjunctive treatment of peroxisomal disorders	**Initial: 3 months approval** • Enrollee is ≥ 2 years of age • Must have a diagnosis of bile acid synthesis disorder due to single enzyme defect (SED) OR • Must be used as an adjunctive treatment of peroxisomal disorder (PD) including Zellweger spectrum disorders, in patients who show signs and symptoms of liver disease, steatorrhea (fatty stools), or complications from decreased fat-soluble vitamins absorption (A, D, E, K) AND	Recommended Dosing: • Recommended initial dosage is 10 to 15 mg/kg/day (given in 1 or 2 divided doses) using available 50 mg and 250 mg capsules and rounded to the nearest whole capsule strength. • For patients with concomitant familial

(PDs) including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea, or complications from decreased fat-soluble vitamin absorption ICD10: E78.70. E78.79, E71.510	• Diagnosis must be confirmed via gas chromatography-mass spectrometry analysis of the urine, which positively identifies elevated bile acids AND • Must have elevated serum aminotransferases with normal serum gamma glutamyl transferase, AND • Member must be seen by a hepatologist, or gastroenterologist • Current body weight and requested dose regimen must be submitted for initial review and each recertification request • Discontinue Cholbam if liver function does not improve within 3 months of starting treatment, if complete biliary obstruction develops, or if there are persistent clinical or laboratory indicators of worsening liver function or cholestasis; continue to monitor liver function and consider restarting a lower dose when parameters return to baseline **Continuation: 2 year approval** • Continued approval beyond 3 months and recertification every 2 years will require documentation of improved liver function via aminotransferase lowering as well as improvement in any clinical symptoms and stability on the requested therapy	hypertriglyceridemia, the recommended dosage is 11 to 17 mg/kg (given in 1 or 2 divided doses).
Ctexli (chenodiol) **Rx Benefit** Treatment of cerebrotendinous xanthomatosis (CTX) in adults ICD10: E75.5	**Initial: 6 months approval** • Must be 18 years of age or older AND • Must be prescribed by, or in consultation with, a hepatologist, metabolic specialist, or gastroenterologist AND • Must have a diagnosis of cerebrotendinous xanthomatosis (CTX) with genetic testing confirming biallelic pathogenic variants in the CYP27A1 gene AND • Must have documentation of at least ONE of the following parameters (baseline value must be provided and will be used to assess response to therapy): o Elevated blood cholestanol OR o Elevated blood or urine bile alcohol (e.g., 23S-pentol) • Ctexli will not be authorized for treatment of gallstones 6. Ctexli will not be authorized for use in combination with Cholbam, cholestyramine, or colestipol **Continuation: 12 month approval** • Documentation of improvement from baseline (upon initial recertification) and/or maintenance of improvement of either: o Blood cholestanol OR o Blood or urine bile alcohol (e.g., 23S-pentol) Quantity limit: 90 tablets per 30 days	Recommended Dosing: • 250 mg administered orally three times daily
Dojolvi (tripheptanoin oral liquid) **Rx Benefit** Source of calories and fatty acids for the treatment of adult and	**Initial: 6 months approval** • Must be prescribed by, or in consultation with, a metabolic disease specialist knowledgeable in the management of long-chain fatty acid oxidation disorders and their dietary management, AND • Must have a molecularly confirmed long-chain fatty acid oxidation disorder based on at least two of the following (i, ii, and/or iii). Of note, infants with positive newborn screening on dried blood spot analysis are required to have confirmatory testing	Recommended Dosing: • Target daily dose of Dojolvi is up to 35% of the patient's total prescribed daily caloric intake (DCI) divided into at least four doses and administered orally diluted with semi-solid foods,

pediatric patients with molecularly confirmed long-chain fatty acid oxidation disorders (LC-FAOD) ICD10: E71.31	○ i. Molecular genetic testing identifying biallelic pathogenic variants confirming a long-chain fatty acid oxidation disorder (such as in CPT1A, CPT2, ACADVL, HADHA, or HADHB), AND/OR ○ ii. Abnormal acylcarnitine analysis on biochemical testing of plasma, AND/OR ○ iii. Biochemical analysis confirming diminished enzyme activity (such as in cultured skin fibroblasts, muscle, liver, leukocytes), AND • Must have evidence of clinical signs and/or symptoms associated with LC-FAOD such as hypoglycemia, hepatopathy, cardiomyopathy, skeletal myopathy, rhabdomyolysis, exercise intolerance, for example, despite current management such as a low-fat, high-carbohydrate diet; avoidance of fasting and/or the use of a medium-chain triglyceride (MCT) oil, or as noted below in i AND/OR ii: ○ i. Patients who are infants or early childhood (3-5 years old) at the time of the request who were diagnosed via a Newborn Screening program with confirmatory testing will not be required to be symptomatic ○ ii. Plan will consider coverage for asymptomatic children who have a confirmed diagnosis with a positive family history of severe disease, or positive genotype indicating severe form of the disease, AND • Provider must attest/confirm that medium-chain triglyceride (MCT) oil products will be discontinued prior to the start of Dojolv **Initial continuation: 6 month approval** **Subsequent continuation: 1 year approval** • Dojolvi continues to be used as monotherapy [i.e., not in combination with any other medium chain triglyceride (MCT) products] Quantity limit of 500ml per 30 days. Requests for quantities above this limit will be evaluated based on the dosing documentation provided. Documentation of the patient's total prescribed Daily Caloric Intake (DCI) and Target percentage of daily caloric intake prescribed and Target Total Daily Dosage (mL) to be administered must be provided with each review	liquids, or formula or enterally via a silicone or polyurethane feeding tube. • The total daily dosage is determined using the following calculation: ○ Caloric value of DOJOLVI = 8.3 kcal/mL ○ Round the total daily dosage to the nearest whole number Total Daily Dosage (__ mL) = $\frac{DCI(__\ kcal)\ x\ __\%\ Target from\ Dojolvi}{8.3\ \frac{kcal}{mL}\ of\ Dojolvi}$
Elaprase (idursulfase) **Medical Benefit** Patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II) ICD10: E76.1, E76.3 HCPCS: J1743	**Initial: 2 year approval** • Enrollee is ≥ 16 months of age AND • Patient must be followed by a physician experienced in metabolic disorders, AND • Must have a diagnosis of Hunter Syndrome (mucopolysaccharidosis II) confirmed by biochemical enzyme analysis for iduronate sulfatase deficiency in white blood cells or cultured skin fibroblasts AND • Must have an affected 1st degree relative OR • Must have clinical symptoms of the disease such as: progressive coarsening of facial features, short stature, joint stiffness, hepatosplenomegaly, hernias, ivory colored papular skin lesions located on the upper back and/or lateral upper arms and thighs, mental retardation, deafness, cerebral ventricular dilation, mild dysostosis multiplex of bone, hypertrichosis, thickened skin, or Mongolian spots.	Recommended Dosing: 0.5 mg/kg IV infusion once a week

	Continuation: 2 year approval • Documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition Current body weight and requested dose regimen must be submitted for initial review and each recertification request.	
Elelyso (taliglucerase alfa) **Medical Benefit** Treatment of patients 4 years and older with a confirmed diagnosis of Type 1 Gaucher disease ICD10: E75.22 HCPCS: J3060	**Initial: 2 year approval** • Enrollee is ≥ 4 years of age AND • Prescribed by or in consultation with a physician knowledgeable in the management of Gaucher disease, AND • Must have a confirmed diagnosis of Gaucher disease (see Diagnosis section below for requirements), AND o Adults: Type 1 (nonneuronopathic) Gaucher disease confirmed by: ▪ Biochemical assay of glucocerebrosidase activity in white blood cells (WBCs) or skin fibroblasts less than or equal to 30% OR ▪ Genotype mutation of two mutant alleles of the glucocerebrosidase gene AND ▪ Symptomatic manifestations of the disease • Skeletal disease as demonstrated by radiological evidence of joint deterioration, pathological fracture, osteopenia, avascular necrosis, osteosclerosis, marrow infiltration, lytic lesions, or Erlenmeyer flask deformity) OR • Hemoglobin ≤ 11.5 for females and ≤ 12.5 g/dl for males (or 1.0 g/dL below the lower limit of normal for age and sex), platelet count <= 60,000 mm3, spleen > 15 times normal size, liver > 2.5 times normal size o Children Type 1 (nonneuronopathic): less than 18 years of age with Type 1 Gaucher disease confirmed by: ▪ Biochemical assay of glucocerebrosidase activity in WBC's or skin fibroblasts is less than or equal to 30%. OR ▪ Genotype mutation of two mutant alleles of the glucocerebrosidase gene AND ▪ Symptomatic manifestations of the disease • Abdominal or bone pain, delayed growth, impaired psychomotor development, fatigue, exertional limitations, marrow infiltration, organomegaly, weakness and cachexia o Adults and Children Type III (neuronopathic): Enzyme replacement therapy is considered off label for this diagnosis; however, consideration will be given for the following scenarios in which ERT has been shown to be beneficial for hematological and visceral disease ▪ Individuals with chronic (not acute) neuronopathic Gaucher disease type 3	Recommended Dosing: Treatment-naïve Patients 4 Years of Age and Older: 60 units/kg (based on actual body weight) administered every other week

	▪ Siblings of individuals with chronic neuronopathic Gaucher disease who have proven diagnosis ▪ Individuals with high-risk genotypes: L444P/L444P (c.1448T>C homozygote), D409H/D409H (c.1342G>C homozygote), L444P/D409H (c.1448T>C/c.1342G>C heterozygote) ▪ Onset of severe systemic disease at age ≤ 2 years of age • Elelyso is administered by intravenous infusion by a healthcare professional and is covered under the medical benefit, AND • Elelyso will not be approved in combination with any other enzyme replacement therapy for Gaucher disease **Continuation: 2 year approval** • Documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition Current body weight and requested dose regimen must be submitted for initial review and each recertification request.	
Galafold (migalastat) **Rx Benefit** Treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data ICD10: E75.21	**Initial: 1 year approval** • Enrollee is ≥ 18 years of age • Therapy is prescribed by or in consultation with an expert in genetics and management of Fabry disease • Must have a diagnosis of Fabry Disease confirmed as follows: o Male patients: ▪ Enzyme assay test in leukocytes, plasma, fibroblasts, or dried blood spots demonstrating complete deficiency or less than 3% of normal of alpha-galactosidase A (alpha-Gal A) activity (classically affected, hemizygous males) OR ▪ Documented GLA gene mutation by gene sequencing o Female patients: ▪ Documented GLA gene mutation by gene sequencing is required for diagnosis, AND • Must have an amenable GLA gene mutation based on in vitro assay data (see manufacturer prescribing information for amenable GLA variants), AND • Must have clinical symptoms of disease as noted below (except for classically affected males) o Males: Classically affected of any age with complete deficiency or less than 3% of normal alphaGal A) activity treatment should begin treatment at time of diagnosis o Atypically affected Males with residual alpha-Gal A activity (3-35% of normal mean): initiate treatment if significant symptoms (see below) or evidence of progression of organ involvement o Females (all ages): Monitor; institute treatment if significant symptoms (see below) or evidence of progression of organ involvement o Symptoms or physical findings of Fabry disease:	Recommended Dosing: 120 mg orally once every other day at the same time of day on an empty stomach

	▪ Angiokeratomas: characteristic lysosomal disease skin rashes ▪ Hypohidrosis: decreased sweating ▪ Acroparesthesia: neuropathic pain in the hands and feet ▪ Cornea verticillata and characteristic corneal and lenticular opacities ▪ Diarrhea, abdominal pain, nausea, vomiting, flank pain, heat and cold intolerance, vertigo, tinnitus, diplopia, fatigue. ▪ Long term consequences include cardiac disease (including hypertrophic cardiomyopathy), arrhythmias, progressing renal disease (proteinuria to end stage renal disease) and stroke, AND • Must have an estimated glomerular filtration rate (eGFR) of at least 30 mL/min/1.73 m2 **Continuation: 2 year approval** • Documentation of adequate renal function [(eGFR) of at least 30 mL/min/1.73 m2] AND • Enrollee has had positive response to therapy for symptomatic individuals (via lab reports, progress notes documenting improvement in clinical symptoms) AND • Enrollee is stable on the requested regimen Galafold must be used as monotherapy and will NOT be covered in combination with Fabrazyme or Elfabrio. Prior approval for any other Fabry disease specific treatment will be terminated upon approval of Galafold. Quantity limit of 14 capsules per 28 days	
Kanuma (sebelipase alfa) **Medical Benefit** Treatment of patients with a diagnosis of Lysosomal Acid Lipase (LAL) deficiency ICD10: E75.5 HCPCS: J2840	**Initial: 2 year approval** • Patient must be followed by a physician experienced in metabolic disorders, AND • Must have a diagnosis of LAL deficiency confirmed by any combination of the following means: laboratory tests, imaging studies, genetic testing, and highly specific dried blood spot and either a or b: o a. The clinical presentation should display an LDL-C concentration of 4.7 mmol/L or greater (or above the 95th percentile for age and sex). Based on review of family history, if disease is confirmed to be autosomal dominant no further testing is required, OR o b. For individuals with unknown family history or recessive pattern, further evaluation should take place to see if any of the following exist. Individuals with at least 3 of these criteria should be tested by dry blood spot test for LAL activity (CPT code 82657). ▪ ALT levels greater than 1.5 of the upper limits of normal (ULN) ▪ HDL-C levels less than 1.3 mml/L or Body mass index of 30 kg/m^2 or more	Recommended Dosing: • For pediatric and adult patients with LAL deficiency, the recommended starting dose is 1 mg/kg administered intravenously every other week. • For patients with rapidly progressive LAL deficiency presenting within the first 6 months of life, the recommended starting dose is 1 mg/kg administered intravenously once weekly. The dose may be increased up to 3 mg/kg once weekly for patients who do not achieve clinical response with the lower dose.

	▪ Liver biopsy suggestive of microvesicular steatosis o Hepatomegaly **Continuation: 2 year approval** • Documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition Current body weight and requested dose regimen must be submitted for initial review and each recertification request	
Kuvan, Javygtor and generic sapropterin **Rx Benefit** Reduce blood phenylalanine (Phe) levels in adult and pediatric patients one month of age and older with hyperphenylalaninemia (HPA) due to tetrahydrobiopterin-(BH4-) responsive Phenylketonuria (PKU) ICD10: E70.0, E70.1	**Initial: 2 months** • Must be prescribed by a healthcare provider experienced in the management of phenylketonuria (PKU), AND • Must have a diagnosis of PKU with hyperphenylalaninemia (HPA) AND • Must adhere to a phenylalanine (Phe) restricted diet • Current body weight and requested dose regimen must be submitted for initial review • Phe levels should be checked one week after initiation of therapy. If Phe levels do not decrease from baseline on a 10 mg/kg/day dose, the dose may be increased to 20 mg/kg/day. If Phe levels do not decrease by at least 30% from baseline after 2 months, the patient is considered a non-responder and further therapy with sapropterin will not be authorized. • Kuvan/Javygtor/generic sapropterin must be used as monotherapy and will not be approved for use in combination with Palynziq **Continuation: Up to 2 years** • Continuation will require documentation of current body weight, requested dose regimen, continued adherence to Phe restricted diet and stability on requested therapy. • Current body weight and requested dose regimen must be submitted for each request for continuation	Recommended Dosing: FDA approved for adults and children 1 (one) month of age and older. Maximum recommended dose is 20 mg/kg/day
Kygevvi (doxecitine and doxribtimine) **Rx Benefit** Treatment of thymidine kinase 2 deficiency (TK2d) in adult and pediatric patients with symptom onset at ≤ 12 years of age ICD10: E88.40, E88.49, G71.3	**Initial: 6 months** • Must be prescribed by or in consultation with a neurologist or specialist experienced in managing mitochondrial myopathies AND • Must have a diagnosis of thymidine kinase 2 deficiency (TK2d) confirmed by genetic testing that detects variants (biallelic pathogenic or likely pathogenic) in the TK2 gene o For patients with clinical suspicion of TK2d and at least one TK2 variant of uncertain significance (VUS) documentation the following must be submitted: ▪ Muscle biopsy mandatory, demonstrating at least one of: • Mitochondrial DNA (mtDNA) depletion (30% of age-matched controls for infantile/childhood onset; quantitative analysis required) • Multiple mtDNA deletions (for late-onset phenotype) • Ragged red fibers and/or cytochrome c oxidase (COX)-deficient fibers	Recommended Dosing: Refer to prescribing information for weight based dosing depending on stage in titration

- Documentation that alternative diagnoses have been excluded (e.g., other mtDNA maintenance defects: POLG, DGUOK, RRM2B, TYMP) AND
- Must have clinical documentation of initial symptom onset at ≤ 12 years of age, consistent with infantile- or childhood-onset TK2d AND
- Must have documentation of a baseline functional assessment
  - Forced vital capacity (FVC) % predicted
    - An age-appropriate respiratory assessment for infants/young children unable to perform spirometry is acceptable
  - Ventilatory support status (none, non-invasive, invasive; hours per day)
  - Nutritional/feeding status (oral intake, dietary modification, enteral feeding)
  - Body weight and growth parameters (percentiles for pediatric patients)
  - Motor function assessment
    - Ambulatory patients
      - North Star Ambulatory Assessment (NSAA) score (0–34) OR
      - 6-Minute Walk Test (6MWT) distance in meters OR
      - Motor Function Measure (MFM-32 or MFM-20) total score
    - Non-ambulatory patients
      - Hammersmith Functional Motor Scale Expanded (HFMSE) score OR
      - Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND) for infants OR
      - Motor Function Measure (MFM-20) total score
- Baseline liver function tests (ALT, AST, bilirubin) are ≤ 2x upper limit of normal prior to treatment initiation AND
- Exclusion Criteria
  - Predominant encephalopathy as primary clinical manifestation
  - Treatment may be considered if myopathy is the predominant feature with secondary/mild neurological involvement
  - Severe hepatic impairment (Child-Pugh C)

Continuation: 6 month approval

- Recertification will require provider attestation of stable or improved motor, respiratory, or other clinical symptoms

Quantity limits:

- 30 packets/30 days
  - Upon each review and dose escalation request, the allowed quantity will be reviewed in accordance with FDA-approved weight-based dosing, and as such, will be limited to the minimum number of packets to obtain the appropriate daily dose. For pediatric patients, a higher quantity may be allowed based on the patients' predicted growth, on a case-by-case basis.

Loargys (pegzilarginase nbln)
 	
Medical Benefit
 	
Treatment of hyperargininemia in adult and pediatric patients 2 years of age and older with Arginase 1 Deficiency (ARG1-D), in conjunction with dietary protein restriction
 	
ICD10: E72.21
 	
HCPCS: no specific code yet
	Initial: 6 month approval
	• Must be prescribed by or in consultation with a metabolic disease specialist, geneticist, or neurologist experienced in managing urea cycle disorders or inborn errors of metabolism
	• The patient must be ≥ 2 years of age
	• The patient must have a confirmed diagnosis of Arginase 1 Deficiency (ARG1-D) as evidenced by ONE of the following:
	  o Genetic testing identifying biallelic pathogenic or likely pathogenic variants in the ARG1 gene OR
	  o For patients with clinical suspicion of ARG1-D and at least one ARG1 variant of uncertain significance (VUS), documentation of the following must be submitted:
	  ▪ Deficient red blood cell (RBC) arginase 1 enzyme activity
	  ▪ Plasma arginine persistently elevated (≥ 3× upper limit of normal) on at least two separate occasions
	  ▪ Documentation that alternative diagnoses have been excluded (e.g., other urea cycle disorders, HHH syndrome, hereditary spastic paraplegia, cerebral palsy)
	• Must have documentation of concurrent dietary protein restriction with or without arginine-free essential amino acid supplementation
	• Must have plasma arginine > 200 µmol/L documented on at least two separate occasions separated by a minimum of 4 weeks, with prescriber attestation that the patient is adherent to dietary protein restriction.
	  o Values may be obtained at any time prior to the authorization request.
	  o Historical values from the patient's medical record are acceptable
	• Must have documentation of clinical manifestations consistent with ARG1-D on at least one of the following: motor impairment, spasticity, developmental delay, cognitive impairment, or seizures
	  o For patients with genetically confirmed ARG1-D who are pre-symptomatic (e.g., identified through newborn screening), coverage may be considered on a case-by-case basis.
	• Must have documentation of a baseline assessment including all of the following:
	  o Plasma arginine concentration obtained within 30 days prior to the first dose
	  o Spasticity assessment obtained within 60 days prior to the first dose: Modified Ashworth Scale (MAS) score with documentation of affected muscle groups, OR clinical documentation of spasticity severity and distribution
	  o Motor function/mobility assessment obtained within 60 days prior to the first dose:
	  ▪ Ambulatory patients: GMFM-D and/or GMFM-E domain scores, OR 6-Minute Walk Test (6MWT) distance, OR 2-Minute Walk Test (2MWT) distance
	  ▪ Non-ambulatory or limited-mobility patients: GMFCS level AND GMFM total score or applicable domain scores
		See Prescribing Information for Approved Dosage

- Pediatric patients (ages 2-5): Age-appropriate developmental motor assessment (e.g., Bayley Scales) is acceptable if standardized walk tests cannot be performed

Continuation: 12 month approval
Recertification will require all of the following:

1. Documentation of plasma arginine level ≤ 200 µmol/L, obtained within 60 days of recertification request
    a) For patients with plasma arginine > 200 µmol/L but current dose is below maximum (0.2 mg/kg/week), coverage will be continued if both of the following are met:
        - Dose escalation is being pursued per the FDA-approved titration algorithm
        - Plasma arginine has decreased ≥ 30% from pre-treatment baseline
    b) For patients with plasma arginine > 200 µmol/L at maximum dose (0.2 mg/kg/week for ≥ 8 consecutive weeks) AND plasma arginine has decreased ≥ 30% from pre-treatment baseline, coverage will be continued if all of the following are met:
        - Adherence to dosing schedule (infusion/injection administration records)
        - Adherence to dietary protein restriction
        - The provider submits a letter of medical necessity (LOMN) that documents clinical justification for continued treatment
    c) For patients with plasma arginine > 200 µmol/L at maximum dose (0.2 mg/kg/week for ≥ 8 consecutive weeks) AND plasma arginine has not decreased ≥ 30% from pre-treatment baseline AND there is no documented clinical improvement in motor function or spasticity from baseline assessments, continued coverage will not be granted
2. There must be documentation of stable or improved status in at least ONE of the following: motor function (GMFM, 6MWT, 2MWT, or clinical documentation) OR spasticity (MAS score or clinical assessment)
3. Confirmation of continued dietary protein restriction
4. Continued approval (includes recertification) will be for 12 months at a time
    a) Exception: continued approval will be for 6 months if plasma arginine level is > 200 µmol/L and the patient meets for 1a or 1b

Must have documentation of current weight for initial review and each recertification request.

Upon each review and dose escalation request, the allowed quantity will be reviewed in accordance with FDA-approved weight-based dosing, and as such, will be limited to the minimum number of vials to obtain the appropriate weekly dose. For pediatric patients, a higher quantity may be allowed based on the patient's predicted growth, on a case-by-case basis.

Mepsevii (vestronidase alfa-vjbk) **Medical Benefit** Pediatric and adult patients for the treatment of Mucopolysaccharidosis VII (MPS VII, Sly syndrome) ICD10: E76.29 HCPCS: J3397	**Initial: 2 year approval** • Patient must be followed by a physician experienced in metabolic disorders, AND • Must have a diagnosis of MPS VII, Sly Syndrome (mucopolysaccharidosis VII) confirmed by at least one of the following methods (i OR ii): o i. Biochemical enzyme analysis for glucuronidase enzyme deficiency in white blood cells or cultured skin fibroblasts OR o ii. Genetic testing • Must have urinary GAG excretion at least three-fold over the mean normal for age AND • Must have clinical signs of lysosomal storage disease including at least one of the following: enlarged liver and spleen, joint limitations, airway obstruction or pulmonary problems, heart valve abnormalities, and limitation of mobility while still ambulatory **Continuation: 2 year approval** • Documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition Current body weight and requested dose regimen must be submitted for initial review and each recertification request.	Recommended Dosing: 4 mg/kg administered every 2 weeks by intravenous (IV) infusion
Naglazyme (galsulfase) **Medical Benefit** Patients with Mucopolysaccharidosis VI (MPS VI; Maroteaux-Lamy syndrome) ICD10: E76.29 HCPCS: J1458	**Initial: 2 year approval** • Patient must be followed by a physician experienced in metabolic disorders, AND • Must have a diagnosis of Mucopolysaccharidosis IV confirmed by biochemical enzyme analysis for aryl sulfatase B enzyme deficiency or accumulation of dermatan sulfate lysosomal enzyme in cultured fibroblasts or isolated leukocytes, AND • Must have at least one of the following documented symptoms: coarse facial features, enlarged tongue, hepatosplenomegaly, hirsutism, prominent forehead, reduced stature, and/or corneal clouding AND • Documentation of at least one of the following baseline tests: o a. 6-minute walk test (6MWT) OR o b. 3-minute stair-climb test **Continuation: 2 year approval** • Documentation of response to therapy, as evidenced by an improvement or stabilization in one of the above baseline tests Current body weight and requested dose regimen must be submitted for initial review and each recertification request.	Recommended Dosing: 1 mg per kg given intravenously once weekly.
nitisinone capsule, Nityr (nitisinone), Orfadin (nitisinone), and Harliku (nitisinone) **Rx Benefit** Treatment of adult and pediatric patients with hereditary tyrosinemia	**Initial: 1 year approval** A. Request for **nitisinone capsule, Nityr (nitisinone) and Orfadin (nitisinone):** 1. Patient must be followed by a physician experienced in metabolic disorders, **AND** 2. Diagnosis confirmed by presence of succinylacetone in blood, urine, or dried blood spots (DBS), **AND** 3. Clinical features of disease such as: failure to thrive, fever, emesis, diarrhea, epistaxis, melena, developmental delay, hepatosplenomegaly, jaundice, ascites, purpura, clotting abnormalities, rickets, cirrhosis, renal disease/Fanconi syndrome,	Recommended Dosing: Nitisinone capsule, Nityr (nitisinone) and Orfadin (nitisinone): • Initial dose should be 0.5 mg/kg dosed twice daily. Dosage can be increased to 0.75 mg/kg twice daily if succinylacetone is

type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine ICD10: E70.21	neurological crisis. Of note, clinical symptoms may be limited in newborns diagnosed during newborn screening, **AND** 4. Documentation of dietary restriction of tyrosine and phenylalanine is required, **AND** 5. Requests for Orfadin capsules will require documentation of serious side effects or drug failure of the equivalent generic product – nitisinone capsules. 6. Requests for Nityr tablets or Orfadin suspension will require documentation of severe intolerance or drug failure of the *preferred* product generic nitisinone capsules. 7. Current body weight and requested dose regimen must be submitted for initial review B. Request for **Harliku (nitisinone)**: 1. Patient must be at least 18 years of age 2. Must be prescribe by or in consultation with a physician experienced in metabolic disorders 3. Diagnosis of elevated urine homogentisic acid (HGA) with alkaptonuria (AKU) must be confirmed by urinary HGA excretion of at least 4.60 g per day and HGC plasma concentration of at least 3.15 ug/mL at baseline 4. Baseline Schober's test of spinal flexion, functional reach, timed get up and go, and 6MW (ft) and range of motion in the worse hip must be submitted 5. Quantity limit is 30 per 30 days 6. Harliku is only approved to reduce the urine homogentisic acid (HGA) in adult patients with confirmed alkaptonuria (AKU); it will not be approved for any other non-FDA approved diagnoses. Harliku is not interchangeable with other nitisinone products **Continuation: 2 year approval** **Nitisinone capsule, Nityr (nitisinone) and Orfadin (nitisinone):** • Documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition • Current body weight and requested dose regimen must be submitted for each recertification request **Harliku (nitisinone)** • Recertification requires documentation of improvement from baseline(s) described in criterion 4, OR sustained clinical benefits	detectable 1 month after initiation • Maximum dose should not exceed 1mg/kg twice daily Harliku (nitisinone): • one 2 mg tablet once daily
Nulibry (fosdenopterin) **Medical Benefit** Reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A ICD10: E61.5 HCPCS: no specific code	**Initial: 6 month approval** • Prescribed by or in consultation with a provider knowledgeable in the management of molybdenum cofactor deficiency (MoCD) Type A AND • Must have a diagnosis of molybdenum cofactor deficiency Type A confirmed by genetic testing that shows a mutation in the MOCS1 gene **Continuation: 2 year approval** • Recertification will require documentation of a positive clinical response to Nulibry (A positive response to therapy could be measured by urine and blood biomarkers (concentrations of s-sulfocysteine [SSC]), improvements in neurological function, gross motor function, developmental milestones, BMI, etc.)	Recommended Dosing: • 0.9 mg/kg via IV infusion once daily for age ≥ 1 year. • < 1 year: dose based on gestational age and body weight with patients < 37 weeks old given initial dose of 0.4 mg/kg once daily, 0.7 mg/kg once daily at month one and 0.9 mg/kg once daily at month three. • 37 weeks or older the initial dose is 0.55 mg/kg once daily, 0.75 mg/kg once daily

		at month one and 0.9 mg/kg once daily at month three.
Olpruva (sodium phenylbutyrate) **Rx Benefit** Adjunctive therapy to standard of care, which includes dietary management, for the chronic management of adult and pediatric patients weighing 20 kg or greater and with a body surface area (BSA) of 1.2 m2 or greater, with urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS) ICD10: E72.2	**Initial: 1 year approval** • Must have a diagnosis of a urea cycle disorder diagnosed through newborn screening, DNA mutation analysis, enzyme analysis or other specialized testing, AND • Olpruva must be prescribed by physician experienced in the management of Urea Cycle Disorders (UCDs) and seen by a geneticist/metabolic specialist AND a nutritionist, AND • Must be used for a diagnosis of urea cycle disorder involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS) AND • Olpruva must be used with dietary protein restriction, AND **Continuation: 2 year approval** • Documentation of continued dietary protein restriction, improvement in any clinical symptoms and stability on the requested therapy Current body weight and height (or body surface area) and requested dose regimen must be submitted for initial review and each recertification request Olpruva will NOT be approved for the treatment of acute hyperammonemia in patients with Urea Cycle Disorders All requests for Olpruva (initial/recertification) will require documentation of severe intolerance to generic sodium phenylbutyrate AND Pheburane. Quantity limit: • 2G and 3G: 180 packets/30 days (1 kit) • 4G, 5G ,6G, and 6.7G: 270 packets/30 days (1 kit)	Recommended Dosing: • 9.9 –13 g/m2/day orally. Divide the calculated total daily dose into three to six doses. Administer as three to six divided doses and take with food. • Round each individual dose of Olpruva to the nearest available dosage strength. The maximum dosage is 20 grams per day
Palynziq (pegvaliase-pqpz) **Rx Benefit** Reduce blood phenylalanine concentrations in adult and pediatric patients 12 years of age and older with phenylketonuria (PKU) who have uncontrolled blood phenylalanine concentrations greater than 600 micromol/L on existing management ICD10: E70.0, E70.1	**Initial: 1 year approval** • Enrollee is ≥ 12 years of age • Therapy is prescribed by a healthcare provider experienced in the management of PKU • Enrollee has diagnosis of phenylketonuria (PKU) with hyperphenylalanemia (HPA) • Documentation of elevated blood phenylalanine level (> 600 µmol/L) within the past 30 days prior to treatment despite existing management with Kuvan/sapropterin (must be used in combination with dietary restrictions) o For those with an inability to tolerate Kuvan/sapropterin OR those who are non-responders to Kuvan/sapropterin (defined as a decrease in phenylalanine levels of less than 30% from baseline after at least a 2-month trial with maximum dose for patient age), documentation of elevated blood phenylalanine level (> 600 µmol/L) will not be required • Palynziq must be used as monotherapy and will not be approved for use in combination with Kuvan/Javygtor/sapropterin • Quantity limits apply: 2.5 mg = 30/30; 10mg = 30/30; 20 mg = 30/30 **Continuation: 2 year approval**	• Induction: 2.5 mg subcutaneously (SC) once a week for 4 weeks then titrated, based on tolerability and blood phenylalanine concentrations, to maintenance dose of 20 mg SC once a day over at least a 5-week period and continued for at least 24 weeks (refer to FDA approved package literature for dose titration schedule). • After 24 weeks dose may be increased to max of 40 mg SC once a day in patients who have not achieved a response (20% reduction in blood phenylalanine concentration from

	• Documentation of achievement and maintenance of at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration less than or equal to 600 µmol/L once maintenance dose is achieved ○ Coverage will not be continued for patients who have not achieved a response (at least a 20% reduction in blood phenylalanine concentration from pre-treatment baseline or a blood phenylalanine concentration less than or equal to 600 µmol/L) after at least 16 weeks of continuous treatment with the maximum dosage of 60 mg once daily.	pretreatment baseline or a blood phenylalanine concentration ≤ 600 µmol/L). • May increase to 60 mg once daily if blood phenylalanine control has not been achieved after 16 weeks on the 40-mg/day dosage. Discontinue therapy if adequate response is not achieved after 16 weeks of 60 mg once daily: MAX, 60 mg/day

Ravicti (glycerol phenylbutyrate)
 	
Rx Benefit
 	
Chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone.
 	
Ravicti must be used with dietary protein restriction and, in some cases, dietary supplements
 	
ICD10: E72.2
	Initial: 1 year approval
	• Must have a diagnosis of a urea cycle disorder diagnosed through newborn screening, DNA mutation analysis, enzyme analysis or other specialized testing, AND
	• Ravicti must be prescribed by physician experienced in the management of Urea Cycle Disorders (UCDs) and seen by a geneticist/metabolic specialist AND a nutritionist, AND
	• Must be used for a diagnosis of urea cycle disorder that cannot be managed by dietary protein restriction and/or amino acid supplementation alone, AND
	• Ravicti must be used with dietary protein restriction, AND
	• Documentation of severe intolerance to generic sodium phenylbutyrate AND Pheburane
	
	Continuation: 2 year approval
	• Documentation of continued dietary protein restriction, improvement in any clinical symptoms and stability on the requested therapy.
	
	Ravicti will NOT be approved for the treatment of acute hyperammonemia in patients with Urea Cycle Disorders or for treatment of N-acetylglutamate synthase (NAGS) deficiency
	
	Current body weight and height (or body surface area / BSA) and requested dose regimen must be submitted for initial review and each recertification request.
	
	Quantity limit is 525 ml per 30 days
		Recommended Dosing:
		• Recommended initial dosage in Phenylbutyrate-naïve patients is 4.5-11.2 mL/m^2/day (5 to 12.4 g/m2 /day) given in 3 divided dosages via oral syringe or dosing cup, rounded up to the nearest 0.5mL, with a maximum of 17.5 mL/day. Should be taken with food.
		• For patients switching from sodium phenylbutyrate to Ravicti, Patients should receive the same amount of phenylbutyric acid from the sodium phenylbutyrate dose. Calculate the dosage of Ravicti (mL) using the following equation
		  ○ Total daily dosage of Ravicti (mL) = total daily dosage of sodium phenylbutyrate tablets (g) x 0.86
		  ○ Total daily dosage of Ravicti (mL) = total daily dosage of sodium phenylbutyrate powder (g) x 0.81
		• Neurotoxicity: (phenylacetate [PAA], the active moiety of Ravicti, may be toxic). Reduce dosage for symptoms of neurotoxicity

		such as: vomiting, nausea, headache, lightheadedness, somnolence, confusion, sleepiness or worsening of numbness, tingling, or burning in hands or feet are present in the absence of high ammonia or other intercurrent illnesses
Sephience (sepiapterin) **Rx Benefit** Treatment of hyperphenylalaninemia (HPA) in adult and pediatric patients 1 month of age and older with sepiapterin-responsive phenylketonuria (PKU). SEPHIENCE is to be used in conjunction with a phenylalanine (Phe)- restricted diet. ICD10: E70.0, E70.1	**Initial: 2 months** 1. Must be prescribed by a healthcare provider experienced in the management of PKU AND 2. Patient must have a diagnosis of phenylketonuria (PKU) with hyperphenylalaninemia (HPA) AND 3. Patient must adhere to a phenylalanine (Phe) restricted diet AND 4. For the initiation of pharmacologic therapy for PKU, there must be documentation of persistent uncontrolled Phe level ≥ 360 µmol/L on two separate occasions, at least one week apart within a 4-week period, while the patient is clinical stable (e.g., no acute illness or dietary lapse) AND 5. Must have an inadequate response to generic sapropterin (brand Kuvan or Javygtor) prior to initiation of Sephience a. Non-responders defined as a decrease in phenylalanine levels of less than 30% from baseline after at least 2-month trial of sapropterin at the maximum dose for patient age **Continuation: 2 years** • Documentation of current body weight, requested dose regimen, continued adherence to Phe restricted diet and stability on requested therapy • Sephience must be used as monotherapy and will not be approved for use in combination with Kuvan/sapropeptrin or Paylnziq AND • Current body weight and requested dose regimen must be submitted for initial review and each recertification request • Quantity limit of 30 packets per 30 days. o Upon each drug review and dose escalation request, the allowed quantity will be reviewed in accordance with FDA-approved age- and weight-based dosing (see table 1, 2, and 3), and, as such, will be limited to minimum number of packets of each strength to obtain the appropriate daily dose. o 60 mg/kg is the maximum daily dose for all patients. • Phe levels should be checked one week after initiation of therapy. If Phe levels do not decrease by at least 30% from baseline after 2 months, the patient is considered a non-responder and further therapy with Sephience will not be authorized.	Recommended starting dosage of Sephience in pediatric and adult patients: • < 6 months: 7.5 mg/kg/day • 6 months to < 1 year: 15 mg/kg/day • 1 year to < 2 years: 30 mg/kg/day • 2 years and older: 60 mg/kg/day For number of packets and volume to prepare mixtures for specific dosing, refer to the prescribing information
Strensiq (asfotase alfa) **Rx Benefit** treatment of patients with perinatal/ infantile- and juvenile-onset	**Initial: 6 month approval** • Patient must be followed by a physician experienced in metabolic disorders, AND • Must have a diagnosis of perinatal/infantile- or juvenile-onset hypophosphatasia (HPP) with symptom onset at ≤ 12 years of age confirmed by both of the following (i and ii): o i. Total serum ALP below the lower limit of normal for age (based upon laboratory-specific reference ranges).	Recommended Dosing: The recommended initial dose is 2 mg/kg of body weight administered subcutaneously 3 times per week, or 1 mg/kg of body weight administered subcutaneously 6 times per week. The dose may be increased to 3 mg/kg administered

hypophosphatasia (HPP) ICD10: E83.3	▪ If laboratory-specific reference ranges are not available, please refer to Table 1 (below) for ALP reference intervals, AND o ii. The presence of elevated ALP substrate levels [increased serum pyridoxal 5'-phosphate (PLP) or urinary phosphoethanolamine (PEA)] AND 3. • Must have evidence of clinical/radiographic symptoms including: o Skeletal manifestations of HPP by radiographic evidence OR o Presence of systemic complications (e.g., neurological, renal, respiratory, muscular, rheumatologic) OR o Dental manifestations of HPP OR o Family history of siblings or parents with HPP AND • Current body weight and requested dose regimen must be submitted for initial review and each recertification request **Continuation: 6 month approval** • Recertification will require documentation of a positive response to therapy and stability on requested regimen (via lab reports and progress notes documenting improvement in any clinical/radiographic symptoms) Clinical documentation must be submitted with each request and be within the previous 6 months Quantity limit: 1 vial per 28 days for all strength vials (18 mg/0.45 mL, 28 mg/0.7 mL, 40 mg/mL and 80 mg/0.8 mL) Upon each review and dose escalation request, the allowed quantity will be reviewed in accordance with FDA-approved weight-based dosing and, as such, will be limited to the minimum number of vials to obtain the appropriate weekly dose.	subcutaneously 3 times per week for insufficient efficacy in perinatal/infantile-onset HPP.
Sucraid (sacrosidase) **Rx Benefit** Congenital sucrase-isomaltase deficiency	**Initial: 1 year approval** • Patient must be followed by a physician experienced in the treatment of CSID, AND • Must have a diagnosis of congenital sucrase-isomaltose deficiency (CSID) confirmed by Small Bowel Biopsy with Disaccharidase Enzyme Testing (definitive test for diagnosing CSID). o For individuals where invasive procedure is contraindicated, diagnosis can be confirmed by a positive sucrose breath test [carbon-13 (13C) sucrose breath test]. Documentation of this contraindication is required. o A sucrose hydrogen breath test alone is not enough to confirm the diagnosis. The sucrose hydrogen breath test is not specific for identifying CSID since other gastrointestinal conditions can also produce a positive hydrogen breath test. • Treatment will not be authorized as part of a therapeutic trial to confirm diagnosis **Recertification: 2 year approval** • Recertification will require documentation of response to therapy, as evidenced by an improvement or stabilization in one of the above baseline tests	Recommended Dosing: • Sucraid is FDA-approved for patients ≥ 5 months of age • Adult dosage: 17,000 units with each meal or snack • Children weighing > 15 kg: 17,000 taken with each meal or snack • Children weighing 15 kg or less: 8,500 units taken with each meal or snack

Vimizim (elosulfase alfa) **Medical Benefit** Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome) ICD10: E76.210 HCPCS: J1322	**Initial: 1 year approval** • Enrollee is ≥ 5 years of age AND • Patient must be followed by a physician experienced in metabolic disorders, AND • Must have a diagnosis of Morquio A Syndrome (Mucopolysaccharidosis IVA) confirmed by biochemical enzyme analysis for N-acetylgalactosamine-6-sulfate sulfatase (GALNS) activity using fibroblasts or leukocytes AND • Must have at least one of the following documented symptoms: short stature, abnormal gait, genu valgum, spinal abnormalities, chest abnormalities, joint abnormalities, respiratory compromise, cardiac valve abnormalities, muscular weakness, visual impairment, hearing loss, or dental abnormalities and oral health challenges AND • Documentation of at least one of the following baseline tests: o a. 6-minute walk test (6MWT) OR o b. 3-minute stair-climb test **Continuation: 2 year approval** • Recertification will require documentation of response to therapy, as evidenced by an improvement or stabilization in one of the above baseline tests. Current body weight and requested dose regimen must be submitted for initial review and each recertification request	Recommended Dosing: 2 mg/kg given intravenously over a minimum range of 3.5 to 4.5 hours, based on infusion volume, once every week
VPRIV (velaglucerase alfa) **Medical Benefit** Long-term enzyme replacement therapy (ERT) for patients with type 1 Gaucher disease ICD10: E75.22 HCPCS: J3385	**Initial: 1 year approval** • Enrollee is ≥ 4 years of age AND • Prescribed by or in consultation with a physician knowledgeable in the management of Gaucher disease, AND • Must have a confirmed diagnosis of Gaucher disease (see Diagnosis section below for requirements), AND o Adults: Type 1 (nonneuronopathic) Gaucher disease confirmed by: ▪ Biochemical assay of glucocerebrosidase activity in white blood cells (WBCs) or skin fibroblasts less than or equal to 30% OR ▪ Genotype mutation of two mutant alleles of the glucocerebrosidase gene AND ▪ Symptomatic manifestations of the disease • Skeletal disease as demonstrated by radiological evidence of joint deterioration, pathological fracture, osteopenia, avascular necrosis, osteosclerosis, marrow infiltration, lytic lesions, or Erlenmeyer flask deformity) OR • Hemoglobin ≤ 11.5 for females and ≤ 12.5 g/dl for males (or 1.0 g/dL below the lower limit of normal for age and sex), platelet count <= 60,000 mm3, spleen > 15 times normal size, liver > 2.5 times normal size.	Recommended Dosing: • The recommended starting VPRIV dosage in naïve adults and naïve pediatric patients 4 years of age and older is 60 Units/kg administered every other week as a 60-minute intravenous infusion

	○ Children Type 1 (nonneuronopathic): less than 18 years of age with Type 1 Gaucher disease confirmed by: ▪ Biochemical assay of glucocerebrosidase activity in WBC's or skin fibroblasts is less than or equal to 30%. OR ▪ Genotype mutation of two mutant alleles of the glucocerebrosidase gene AND ▪ Symptomatic manifestations of the disease • Abdominal or bone pain, delayed growth, impaired psychomotor development, fatigue, exertional limitations, marrow infiltration, organomegaly, weakness and cachexia. ○ Adults and Children Type III (neuronopathic): Enzyme replacement therapy is considered off label for this diagnosis; however, consideration will be given for the following scenarios in which ERT has been shown to be beneficial for hematological and visceral disease ▪ Individuals with chronic (not acute) neuronopathic Gaucher disease type 3 ▪ Siblings of individuals with chronic neuronopathic Gaucher disease who have proven diagnosis ▪ Individuals with high-risk genotypes: L444P/L444P (c.1448T>C homozygote), D409H/D409H (c.1342G>C homozygote), L444P/D409H (c.1448T>C/c.1342G>C heterozygote) ▪ Onset of severe systemic disease at age ≤ 2 years of age **Continuation: 2 year approval** • Documentation of continued dietary protein restriction, improvement in any clinical symptoms and stability on the requested therapy. Current body weight and requested dose regimen must be submitted for initial review and each recertification request Commercial: Requests for VPRIV, for NEW STARTS, AND EXISTING USERS at the time of recertification, will require documentation of serious side effects or drug failure with Elelyso (taliglucerase alfa)	
Xuriden (uridine triacetate) **Rx Benefit** Adult and pediatric patients for the treatment of hereditary orotic aciduria ICD10: E79.89	**Initial: 6 month approval** • Patient must be followed by a physician experienced in metabolic disorders AND • Diagnosis must be confirmed by: ○ Genetic testing of the UMPS gene OR ○ Urine test that reveals very high amounts of orotic acid, with milder elevations of orotidine. • Must have at least one of the following documented symptoms (prior to treatment with uridine or Xuriden) attributed to the disease: Urinary orotic acid level significantly above the normal range, blood abnormalities (anemia, decreased white blood cell and neutrophil	Recommended Dosing: • Recommended dose for children and adults is 60 mg/kg once a day • Increase to 12 0mg/kg (maximum 8 grams) for insufficient efficacy (e.g., urine orotic acid levels remaining above normal or increasing above the usual/expected range for the patient; lab values

	counts, etc.), urinary tract obstruction, developmental delays, failure to thrive, congenital malformations, and/or immune deficiencies AND • Must have trial and failure to the preferred product: over the counter (OTC) uridine **Continuation: 2 year approval** • Documentation of a positive response to therapy and stability on requested regimen (via lab reports and progress notes) Current body weight and requested dose regimen must be submitted for initial review and each recertification request, AND Maximum daily dose is 8 grams per day according to the FDA approved labeling Quantity limit of 120 packets per 30 days	affected by orotic acid [red or white blood cell indices] worsening; worsening disease signs/symptoms) See FDA approved labeling for 60 mg/kg and 120 mg/kg weight-based dosing tables
Yargesa/ Zavesca / miglustat **Rx Benefit** Treatment of adult patients with mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g., due to allergy, hypersensitivity, or poor venous access) ICD10: E75.22	**Initial: 1 year approval** • Must meet for ONE of the following diagnoses (A OR B): o a. For a diagnosis of Gaucher disease ▪ i. Must be prescribed by or in consultation with a physician knowledgeable in the management of Gaucher disease, AND ▪ ii. Must have a confirmed diagnosis of Type 1 Gaucher disease (see Diagnosis section below for requirements) • a. Adults Type 1 (nonneuronopathic): greater than 18 years of age with Type 1 Gaucher disease confirmed by i (a OR b) AND ii: o i. One of the following: ▪ Biochemical assay of glucocerebrosidase activity in white blood cells (WBCs) or skin fibroblasts less than or equal to 30% OR ▪ Genotype mutation of two mutant alleles of the glucocerebrosidase gene o ii. Symptomatic manifestations of the disease ▪ 1. Skeletal disease as demonstrated by radiological evidence of joint deterioration, pathological fracture, osteopenia, avascular necrosis, osteosclerosis, marrow infiltration, lytic lesions, or Erlenmeyer flask deformity) OR ▪ 2. Hemoglobin ≤ 11.5 for females and ≤ 12.5 g/dl for males (or 1.0 g/dL below the	Recommended dose: 100 mg three times a day

	lower limit of normal for age and sex), platelet count <= 60,000 mm3, spleen > 15 times normal size, liver > 2.5 times normal size. • Children Type 1 (nonneuronopathic): less than 18 years of age with Type 1 Gaucher disease confirmed by i (a OR b) AND ii: o i. One of the following: ▪ Biochemical assay of glucocerebrosidase activity in WBC's or skin fibroblasts is less than or equal to 30%. OR ▪ Genotype mutation of two mutant alleles of the glucocerebrosidase gene o ii. Symptomatic manifestations of the disease ▪ Abdominal or bone pain, delayed growth, impaired psychomotor development, fatigue, exertional limitations, marrow infiltration, organomegaly, weakness and cachexia o For a diagnosis of Niemann-Pick disease type C (NPC) the following criteria must be met: ▪ i. Must be prescribed by or in consultation with a geneticist, neurologist, or metabolic disorder specialist, or a physician who specializes specializing in the treatment of Niemann-Pick disease type C (NPC) AND ▪ ii. Must have a diagnosis of NPC confirmed with documentation biallelic pathogenic variants in either NPC1 or NPC2 identified by molecular genetic testing AND ▪ iii. Must have neurological, psychiatric, and/or cognitive symptoms related to NPC AND ▪ iv. Must provide documentation of disease severity status using an objective measurement scale at baseline (prior to initiating a miglustat product) which will be used to assess clinical response to therapy. (e.g., Niemann-Pick disease type C Clinical Severity Scale (NPCCSS)- 17, rescored 4-domain NPC Clinical Severity Scale (R4DNPCCSS), fSARA) AND **Continuation: 2 year approval** • For a diagnosis of Niemann-Pick disease type C: Enrollee has demonstrated stabilization or improvement based on objective measurement scale provided upon initial approval (criterion iv) Yargesa and Zavesca will not be authorized without documentation of serious	

	side effects or drug failure to the AB rated generic equivalent miglustat AND Yargesa, Zavesca/miglustat is approved for whom enzyme replacement therapy (taliglucerase alfa, imiglucerase, or velaglucerase alfa) is not a therapeutic option due to one or more of the following: allergy, hypersensitivity, or poor venous access AND Yargesa, Zavesca/miglustat will not be approved for use in combination with enzyme replacement therapy (taliglucerase alfa, imiglucerase, or velaglucerase alfa) as this is considered investigational, Quantity limit of 90 capsules per 30 days • For a diagnosis of Gaucher disease, the maximum dose is 100 mg (1 capsule) three times a day • For a diagnosis of NPC, a quantity limit exception may be granted for up to 180 capsules per 30 days, to allow for maximum dose of 200 mg (2 capsules) three times a day	
Zanvastro (zilganersen) **Medical benefit** Treatment of Alexander disease in pediatric and adult patients ICD10: G31.86 HCPCS: J3590 (unclassified)	**Zanvastro for Commercial/Exchange/Essential Plan/Child Health Plus (CHP):** Based on a review of the available peer-reviewed evidence, Zanvastro (zilganersen) is considered not medically necessary for the treatment of Alexander Disease. In the Phase 1-3 study (NCT04849741), zilganersen 50 mg demonstrated a statistically significant stabilization of gait speed on the 10-Meter Walk Test at Week 61, with a least square mean difference of approximately 33.3% vs control (P = .041). Of note, the zilganersen group had a higher mean baseline gait speed of 1.201 vs. 1.053 in the pooled control. The participant population enrolled in the main study had a broad age range, with a mean (SD) age of 12.3 (10.6) and a range of 2.0 to 53.7 years. On the Most Bothersome Symptom (MBS) scale at week 61, 11/19 patients reported no change or worse on zilganersen vs. 14/16 patients in the pooled control. 68.4% of patients reported improvement or no change in the zilganersen group vs. 43.8% in the placebo group. The MBS evaluated the impact of zilganersen on the symptom that each participant considered to be most bothersome at baseline as reported by the participant or caregiver in an interview. On the Patient Global Impression of Change (PGIC) scale that captured change in patient's global health status at week 61 relative to day 1, 66.7% of patients reported no change or worse on zilganersen vs. 94.1% on placebo, demonstrating the majority of patients did not feel a little to much better on therapy. On the Clinician Global Impression of Change scale at week 61 relative to day 1, 79.2% of clinicians reported no change to worse for patients on zilganersen vs. 76.5% on placebo. 54.2% reported no change and 25% a little worse in the zilganersen group vs 23.5% no change, 41.2% a little worse, and 11.8% much worse in the placebo group. Similar to the PGIC, the majority of clinicians did not find patients on therapy to be a little or much better on therapy. Despite observed stabilization in gait, and potential stabilization to modest improvement in symptoms and impression of change, uncertainty regarding clinical benefit remains. Due to the heterogeneous nature of the disease, as a disease-modifying therapy, additional evidence is needed to demonstrate	See Prescribing Information for approved dosing

benefit outside of gait alone.

Alexander disease is an extremely rare, usually progressive and fatal, neurological disorder that affects not only gait and mobility, but also intellectual development, gastrointestinal functioning, autonomic functioning amongst others. Therefore, disease rarity, first-in-indication status, and unmet needs were not considered sufficient to resolve the uncertainty regarding the clinical meaningfulness of the demonstrated incremental benefit.

Reconsiderations of Medical Necessity
This determination will be reevaluated when new evidence materially addresses the uncertainty regarding the clinical meaningfulness of zilganersen's treatment-attributable benefit. Evidence that may support reconsideration includes:

- Replication or confirmation of clinically meaningful responder benefit in an additional adequately designed study
- Demonstration of sustained benefit beyond the currently established 61-week controlled treatment period
- Demonstration of improvement in survival
- Comparative or add-on evidence demonstrating clinically meaningful incremental benefit of comorbid conditions (ex. respiratory and seizure conditions) relative to established therapies

Zanvastro for Medicare Advantage/Medicaid Managed Care (MMC)/Health and Recovery Plans (HARP):

1. Must be prescribed by or in consultation with a neurologist, medical geneticist, or other provider with expertise in the diagnosis and management of Alexander disease or leukodystrophies
2. Must have a diagnosis of Alexander disease confirmed by:
    a. Documented gene heterozygous pathogenic or likely pathogenic variant in GFAP identified by molecular genetic testing, AND
    b. Neuro imaging consistent with a diagnosis of Alexander disease:
        i. Extensive cerebral white matter abnormalities with a frontal preponderance
        ii. Periventricular rim of decreased signal intensity on T2-weighted images and elevated signal intensity on T1-weighted images
        iii. Abnormalities of the basal ganglia and thalami that may include one or both of the following:
            1. Swelling and increased signal intensity on T_2-weighted images
            2. Atrophy and increased/decreased signal intensity on T_2-weighted images
        iv. Brainstem abnormalities, particularly involving the medulla and midbrain
        v. Contrast enhancement of one or more of the following (ventricular lining, periventricular rim, frontal white matter, optic chiasm, basal ganglia, thalamus, fornix, dentate nucleus, and brainstem)
3. Must have one or more clinical manifestations consistent with Alexander disease, including but not limited to developmental delay or regression, seizures, megalencephaly/macrocephaly, motor impairment, pyramidal tract signs or spasticity, gait impairment, ataxia or other cerebellar manifestations, bulbar or pseudobulbar dysfunction (e.g., dysphagia, dysarthria, or dysphonia), feeding difficulties or failure to thrive, recurrent/intractable vomiting, autonomic dysfunction, sleep-disordered breathing, or ocular motor abnormalities

	4. Must not have permanent ventilator dependence 5. Must have documentation of baseline: a. For ambulatory individuals able to complete the assessment: 10-Meter Walk Test (10MWT) b. For individuals for whom the 10MWT is not developmentally or functionally appropriate: Gross Motor Function Measure-88 (GMFM-88) c. Another objective, clinically appropriate measure of the patient's predominant disease manifestation when neither the 10MWT nor GMFM-88 is appropriate. 6. Zanvastro must be administered in accordance with the current FDA-approved prescribing information. 7. Zanvastro will not be authorized for any non-FDA approved indication 8. Initial approval will be for 12 months to assess response to treatment and adverse events a. Continued approval will be for 12 months b. Recertification will require provider attestation that the patient has experienced clinical benefit from treatment, as demonstrated by stability or improvement in an appropriate disease-specific clinical or functional measure (e.g., 10MWT, GMFM-88, or another objective measure appropriate to the patient's predominant manifestations), and that the patient does not have unacceptable treatment-related toxicity.	
Zycubo (copper histidinate) **Medical benefit** Treatment of Menkes disease in pediatric patients. ICD10: E83.09 HCPCS: No specific code yet	• Must be prescribed by, or in consultation with, a pediatric geneticist, pediatric neurologist, or metabolic disease specialist with experience in copper metabolism disorders • Must have a diagnosis of classic Menkes disease as evidenced by BOTH of the following: o Molecular genetic testing report demonstrating pathogenic or likely pathogenic ATP7A variant o A plasma catecholamine analysis (dopamine:norepinephrine ratio and/or DHPAA:DHPG ratio) confirming functional copper deficiency • Must have documentation of biochemically confirmed low serum copper (< 75 mcg/dL) AND low ceruloplasmin (< 20 mg/dL) • Must meet one of the following: o If treatment is initiated within 4 weeks of birth (corrected for prematurity), documentation must be submitted confirming the patient is presymptomatic or minimally symptomatic at the time of treatment initiation OR o If treatment is initiated after 4 weeks but within 6 months of birth (corrected for prematurity), documentation shared decision-making with family acknowledging limited neurodevelopmental benefit expected must be submitted OR o If treatment is initiated after 6 months of birth (corrected for prematurity), there must be attestation that family understands treatment is unlikely to improve neurodevelopment but may extend survival with palliative intent documented. • Baseline requirements o Serum copper and ceruloplasmin o Serum electrolytes (sodium, potassium, phosphorus, bicarbonate) o Kidney function (BUN, creatinine)	See Prescribing Information for approved dosing

	o Liver function (AST, ALT, bilirubin) o Complete blood count o Urinary β2-microglobulin (if available) o Neurodevelopmental assessment (Denver II or equivalent) • Documentation of molecular generic testing report showing the specific ATP7A pathogenic variant, including: o Variant nomenclature (HGVS format, e.g., c.2555C>T, p.Pro852Leu) o Variant classification (pathogenic, likely pathogenic, VUS) o Mutation type (missense, nonsense, frameshift, splice site, deletion, duplication) o Exon/intron location o Inheritance status (inherited vs. de novo) o Laboratory performing the test (CLIA-certified) Reauthorization/Continuation criteria • Absence of treatment-limiting toxicity (or documentation of dose modification) • Laboratory monitoring results demonstrating compliance with FDA schedule o Baseline requirements must be monitored on the following cadence based on age ▪ Age 1 month to ≤ 7 months: Every 6 weeks ▪ Age 7 months to ≤ 24 months: Every 3 months ▪ Age 25 months and up: Every 6 months • Discontinuation o Severe renal tubular toxicity unresponsive to dose reduction ▪ Persistent non-anion gap metabolic acidosis, severe electrolyte wasting requiring hospitalization, progressive renal insufficiency o Severe hepatotoxicity ▪ ALT/AST > 10× ULN, evidence of hepatic synthetic dysfunction, clinical hepatitis o Severe hematologic toxicity ▪ Transfusion-dependent anemia, pancytopenia o No biochemical response ▪ Serum copper remains < 50 mcg/dL despite compliant dosing o Progressive neurological decline despite treatment ▪ Loss of previously acquired milestones, intractable seizures, vegetative state Quantity Limit: 30 vials/30 days	

Appendix

Functional Scale for the Assessment and Rating of Ataxia (fSARA)

SARA Domain	Item	Modified Domain Score*
Domain 1: Gait	Normal, no difficulties in walking, turning, and walking tandem (up to one misstep allowed)	0
	Slight difficulties, only visible when walking 10 consecutive steps in tandem	1
	Clearly abnormal, tandem walking > 10 steps not possible	1
	Considerable staggering, difficulties in half-turn, but without support	2
	Marked staggering, intermittent support of the wall required	2
	Severe staggering, permanent support of one stick or light support by one arm required	2

	Walking > 10 m only with strong support (two special sticks or stroller or accompanying person)	3
	Walking < 10 m only with strong support (two special sticks or stroller or accompanying person)	3
	Unable to walk, even supported	4
Domain 2: Stance	Normal, able to stand in tandem > 10 s	0
	Able to stand with feet together without sway, but not in tandem for > 10 s	1
	Able to stand with feet together for >10 s, but only with sway	1
	Able to stand for > 10 s without support in natural position, but not with feet together	2
	Able to stand for > 10 s in natural position only with intermittent support	3
	Able to stand > 10 s in natural position only with constant support of one arm	3
	Unable to stand for > 10 s even with constant support of one arm	4
Domain 3: Sitting	Normal, no difficulties sitting > 10 s	0
	Slight difficulties, intermittent sway	1
	Constant sway, but able to sit > 10 s without support	2
	Able to sit for > 10 s only with intermittent support	3
	Unable to sit for > 10 s without continuous support	4
Domain 4: Speech Disturbance	Normal	0
	Suggestion of speech disturbance	1
	Impaired speech, but easy to understand	1
	Occasional words difficult to understand	2
	Many words are difficult to understand	3
	Only single words understandable	4
	Speech unintelligible, anarthria	4

*Represents modified domain scores recommended by the Food and Drug Administration

Rescored 4-domain Niemann-Pick type C Clinical Severity Score (R4DNPCCSS)

<table>
<tr><th>Domain</th><th>Scoring Criteria</th><th>Score Range*</th></tr>
<tr><td>Ambulation</td><td>0 = Normal
1 = Clumsy
2 = Ataxic unassisted gait or not walking by 18 months
4 = Assisted ambulation or not walking by 24 months
5 = Wheelchair dependent</td><td>0-5</td></tr>
<tr><td>Fine Motor Skills</td><td>0 = Normal
1 = Slight dysmetria/dystonia (independent manipulation)
2 = Mild dysmetria/dystonia (requires little to no assistance, able to feed self without difficulty)
4 = Moderate dysmetria/dystonia (limited fine motor skills, difficulty feeding self)
5 = Severe dysmetria/dystonia (gross motor limitation, requires assistance for selfcare activities)</td><td>0-5</td></tr>
<tr><td>Swallow</td><td><table><tr><td>Response Category</td><td>Rescored**</td></tr><tr><td>Normal, no dysphagia</td><td>0</td></tr><tr><td>Cough while eating</td><td>1</td></tr><tr><td>Intermittent dysphagia with liquids</td><td>2</td></tr><tr><td>Intermittent dysphagia with solids</td><td>2</td></tr><tr><td>Intermittent dysphagia with liquids and solids</td><td>2</td></tr><tr><td>Dysphagia with liquids</td><td>3</td></tr><tr><td>Dysphagia with solids</td><td>3</td></tr><tr><td>Dysphagia with liquids and intermittent dysphagia with solids</td><td>3</td></tr><tr><td>Intermittent dysphagia with liquids and dysphagia with solids</td><td>3</td></tr><tr><td>Dysphagia with liquids and solids</td><td>3</td></tr><tr><td>Nasogastric tube or gastric tube for supplemental feeding</td><td>4</td></tr><tr><td>Nasogastric tube or gastric tube feeding only</td><td>5</td></tr></table></td><td>0-5</td></tr>
<tr><td>Speech</td><td>0 = Normal
1 = Mild dysarthria (easily understood)
2 = Severe dysarthria (difficult to understand)
3 = Non-verbal/functional communication skills for needs
5 = Minimal communication</td><td>0-5</td></tr>
<tr><td>R4DNPCCSS</td><td>Sum of all scores of the following domains with rescored Swallow domain: Ambulation, fine motor</td><td>0-20</td></tr>
</table>

	skills, swallow (rescored), speech	

*A higher score equates to more severe clinical impairment
**[Note: for the swallowing domain the scoring categories were assigned a revised score value following the FDA's recommendation, this rescored version is present in this chart]

References

		Updated	Accessed
1	FDA approved prescribing information for each individual drug		
2	Patterson MC, Lloyd-Price L, Guldberg C, et al. Validation of the 5-domain Niemann-Pick type C Clinical Severity Scale. Orphanet J Rare Dis. 2021;16(1):79. Published 2021 Feb 12. doi:10.1186/s13023-021-01719-2	2/2021	4/2025
3	Zevra. Arimoclomol for treatment of Niemann-Pick disease type C. Briefing document for the Food and Drug Administration Genetic Metabolic Disease Advisory Committee. Available at: https://www.fda.gov/advisory-committees/advisory-committee-calendar/updated-public-participation-information-august-2- 2024-meeting-genetic-metabolic-diseases-advisory#event-materials	8/2025	4/2025
4	U.S. Food and Drug Administration. Drug Approval Package: Aqneursa. Integrated Review. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2024/219132Orig1s000TOC.cfm	10/2024	4/2025
5	Gaucher Disease. National Organization for Rare Disorders. Available at: https://rarediseases.org/rare-diseases/gaucher-disease/	9/2024	4/2025
6	Hughes DA, Pastores GM. Gaucher Disease. 2000 Jul 27 [Updated 2023 Dec 7]. In: Adam MP, Feldman J, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1269/	12/2023	4/2025
7	Bokhari SRA, Zulfiqar H, Hariz A. Fabry Disease. [Updated 2023 Jul 4]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK435996/	7/2023	4/2025
8	Maurer M, Kopp JB, Schiffmann R. Fabry disease: Clinical features and diagnosis. UpToDate https://www.uptodate.com/contents/fabry-disease-clinical-features-and-diagnosis	7/2023	4/2025
9	Germain DP, Hughes DA, Nicholls K, et al. Treatment of Fabry's Disease with the Pharmacologic Chaperone Migalastat. *N Engl J Med*. 2016;375(6):545-555. doi:10.1056/NEJMoa1510198	8/2016	4/2025
10	Ortiz A, Germain DP, Desnick RJ, et al. Fabry disease revisited: Management and treatment recommendations for adult patients. Molecular Genetics and Metabolism 2018;123:416-427	4/2018	4/2025
11	Hopkin R, Jeffries L, Laney D, et.al. The Management and treatment of children with Fabry disease: A United States-based perspective. Molecular Genetics and Metabolism. 2016; 117 (2): 104-113.	2/2016	4/2025
12	Ah Mew N, Simpson KL, Gropman AL, et al. Urea Cycle Disorders Overview. 2003 Apr 29 [Updated 2017 Jun 22]. In: Adam MP, Feldman J, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1217/	6/2017	4/2025
13	Balasubramaniam S, Duley JA, Christodoulou J. Inborn errors of pyrimidine metabolism: clinical update and therapy. *J Inherit Metab Dis*. 2014;37(5):687-698. doi:10.1007/s10545-014-9742-3	9/2014	4/2025
14	Fietz M, AlSayed M, Burke D, et al. Diagnosis of neuronal ceroid lipofuscinosis type 2 (CLN2 disease): Expert recommendations for early detection and laboratory diagnosis. *Mol Genet Metab*. 2016;119(1-2):160-167. doi:10.1016/j.ymgme.2016.07.011	7/2016	4/2025
15	Laurent MR, Harvengt P, Mortier GR, et al. X-Linked Hypophosphatemia. 2012 Feb 9 [Updated 2023 Dec 14]. In: Adam MP, Feldman J, Mirzaa GM, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2025. Available from: https://www.ncbi.nlm.nih.gov/books/NBK83985/	12/2023	4/2025
16	Scheinman SJ, Drezner MK. Hereditary hypophosphatemia rickets and tumor-induced osteomalacia. UpToDate, Inc. Available at: https://www.uptodate.com/contents/hereditary-hypophosphatemic-rickets-and-tumor-induced-osteomalacia	12/2024	4/2025
17	Bacon S, Crowley R. Developments in rare bone diseases and mineral disorders. *Ther Adv Chronic Dis*. 2018;9(1):51-60. doi:10.1177/2040622317739538	11/2017	4/2025
18	Thomas J, Levy H, Amato S, et al. Pegvaliase for the treatment of phenylketonuria: Results of a long-term phase 3 clinical trial program (PRISM). *Mol Genet Metab*. 2018;124(1):27-38. doi:10.1016/j.ymgme.2018.03.006	3/2018	4/2025

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted in above application if administered under the medical benefit. Pharmacy benefit: Not applicable.
SELECT/HARP PLAN:	Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program.

CDPHP Pharmacy Services 10/8/2026

New: 6/2025

Revised	Reviewed
12/2025, 2/2026, 5/2026, 10/2026	

Revision Date	Changes Made
12/2025	Added Harliku (nitisinone) criteria Moved Kuvan, Javygtor and generic sapropterin from the Clinical Review Prior Authorization (CRPA) Rx policy to the Inborn Errors of Metabolism Policy Added Ctexli (chenodiol) Updated approval timeframes Added newly approved Sephience (sepiapterin) to policy
2/2026	Removed statement from Palynziq renewal about Requests will be reviewed per criteria every 12 months
3/2026	Updated Palynziq age range based on updated FDA approval for those ages 12+
5/2026	Made policy applicable to Medicare for drugs administered under the medical benefit Added Kygevvi (doxecitine and doxribtimine) Moved Sucraid from standalone policy
5/2026	Added Avlayah, Loargys, and Zycubo
10/2026	Added Zanvastro

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The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

The Inflammatory Conditions Clinical Review Prior Authorization- Medical Benefit policy contains criteria for medications that have significant concerns about potential efficacy, quality, toxicity, or utilization, but do not warrant a stand-alone policy. The Pharmacy Management clinical team and members of the Pharmacy and Therapeutics (P&T) committee review the drugs falling into this policy.

CDPHP administers benefits to members for drugs contained in this policy only if the member has a medical benefit with CDPHP. Prior authorization is obtained thought the CDPHP pharmacy department.

Summary

Effective Date of Policy:	9/24/2026
Indications	Varies by drug
ICD10 Diagnosis Codes	HCPCS: Actemra (tocilizumab) Intravenous Infusion (J3262). Cimzia (certolizumab pegol) (J0717), Cosentyx (secukinumab) Intravenous Infusion (J3247), Entyvio (vedolizumab) Intravenous Infusion (J3380) Ilumya (tildrakzumab) (J3245), Skyrizi (riskankizumab) Intravenous Infusion (J2327), Spevigo (spesolimab-sbzo) (J1747), Stelara (Ustekinumab)/ Selarsdi (ustekinumab-aekn)/Yesintek (ustekinumab-kfce) (J3357), J3358, Q9998, Q5100), Tremfya (J1628)
Availability	Varies by drug
Duration	1 year unless otherwise noted

This policy is only applicable if medication is administered under the medical benefit

Required Criteria for Approval

Actemra (tocilizumab) Intravenous Infusion

1. The enrollee must have a diagnosis of moderately to severely active **Rheumatoid Arthritis**
    a. The medication must be prescribed by or in consultation with a Rheumatologist
    b. The enrollee must be 18 years of age or older
    c. The enrollee must have tried or is intolerant to at least one conventional disease-modifying antirheumatic drug (DMARD) such as methotrexate, leflunomide, sulfasalazine or hydroxychloroquine either alone or in combination for at least 3 months
    d. The recommended starting dose is 4 mg/kg every 4 weeks
        i. Depending on clinical response, the dose can be increased to 8 mg/kg (up to 800 mg per dose) every 4 weeks
2. The enrollee must have a diagnosis of **Giant Cell Arteritis**
    a. The medication must be prescribed by or in consultation with a Rheumatologist, Neurologist, or Ophthalmologist
    b. The enrollee must be 18 years of age or older
    c. The enrollee must have trialed at least one systemic corticosteroid
    d. The recommended dose is 6 mg/kg every 4 weeks (maximum dose 600 mg) in combination with a tapering dose of corticosteroids
3. The enrollee must have a diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**
    a. The medication must be prescribed by or in consultation with a Rheumatologist
    b. The enrollee must be 2 years of age or older
    c. The enrollee has tried at least one other systemic therapy for this condition OR patient has an absolute contraindication to methotrexate, sulfasalazine or leflunomide OR patient has aggressive disease, as determined by the prescriber
    d. The recommended dose for patients weighing less than 30 kg is 10 mg/kg every 4 weeks
    e. The recommended dose for patients weighing more than 30 kg is 8 mg/kg every 4 weeks

4. The enrollee must have a diagnosis of **Systemic Juvenile Idiopathic Arthritis**
    a. The medication must be prescribed by or in consultation with a Rheumatologist
    b. The enrollee must be 2 years of age or older
    c. The enrollee has tried at least one other systemic therapy for this condition OR patient has an absolute contraindication to methotrexate, sulfasalazine or leflunomide OR patient has aggressive disease, as determined by the prescriber
    d. The recommended dose for patients weighing less than 30 kg is 12 mg/kg every 2 weeks
    e. The recommended dose for patients weighing more than 30 kg is 8 mg/kg every 2 weeks
5. Actemra is being used for the treatment of **cytokine release syndrome associated with Chimeric Antigen Receptor (CAR) T-Cell Therapy**
    a. Enrollee has been or will be treated with a CAR T-cell therapy
    b. The recommended dosing is as follows:
        i. For patients < 30 kg: up to 12 mg/kg (maximum of 800 mg per dose)
        ii. For patients ≥ 30 kg: up to 8 mg/kg (maximum of 800 mg per dose)
6. IV tocilizumab has been FDA approved for the treatment of hospitalized adult patients, and Actemra with additional indication for pediatric patients (2 years of age or older), with COVID-19 who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) for inpatient use only; therefore, coverage in the outpatient setting will not be authorized.

HCPCS: J3262

Cimzia (certolizumab pegol)

1. The enrollee must have a diagnosis of **Ankylosing Spondylitis**
    a. The medication must be prescribed by or in consultation with a Rheumatologist
    b. The enrollee must be 18 years of age
    c. The recommended dosing is as follows:
        i. Initial dosing: subcutaneous injection of 400 mg (given as two injections of 200 mg) at weeks 0, 2, and 4
        ii. Maintenance dosing: 400 mg subcutaneously every 4 weeks OR 200 mg subcutaneously every other week
2. The enrollee must have a diagnosis of **Crohn's disease**
    a. The medication must be prescribed by or in consultation with a gastroenterologist
    b. The enrollee must be at least 18 years of age
    c. The enrollee meets at least one of the following criteria:
        i. Has tried or is currently taking a systemic corticosteroid or a systemic corticosteroid is contraindicated
        ii. Has tried at least one other conventional systemic therapy for Crohn's disease
        iii. Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas
        iv. Has a history of ileocolonic resection
    d. The recommended dosing is as follows:
        i. Initial dosing: subcutaneous injection of 400 mg (given as two injections of 200 mg) at weeks 0, 2, and 4
        ii. Maintenance dosing: 400 mg subcutaneously every 4 weeks
3. The enrollee must have a diagnosis of **Non-Radiographic Axial Spondyloarthritis**
    a. The medication must be prescribed by or in consultation with a rheumatologist
    b. The enrollee must be at least 18 years of age
    c. The enrollee has objective signs of inflammation, defined as at least one of the following:
        i. C-reactive protein (CRP) above the upper limit of normal
        ii. Sacroiliitis reported on magnetic resonance imaging (MRI)
    d. The recommended dosing is as follows:
        i. Initial dosing: subcutaneous injection of 400 mg (given as two injections of 200 mg) at weeks 0, 2, and 4
        ii. Maintenance dosing: 400 mg subcutaneously every 4 weeks OR 200 mg subcutaneously every other week
4. The enrollee must have a diagnosis of **Plaque Psoriasis**
    a. The medication must be prescribed by or in consultation with a dermatologist
    b. The enrollee must be at least 18 years of age
    c. The enrollee must meet at least one of the following criteria:
        i. Has tried at least one traditional systemic agent for psoriasis for at least 3 months unless intolerant
        ii. Has a contraindication to methotrexate, as determined by the prescriber

d. The recommended dosing is as follows:
    i. Subcutaneous injection of 400 mg every other week
    ii. For some patients with a body weight ≤ 90 kg, a dose of 400 mg at weeks 0, 2, and 4 followed by 200 mg every other week may be considered

5. The enrollee must have a diagnosis of **Polyarticular Juvenile Idiopathic Arthritis**
    a. The medication must be prescribed by or in consultation with a rheumatologist
    b. The enrollee must be at least 2 years of age
    c. The enrollee must meet one of the following criteria:
        i. Has tried at least one other agent for this condition
        ii. Will be starting on therapy concurrently with methotrexate, sulfasalazine, or leflunomide
        iii. Has an absolute contraindication to methotrexate, sulfasalazine or leflunomide
        iv. Has aggressive disease, as determined by the prescriber
    d. The recommended dosing is weight-based as follows:
        i. 10 kg to less than 20 kg: 100 mg at weeks 0, 2, and 4 followed by 50 mg every other week
        ii. 20 kg to less than 40 kg: 200 mg at weeks 0, 2, and 4 followed by 100 mg every other week
        iii. Greater than or equal to 40 kg: 400 mg at weeks 0, 2, and 4 followed by 200 mg every other week
6. The enrollee must have a diagnosis of **Psoriatic Arthritis**
    a. The medication must be prescribed by or in consultation with a dermatologist or rheumatologist
    b. The enrollee must be at least 18 years of age
    c. The recommended dosing is as follows:
        i. Initial dosing: subcutaneous injection of 400 mg (given as two injections of 200 mg) at weeks 0, 2, and 4
        ii. Maintenance dosing: 400 mg subcutaneously every 4 weeks OR 200 mg subcutaneously every other week
7. The enrollee must have a diagnosis of **Rheumatoid Arthritis**
    a. The medication must be prescribed by or in consultation with a rheumatologist
    b. The enrollee must be at least 18 years of age
    c. The enrollee must have tried or is intolerant to at least one conventional disease-modifying antirheumatic drug (DMARD) such as methotrexate, leflunomide, sulfasalazine, or hydroxychloroquine either alone or in combination for at least 3 months
    d. The recommended dosing is as follows:
        i. Initial dosing: subcutaneous injection of 400 mg (given as two injections of 200 mg) at weeks 0, 2, and 4
        ii. Maintenance dosing: 400 mg subcutaneously every 4 weeks OR 200 mg subcutaneously every other week

HCPCS: J0717

Cosentyx (secukinumab) Intravenous Infusion

1. The enrollee must have a diagnosis of **Ankylosing Spondylitis**
    a. The medication must be prescribed by or in consultation with a rheumatologist
    b. The enrollee must be at least 12 years of age
    c. Must have refractory disease defined by failure of or intolerance to at least TWO different NSAIDS at maximum strength for at least 1 month each
    d. The recommended dosing is as follows:
        i. With a loading dose: A single 6 mg/kg loading dose followed by 1.75 mg/kg (up to a maximum of 300 mg per dose) every 4 weeks
        ii. Without a loading dose: 1.75 mg/kg (up to a maximum of 300 mg) every 4 weeks
2. The enrollee must have a diagnosis of **Non-Radiographic Axial Sponyloarthritis**
    a. The medication must be prescribed by or in consultation with a rheumatologist
    b. The enrollee must be at least 18 years of age
    c. Must have refractory disease defined by failure of or intolerance to at least TWO different NSAIDS at maximum strength for at least 1 month each
    d. The recommended dosing is as follows:
        i. With a loading dose: A single 6 mg/kg loading dose followed by 1.75 mg/kg (up to a maximum of 300 mg per dose) every 4 weeks
        ii. Without a loading dose: 1.75 mg/kg (up to a maximum of 300 mg) every 4 weeks

3. The enrollee must have a diagnosis of **Psoriatic Arthritis**
    a. The medication must be prescribed by or in consultation with a Rheumatologist or dermatologist
    b. The enrollee must be at least 18 years of age
    c. The recommended dosing is as follows:
        i. With a loading dose: A single 6 mg/kg loading dose followed by 1.75 mg/kg (up to a maximum of 300 mg per dose) every 4 weeks
        ii. Without a loading dose: 1.75 mg/kg (up to a maximum of 300 mg) every 4 weeks

HCPCS: J3247

Entyvio (vedolizumab) Intravenous Infusion

1. The enrollee must have a diagnosis of **Crohn's disease**
    a. The medication must be prescribed by or in consultation with a gastroenterologist
    b. The enrollee must be at least 18 years of age
    c. The enrollee meets at least one of the following criteria:
        i. Documentation that azathioprine, 6-mercaptopurine, or methotrexate is not effective, contraindicated, or not tolerated
        ii. Treatment with a biologic medication as first-line therapy will be assessed on a case-by-case basis through a letter of medical necessity and clinical progress notes based on severity of the disease (such as but not limited to enterocutaneous [perianal or abdominal] fistulas, rectovaginal fistulas, ileocolonic resection
    d. The recommended dose is 300 mg at weeks 0, 2, and 6, followed by 300 mg every 8 weeks
2. The enrollee must have a diagnosis of **Ulcerative Colitis**
    a. The medication must be prescribed by or in consultation with a gastroenterologist
    b. The enrollee must be at least 18 years of age
    c. Enrollee must meet ONE of the following:
        i. Must have tried and failed or has documented intolerance to at least ONE of the following conventional therapies for at least 3 months:
            1. I. Thiopurines: Azathioprine/6-mercaptopurine (6-MP)
            2. 5-Aminosalicylates: Sulfasalazine, Mesalamine, Olsalazine
            3. IV or oral steroids - note, a 3-month trial of systemic steroid therapy will not be required
        ii. The patient has been diagnosed with pouchitis and has tried an antibiotic, corticosteroid enema, or mesalamine enema
    d. The recommended dose is 300 mg at weeks 0, 2, and 6, followed by 300 mg every 8 weeks

HCPCS: J3380

Ilumya (tildrakzumab)

1. The enrollee must have a diagnosis of moderate to severe chronic **Plaque Psoriasis** that involves at least 10% of their body surface area. Consideration will be given to those who have less than 10% body surface area involvement but have severe disease of sensitive areas or areas causing significant disruption in normal activities (such as the hands, feet, face, genitalia)
    a. The medication must be prescribed by or in consultation with a dermatologist or rheumatologist
    b. The enrollee must be at least 18 years of age
    c. The patient must be a candidate for systemic therapy or phototherapy and meet for ONE of the following:
        i. The patient must have had a 3-month trial of systemic therapy (i.e., acitretin, methotrexate, or cyclosporine) that resulted in an inadequate response (failure). A 3-month trial will not be required if the member experienced serious side effects during a trial of one of the aforementioned agents OR
        ii. The patient must have had a 3-month trial of Ultraviolet B (UVB) Phototherapy or Psoralen Ultraviolet A (PUVA) Phototherapy that resulted in an inadequate response (failure)
    d. The recommended dosing is 100 mg by subcutaneous injection at weeks 0, 4, and then every 12 weeks thereafter
2. Coverage for Ilumya will only be authorized under the medical benefit

HCPCS: J3245

Skyrizi (riskankizumab) Intravenous Infusion

1. The enrollee must have a diagnosis of **Crohn's disease**
    a. The medication must be prescribed by or in consultation with a gastroenterologist
    b. The enrollee must be at least 18 years of age
    c. The enrollee meets at least one of the following criteria:
        i. has tried or is currently taking a systemic corticosteroid or a systemic corticosteroid is contraindicated
        ii. has tried at least one other conventional systemic therapy for Crohn's disease
        iii. has enterocutaneous (perianal or abdominal) or rectovaginal fistulas
        iv. has a history of ileocolonic resection
    d. Skyrizi IV infusion will be used as induction therapy only
    e. The recommended dose is 600 mg at weeks 0, 4, and 8
2. The enrollee must have a diagnosis of **Ulcerative Colitis**
    a. The medication must be prescribed by or in consultation with a gastroenterologist
    b. The enrollee must be at least 18 years of age
    c. The enrollee meets at least one of the following criteria:
        i. has tried or is currently taking a systemic corticosteroid or a systemic corticosteroid is contraindicated
        ii. has tried at least either a thiopurine or 5-aminosalicylate for at least 3 months
        iii. has a diagnosis of pouchitis AND has tried an antibiotic, corticosteroid enema, or mesalamine enema
    d. Skyrizi IV infusion will be used as induction therapy only
    e. The recommended dose is 1200 mg at weeks 0, 4, and 8

HCPCS: J2327

Spevigo (spesolimab-sbzo)

1. The patient must be at least 12 years of age **AND**
2. The patient must weigh at least 40 kilograms (kg) **AND**
3. Must be prescribed by a dermatologist or a physician specializing in the treatment of autoinflammatory conditions **AND**
4. The patient must have a confirmed diagnosis of generalized pustular psoriasis (GPP) defined as the presence of primary, sterile, macroscopically visible pustules on non-acral skin (excluding cases where pustulation is restricted to psoriatic plaques) **AND**
5. Must be used for the treatment of a generalized pustular psoriasis (GPP) moderate to severe flare in patients with a history of at least 2 moderate to severe GPP flares defined as:
    a. A Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of ≥ 3 **AND**
    b. New appearance or worsening of existing pustules **AND**
    c. A GPPGA pustulation sub score of ≥ 2 **AND**
    d. ≥ 5% body surface covered with erythema and the presence of pustules **OR**
6. Requests for **an additional dose** used to treat the **same flare** will be covered if the patient meets the following criteria:
    a. The additional dose will be used no sooner than 1 week after the initial dose **AND**
    b. The patient has a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) total score of 2 or higher at the end of week 1 (range, 0 [clear skin] to 4 [severe disease]) **AND**
    c. The patient has a GPPGA pustulation subscore of 2 or higher at the end of week 1 (range, 0 [no visible pustules] to 4 [severe pustulation])
7. Requests for Recertification
    a. Individuals that have previously received at least 1 dose of Spevigo for the treatment of a prior GPP flare will be covered for a recurrent flare if the patient achieved a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) score of 0 or 1 after previous treatment AND had an increase of at least 2 points in both GPPGA total score and pustulation subscore after previous treatment
8. Spevigo IV will not be covered for the ongoing treatment of GPP (as a one-time loading dose or as maintenance treatment)
9. Approval timeframe: Treatment of a flare with intravenous (IV) Spevigo: 1 week per request (new, additional, and recertification)
10. Approved Dosing:
    a. Experiencing a flare: 900 mg dose by intravenous (IV) infusion over 90 minutes
    b. If GPP flare symptoms persist, an additional intravenous (IV) 900 mg dose (over 90 minutes) may be administered one week after the initial dose (the criteria listed in 6 must be met for coverage for an additional dose)

HCPCS: J1747

Stelara (Ustekinumab)/ Selarsdi (ustekinumab-aekn)/Yesintek (ustekinumab-kfce)

1. The enrollee must have a diagnosis of **Crohn's disease**
- a. The medication must be prescribed by or in consultation with a gastroenterologist
- b. The enrollee must be at least 2 years of age
- c. The enrollee meets at least one of the following criteria:
  - i. has tried or is currently taking a systemic corticosteroid or a systemic corticosteroid is contraindicated
  - ii. has tried at least one other conventional systemic therapy for Crohn's disease
  - iii. has enterocutaneous (perianal or abdominal) or rectovaginal fistulas
  - iv. has a history of ileocolonic resection
- d. Approved dosing:
  - i. Adult patients:
    1. Induction dose - At week 0, a one-time weight-based IV loading dose given by a healthcare professional. This will be covered under the medical benefit.
       - a. 55 kg or less: 260 mg
       - b. Greater than 55 kg to 85 kg: 390 mg
       - c. Greater than 85 kg: 520 mg
    2. Maintenance dosing:
       - a. Starting at week 8, ustekinumab 90mg is given subcutaneously every 8 weeks.
       - b. This can be self-injected under the Rx benefit or given subcutaneously by a healthcare professional under the medical benefit.
  - ii. Pediatric patients:
    1. For pediatric patients weighing 10 kg or more: A single intravenous infusion using weight-based dosing given by a healthcare professional. This will be covered under the medical benefit.
       - a. 10 kg-25 kg: 10 mg/kg
       - b. Greater than 25 kg to 55 kg: 260 mg
       - c. Greater than 55 kg to 85 kg: 390 mg
       - d. Greater than 85 kg: 520 mg
    2. Maintenance weight-based dosing:
       - a. 10 kg to 35 kg: a subcutaneous 2.5 mg/kg dose administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.
       - b. Greater than 35 kg: a subcutaneous 90 mg dose administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.
       - c. This can be self-injected or given by caregivers under the Rx benefit or given subcutaneously by a health care professional under the medical benefit

2. The enrollee must have a diagnosis of **Ulcerative Colitis**
- a. The medication must be prescribed by or in consultation with a gastroenterologist
- b. The enrollee must be at least 2 years of age
- c. The enrollee meets at least one of the following criteria:
  - i. Has tried or is currently taking a systemic corticosteroid or a systemic corticosteroid is contraindicated
  - ii. Has tried at least either a thiopurine or 5-aminosalicylate for at least 3 months
  - iii. Has a diagnosis of pouchitis AND has tried an antibiotic, corticosteroid enema, or mesalamine enema
- d. Approved dosing
  - i. Adult patients:
    1. Induction dose - At week 0, a one-time weight-based IV loading dose given by a healthcare professional. This will be covered under the medical benefit.
       - a. 55 kg or less: 260 mg
       - b. Greater than 55 kg to 85 kg: 390 mg
       - c. Greater than 85 kg: 520 mg
    2. Maintenance dosing:
       - a. Starting at week 8, ustekinumab 90mg is given subcutaneously every 8 weeks.
       - b. This can be self-injected under the Rx benefit or given subcutaneously by a healthcare professional under the medical benefit.

ii. Pediatric patients:
    1. Induction dose- for pediatric patients weighing 10 kg or more: A single intravenous infusion using weight-based dosing given by a healthcare professional. This will be covered under the medical benefit.
        a. 10 kg-25 kg: 10 mg/kg
        b. Greater than 25 kg to 55 kg: 260 mg
        c. Greater than 55 kg to 85 kg: 390 mg
        d. Greater than 85 kg: 520 mg
    2. Maintenance weight-based dosing:
        a. 10 kg to 35 kg: a subcutaneous 2.5 mg/kg dose administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.
        b. Greater than 35 kg: a subcutaneous 90 mg dose administered 8 weeks after the initial intravenous dose, then every 8 weeks thereafter.
        c. This can be self-injected or given by caregivers under the Rx benefit or given subcutaneously by a healthcare professional under the medical benefit

3. The enrollee must have a diagnosis of **Plaque Psoriasis**
    a. The medication must be prescribed by or in consultation with a dermatologist
    b. The enrollee must be at least 6 years of age
    c. The enrollee must meet one of the following criteria:
        i. Has tried at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant or if traditional agent therapy is contraindicated
    d. The recommended dose is as follows:
        i. Pediatric dosing:
            1. For those weighing < 60 kg: 0.75 mg/kg at weeks 0, 4, and then every 12 weeks thereafter
            2. For those weighing 60–100 kg: 45 mg at weeks 0, 4, and then every 12 weeks thereafter
            3. For those weighing > 100 kg: 90 mg at weeks 0, 4, and then every 12 weeks thereafter
        ii. Adult dosing:
            1. For those weighing ≤ 100 kg: 45 mg at weeks 0, 4, and then every 12 weeks thereafter
            2. For those weighing > 100 kg: 90 mg at weeks 0, 4, and every 12 weeks thereafter
4. The enrollee must have a diagnosis of **Psoriatic Arthritis**
    a. The medication must be prescribed by or in consultation with a dermatologist or rheumatologist
    b. The enrollee must be at least 6 years of age
    c. The recommended dosing is as follows:
        i. Pediatric dosing:
            1. For those weighing < 60 kg: 0.75 mg/kg at weeks 0, 4, and then every 12 weeks thereafter
            2. For those weighing 60–100 kg: 45 mg at weeks 0, 4, and then every 12 weeks thereafter
            3. For those weighing > 100 kg with co-existent moderate-to-severe plaque psoriasis: 90 mg at weeks 0, 4, and then every 12 weeks thereafter
        ii. Adult dosing:
            1. For those weighing ≤ 100 kg: 45 mg at weeks 0, 4, and then every 12 weeks thereafter
            2. For those weighing > 100 kg with co-existent moderate-to-severe plaque psoriasis: 90 mg at weeks 0, 4, and every 12 weeks thereafter

HCPCS: J3357, J3358, Q9998, Q5100

Tremfya (guselkumab)

Note: Tremfya (guselkumab) will be approved under the medical for induction dosing only if the following criteria are met:

Moderately to severely active Ulcerative Colitis

1. Must be prescribed by or in consultation with a gastroenterologist
2. Must be at least 18 years of age
3. Must meet **ONE** of the following:
    a. Must have tried and had an inadequate response or documented intolerance to at least ONE of the following conventional therapies for at least 3 months:

i. Thiopurines: azathioprine/6-mercaptopurine (6-MP)
ii. 5-Aminosalicylates: sulfasalazine, mesalamine, olsalazine
iii. IV or oral steroids – note, a 3-month trial of systemic steroid therapy will not be required

b. The patient has been diagnosed with pouchitis and has tried an antibiotic, corticosteroid enema, or mesalamine enema

4. Coverage of Tremfya for Ulcerative Colitis will be limited to the following:
   a. **Induction**: One of the following
      i. 200 mg IV at week 0, 4, and 8. Approval is for 3 induction doses in 12 weeks as a medical benefit **OR**
      ii. 400 mg (Induction Pack for UC or CD: 2 x 200 mg/2 mL single-dose prefilled pens) administered by subcutaneous injection at week 0, 4, and 8. Approval is for 3 induction doses in 12 weeks *(refer to Inflammatory Conditions Clinical Review Prior Authorization (CRPA) Policy – PHARMACY BENEFIT ONLY, 1350/20.000558)*

Moderately to severely active Crohn's Disease

1. Must be prescribed by or in consultation with a gastroenterologist
2. Must be at least 18 years of age
3. Must have had an inadequate response, intolerance or contraindication to azathioprine, 6-mercaptopurine, or methotrexate
   a. Treatment with a biologic medication as first-line therapy will be assessed on a case-by-case basic through documentation of medical necessity and clinical progress notes based on severity of disease (such as but not limited to enterocutaneous [perianal or abdominal] fistulas, rectovaginal fistulas, ileocolonic resection)
4. Coverage for Crohn's Disease will be limited to the following:
   a. **Induction:** One of the following
      i. 200 mg administered by intravenous infusion at week 0, 4, and 8. Approval is for 3 induction doses in 12 weeks as a medical benefit **OR**
      ii. 400 mg (Induction Pack for UC or CD: 2 x 200 mg/2 mL single-dose prefilled pens) administered by subcutaneous injection at week 0, 4, and 8. Approval is for 3 induction doses in 12 weeks *(refer to Inflammatory Conditions Clinical Review Prior Authorization (CRPA) Policy – PHARMACY BENEFIT ONLY, 1350/20.000558)*

HCPCS: J1628

Exclusion Criteria

- Drugs listed in this policy as well as other immunomodulating therapies or Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) not listed in this policy should not be administered in combination with another biologic or targeted synthetic DMARD used for an inflammatory condition. Combination therapy is generally not recommended due to the added risk of immunosuppression, potential for a higher rate of adverse effects, and lack of evidence for additive therapy.
  - NOTE: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine)
- Requests for non-FDA approved uses are not covered per this policy; review as per Off-Label Uses of FDA-Approved Drugs Policy Control Number: 1350/20.000048

Continuation Criteria

- Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition.
- Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the requested product is medically necessary.

Considerations

- Patient must have medical coverage administered by CDPHP.
- Prior authorization is obtained through the CDPHP pharmacy department.
- An exception can be made to the requirement of a trial of at least one conventional agent if the member has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count.

- Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE CHOICES: Not applicable

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 9/24/2026

New: 6/25

Policy History

Revised	Reviewed
9/2025, 12/2025, 1/2026, 2.2026, 6/2026, 9/2026	7/2026

Revision Date	Changes Made
9/2025	Added Spevigo (spesolimab-sbzo) for generalized pustular psoriasis flares
12/2025	Added statement to Actemra not being covered outpatient for COVID-19 Removed Simponi Aria from policy as changed to no PA required
1/2026	Added Selarsdi and Yesintek as Stelara biosimilars
2/2026	Updated Entyvio criteria wording Updated Cosentyx: Added NSAID requirement for diagnosis of ankylosing spondylitis and non-radiographic axial spondylitis. And removed CRP and MRI requirement for non-radiographic axial spondylitis Updated Ilumya: Added rheumatologist as provider, specified severity and BSA, updated to trial of systemic therapy or phototherapy, clarified Ilumya will only be authorized under the medical benefit
2/2026	Added Tremfya to make clearer IV vs. SQ induction
6/2026	Updated Cosentyx age for AS down to 12 years of age
9/2026	Updated with dosing for Stelara pediatric Crohn's and UC

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: INPATIENT PHYSICAL REHABILITATION: ACUTE, SUBACUTE & SKILLED

POLICY EFFECTIVE DATE:	8/1/2023
Policy Control #:	1370/20.000204
Next Annual Review:	July 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

DESCRIPTION

Inpatient physical rehabilitation is designed to provide rehabilitation therapy in a resource-intensive environment for patients who, due to the complexity of their nursing, medical management, and rehabilitation needs, require and can reasonably be expected to benefit from an inpatient stay and an interdisciplinary team approach to the delivery of rehabilitation care. Rehabilitation is the ongoing process of therapy and education that assists the member with attaining maximum functional status.

POSITION STATEMENT

CDPHP administers benefits for inpatient physical rehabilitation provided in an approved rehabilitation unit or facility when determined to be medically necessary and in accordance with the criteria stated below.

Requests for all levels of inpatient rehabilitation services must be reasonable and necessary (in terms of efficacy, duration, frequency, and amount) for the treatment of the member's condition in accordance with the criteria outlined below and cannot be provided in a less intensive clinical setting (e.g., outpatient services or home care).

Inpatient rehabilitation services may be habilitative or rehabilitative in nature.

- **Rehabilitation services are** health care services that help a person keep, get back, or

improve skills and functioning for daily living that have been lost or impaired because a person was sick, hurt, or disabled.

- **Habilitation Services** are health care services that help a person keep, learn, or improve skills and functioning for daily living. They include the management of limitations and disabilities, including services or programs that help maintain or prevent deterioration in physical, cognitive, or behavioral function.
  - Refer to specific member contracts for availability of benefits, if any, relating to habilitative services.

The following are **general requirements** for all levels of inpatient physical rehabilitation:

- Transfer to an inpatient rehabilitation facility is ordered by a physician.
- The inpatient rehabilitation facility is a CDPHP provider.
- There is a plan of care, defined at the time of admission, which includes identification of specific patient needs and clear measurable goals that can be achieved in a reasonable and predictable period of time, and that result in significant clinical improvement leading to increased independence. At the discretion of the Plan's medical director, the facility may be given the initial 48 hours of the stay to define or further clarify the plan.
- The patient's physical and mental condition makes it possible to actively participate in, and significantly benefit from, the inpatient rehabilitation program.
- The expectation exists for restoring function within the individual's mental/physical limitations with the goal of continuing rehabilitation at a less intensive setting as soon as the patient's condition allows.

Inpatient Acute Rehabilitation

*In an **acute** rehabilitation setting, CDPHP expects the program will offer at least three hours of combined services daily, six days a week, that are comprehensive and skilled, including, but not limited to: physical, occupational, and speech therapies, along with cognitive and/or recreational therapies, as needed. There is to be daily documentation of the patient's progress.*

In addition, the following criteria is to be met:

- The complexity of the individual's nursing, medical management, and rehabilitation needs (e.g., physical, occupational, speech therapy) require an inpatient interdisciplinary team approach for delivery of care, under the direction of a physiatrist or other physician with rehabilitation experience.

The following special patient circumstances will be reviewed on an individual case basis by a CDPHP medical director for approval of inpatient acute rehabilitation:

- When the patient's medical condition indicates a higher level of care than may be required by the rehabilitation needs alone either due to services required to treat the

medical condition or due to the impact of the condition on the rehabilitation; **or**

- When a patient who was active prior to an acute hospitalization becomes deconditioned and will not meet acute inpatient rehabilitation criteria immediately upon admission but appears to be able to achieve that level of rehabilitation within a short time.

Inpatient Subacute Rehabilitation

*In a **subacute** rehabilitation setting, CDPHP expects the program will offer from 1½ to up to three hours of combined services daily, five days a week, that are comprehensive and skilled, including, but not limited to: physical, occupational, and speech therapies, along with cognitive and/or recreational therapies, as needed. There is to be documentation of the patient's progress at least every other day.*

Inpatient Skilled Nursing Facility Rehabilitation

*In a **skilled nursing facility** rehabilitation setting**,** CDPHP expects the program will offer from 20 minutes up to 1½-hours of skilled rehabilitation services at least five days per week that are comprehensive and skilled, including, but not limited to: physical, occupational, and speech therapies, along with cognitive and/or recreational therapies, as needed. There is to be documentation of the patient's progress at least two times a week*.

Additional Services

CDPHP provides reimbursement for the following services, in addition to all levels of inpatient physical rehabilitation, when the criteria outlined below is met:

Active Weaning of Ventilator-Dependent Individual

Medical record documentation to support all of the following:

- Pulmonary or critical care physician documents medical opinion that member is able to be weaned and/or weaning barrier assessment.
- Documentation of wean should consist of ventilator modes, PEEP, oxygenation, airway resistance/ling compliance, and medical stability with wean attempts.

Services are provided for attempts to wean from ventilator and not for chronic long-term ventilator support.

- If no documented progression in one month, physician documentation of re-assessment and/or weaning barriers to attempts with goals is required.
- Weekly assessment of documented weaning progression will occur thereafter by a CDPHP medical director for continued additional reimbursement.

POLICY NAME: INPATIENT PHYSICAL REHABILITATION: ACUTE, SUBACUTE & SKILLED

Dialysis Management

Includes coverage of cost for the following services only:

- When the skilled nursing facility is paying for transportation of the member to and from dialysis.
- When the skilled nursing facility provides staff to accompany the member to and from dialysis.
- When the member is receiving dialysis within the skilled nursing facility such as peritoneal dialysis.

Six-Day Rehabilitation Program

Coverage is provided for an additional therapy day, either Saturday or Sunday, as supported in medical record documentation.

Skilled Nursing Level Criteria:

Level 1:

- Basic skilled services – may include IV hydration, IV antibiotics, Lovenox, daily skilled wound care
- Combined Restorative rehab services up to 0.5 hours/day, five times/week
- Care of chronic tracheostomy/suctioning
- Tube feedings management
- New Oxygen use, nebs, respiratory treatments
- Insulin dependent Diabetics on daily insulin scale (for Medicare Choice members. Commercial members should require Medical Director Review for coverage determination.)

Level 2:

- Basic Skilled Services – may include IV hydration, IV antibiotics
- Combined restorative rehab services up to 1.75 hours/day five times/week
- Wound management including skilled wound care – daily dressing changes
- Members with tracheostomy that requires frequent suctioning (q2-4 hours and prn)
- Wound vac management if there is a separate auth for the wound vac.

Level 3:

- Basic skilled services – may include IV hydration, IV antibiotics AND combined rehab services up to 1.75 hours/day up to six days/week

OR

- Extensive wound management AND combined rehab services up to 1.75 hours/day up to five days/week. Extensive wound management defined:
    - Complicated wound care needs, wound vac procedures and/or wound packing that is required more than once per day. May also include the management of Stage 3 or Stage 4 decubiti and venous/arterial insufficiency ulcers that require extensive wound management.
    - Application of ointments, dry dressings, wet soaks, and use of protective dressings does not correlate with extensive wound management.

Level 4

- Vent dependent with active weaning program. RT notes and weaning info required for review.
- If no documented progression in one month, physician documentation of re-assessment and/or weaning barriers to attempts with goals is required.

Level 5

- Vent weaning AND hemodialysis being done on-site at the skilled nursing facility.

POLICY CONSIDERATIONS

CDPHP utilizes nationally published guidelines *(InterQual®)* to assist with all medical necessity determinations relating to admission and appropriateness of continued acute and subacute inpatient rehabilitation, and skilled nursing facility stay.

The patient requires active and ongoing therapeutic intervention of multiple therapy disciplines (physical therapy, occupational therapy, speech-language pathology, or prosthetics/orthotics), one of which must be physical or occupational therapy.

Deficits are present in areas of functional mobility, self-care skills, cognitive status, or neurosensory areas, and not limited to cognitive therapy only.

Patient is willing to participate in therapies and can follow commands with sufficient cognitive ability and motivation.

Discharge planning is expected to begin upon admission, and must be proactive in nature, with early social work intervention for anticipated socioeconomic issues.

Skilled therapies are available during weekends and holidays for acute and subacute levels of rehabilitation.

Other teaching needs are concurrently addressed, such as diabetic and colostomy care, and self-catheterization.

Services are subject to all applicable limitations and/or cost-share as stated in the enrollee's contract.

Discharge Indicators

The patient will be considered eligible for discharge when one or more of the following are met:

- The patient's rehabilitative needs can be met more appropriately in a less intensive clinical setting; **or**
- The patient has attained maximum independence in functioning within the limitations imposed by disease or injury; **or**
- The patient demonstrates successful adaptation to the outpatient setting on home visit when appropriate; **or**
- The treatment team documents the refusal of the patient to actively participate in rehabilitation program; **or**
- Medical complications occur that preclude participation in the rehabilitation documented; **or**
- There is no documented measurable improvement in functional status for one week; **or**
- The patient's function returns to their pre-morbid status

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy. • Services in a skilled nursing facility or rehabilitation facility are excluded from coverage.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy. In accordance with guidelines from the Centers for Medicare & Medicaid Services (CMS), an enrollee or their designee must receive a *Notice of Medicare Non-coverage (NOMNC)* no later than two days prior to termination of inpatient subacute and inpatient skilled nursing facility rehabilitation services. Participating providers will provide the CDPHP NOMNC to enrollees, which includes completion of valid delivery, faxing a copy to CDPHP, and maintaining a copy in the enrollee's medical record upon

	completion of services. In accordance with guidelines from the Centers for Medicare & Medicaid Services (CMS), an enrollee or their designee must receive an *Important Message (IM)* no later than two days prior to termination of inpatient acute rehabilitation services. Participating providers will provide the CDPHP IM to enrollees, which includes completion of valid delivery, faxing a copy to CDPHP, and maintaining a copy in the enrollee's medical record upon completion of services.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. Medicare Guidelines, Skilled nursing Facility Manual Chapter 2 Section 214.5. "Daily Skilled Services Defined".
2. Medicare Managed Care Manual, Chapter 13: Medicare Managed Care Beneficiary Grievances, Organization Determinations, and Appeals Applicable to Medicare Advantage Plans, Cost Plans, and Health Prepayment Plans, Section 90.3: Notice of Medicare Non-Coverage (NOMNC), 9/21/07.
3. Center for Medicare Advocacy, Grijalva v. Shalala, https://medicareadvocacy.org/grijalva-v-shalala/
4. Griffin, Kathleen: Subacute Care. Best Practices in Medical Management, 1998 pp. 283-285.
5. Rockville (MD): Post-stroke Rehabilitation. U.S. Department of Health and Human Services, Public Health Service, AHCPR; 1995 May. 248 (Clinical practice guideline; no.16).

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POLICY APPROVAL DATES

New:	02/99
Revised:	12/00, 01/03, 11/03, 06/04, 09/04, 03/05, 04/06, 07/08, 07/10, 07/11, 07/12, 07/14, 11/15, 07/16, 09/16, 07/17, 07/20, 11/21, 3/22, 7/23
Reviewed:	02/01, 03/07, 03/08, 07/09, 07/13, 07/15, 07/18, 7/19, 7/21, 7/22, 7/24, 7/25, 7/26

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: INPATIENT PHYSICAL REHABILITATION: ACUTE, SUBACUTE & SKILLED

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
8/1/2023	Under Skilled Nursing Level 1 Criteria, added the following condition: • daily skilled wound care
1/1/22* *No change to effective date for this update	Added criteria for skilled nursing to the Position Statement.
1/1/22	Removed reference to MCG guidelines and replaced with InterQual.
11/1/20	Removed reference to obsolete Cognitive Rehabilitation policy. Removed section for small group/individual plans from Product Variations section.

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MEDICAL POLICY

Medical Policy Title	**Interfacility Transfer of a Registered Inpatient**
Policy Number	**11.01.18**
Current Effective Date	**November 1, 2026**
Next Review Date	**March 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

This medical policy does not address the coverage of transportation of a registered inpatient but rather addresses the transferred admission of the patient from one acute care facility to another acute care facility.

POLICY STATEMENT(S)

I. Interfacility transfer of a registered inpatient from one acute care facility to another acute care facility, to obtain necessary, specialized diagnostic and/or therapeutic services is considered **medically appropriate** and, therefore, both hospital stays are eligible for coverage when **BOTH** criteria are met:

   A. The necessary diagnostic and/or therapeutic services are not available in the facility in which the patient is registered; **and**

   B. The provider of the necessary service(s) is the participating facility nearest to the facility in which the patient is currently admitted that has the required capabilities for providing the necessary services.

II. Interfacility transfers for any other reasons are considered **not medically necessary** and, therefore, admission to the receiving facility is **not eligible for coverage**.

III. If a newborn is transferred to a second facility for a higher level of care, then the transfer of the mother will be considered **medically necessary** unless the mother's medical status is such that her medical discharge is anticipated within 24 hours. (Refer to Policy Guideline I for additional information.)

RELATED POLICIES

Corporate Medical Policy

10.01.07 Ambulance: Land/Ground

11.01.06 Ambulance: Air

POLICY GUIDELINE(S)

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

I. If a newborn has been transferred to a second facility for medically necessary tertiary care that the birth facility is unable to provide, then the interfacility transfer of the newborn to return to the birth hospital will be **eligible for coverage** when:

   A. The newborn has completed tertiary care according to the InterQual® Level of Care Criteria Acute Pediatric for Level III or Level IV NICU care; and the criteria of 1 **AND** 2 **OR** 3 are met:

      1. The birth hospital is greater than 50 miles/one (1) hour driving time from the tertiary care facility;

         AND

      2. It is anticipated that the newborn will remain in the receiving facility for at least three (3) days for convalescent care;

         OR

      3. Bed space is needed in the tertiary care facility, and the newborn can be safely cared for in the receiving acute hospital.

   Note: Please contact your local Customer (Member/Provider) Service Department to determine specific regional interfacility newborn transfer requirements.

II. Coverage is not available for elective or convenience interfacility transfers (e.g., transferring a patient back to the originating facility when not medically necessary).

III. The receiving facility in an interfacility transfer should be the nearest participating facility that can provide the necessary care, unless there are extenuating circumstances. In the case of inability, lack of capacity, or refusal of the nearest participating facility to accept the patient, the patient should then be transferred to the next nearest participating facility that can provide the necessary care. Review by a Health Plan Medical Director is required in these circumstances.

IV. Prior authorization for interfacility transfer is contract-dependent, and, where a member's subscriber contract requires, authorization must be obtained prior to transfer of the patient. Some members' subscriber contracts exclude coverage for the transfer of a member between health care facilities.

V. Accepting the transfer of a registered inpatient from another facility through the emergency room, when the patient is not in need of emergent services, does not negate the requirement for prior authorization of the transfer if the member contract requires prior authorization for inpatient admissions.

VI. The transfer of a registered inpatient to another facility for a diagnostic procedure that is designated by the Health Plan as an outpatient procedure, is not considered an interfacility transfer if it does not meet the InterQual® Acute Inpatient Level of Care Criteria.

VII. Hospital contracts with some health care systems provide for only one diagnostic related group (DRG) payment, irrespective of the number of facilities in which the patient becomes registered. Intra-system transfers with one DRG payment do not require prior authorization.

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VIII. A medically necessary determination for the interfacility transfer service of a registered inpatient to another facility does not automatically translate to an approval for transportation. A clinical review of the mode of ambulance transport service (air or land/ground) to the specified facility should also be performed in accordance with the applicable Corporate Medical Policy.

DESCRIPTION

Interfacility, or interhospital, transfer of a registered inpatient involves the transfer of a registered hospital inpatient to another acute care facility, to obtain medically necessary, specialized diagnostic or therapeutic services.

For an interfacility transfer to occur, the transferring physician should ensure that all required documentation relating to the transfer of patients is completed.

SUPPORTIVE LITERATURE

Not Applicable

PROFESSIONAL GUIDELINE(S)

Not Applicable

REGULATORY STATUS

Not Applicable

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
Multiple codes	

REFERENCES

Altieri Dunn SC, et al. SafeNET: Initial development and validation of a real-time tool for predicting mortality risk at the time of hospital transfer to a higher level of care. PLoS One. 2021 Feb 8; 16(2):e0246669.

Mueller S, et al. Inter-hospital transfer and patient outcomes: a retrospective cohort study. BMJ Qual Saf. 2019 Nov;28(11):e1.

Tanenbaum J, et al. Quantifying health insurance eligibility impact on interhospital transfers of injured patients: Evidence from the affordable care act's dependent coverage provision. Surgery 2025;178:108921.

White MJ, et al. Interfacility transfers among patients with complex chronic conditions. Hosp Pediatr. 2020 Feb;10(2):114-122.

SEARCH TERMS

Inpatient Transfer

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Interfacility Transfers of Registered Inpatients are not addressed in National or Regional Medicare coverage determinations or policies.

However, a payment formula is located in the National Archives and Records Administration. Code of Federal Regulations. (Chapter IV, Part 412.4./Prospective payment systems for inpatient hospital services. Discharges and transfers.) Available at: eCFR : 42 CFR Part 412 -- Prospective Payment Systems for Inpatient Hospital Services [accessed 2026 Feb 5]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.

- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 7/26 **Revised**: **Reviewed**:	
Date	**Summary of Changes**
11/1/2026	• New

MEDICAL POLICY

Medical Policy Title	**Interventional Pain Management for Managed Medicaid (MMC), Health and Recovery Plan (HARP), Child Health Plus (CHP), and Essential Plan (EP) Members**
Policy Number	**7.01.122**
Current Effective Date	**January 1, 2027**
Next Review Date	**September 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

SECTION LINKS

Epidural Steroid Injection (ESI)
- Initial
- Repeat

Selective Nerve Root Block (SNRB)
- Diagnostic

Facet Joint Injection/ Medial Branch Blocks
- Initial
- Repeat
- Alternative to Radiofrequency Ablation/Neurotomy

Radiofrequency neurolysis (denervation/ablation)
- Initial
- Repeat

Sacroiliac Joint Injection
- Diagnostic
- Therapeutic
- Repeat

POLICY STATEMENT(S)

Initial Epidural Steroid Injection (ESI)

I. An initial ESI (caudal, interlaminar, or transforaminal) is considered **medically appropriate** when documentation meets **ALL** the following:

   A. The individual is diagnosed with **ANY** of the following:

      1. Degenerative lumbar spondylolisthesis with neurological findings and/or deficits (e.g., back pain, leg pain, motor weakness);

2. Failed back surgery syndrome (FBSS) or epidural fibrosis; **or**
3. Spinal stenosis (foraminal, central, or disc disease);

B. Pain-related symptoms meet **all** the following:

1. Radicular pain, acute or chronic, with or without motor weakness;
2. Pain causes a functional impairment;
3. A minimum of 6 weeks of conservative management during the previous 6 months failed, or was not tolerated, and includes **BOTH** of the following:
   a. Non-pharmacologic management with **either**:
      i. Chiropractic care; **or**
      ii. Supervised physical therapy (PT); **and**
   b. Pharmacological management with **either**:
      i. Medication directed at the underlying disease process; **or**
      ii. Oral analgesics;

II. An initial ESI is considered **not medically necessary** for **ANY** of the following contraindications:

A. Allergy or hypersensitivity to any component of the injectate;
B. Local infection at the planned injection;
C. Systemic infection;
D. Infectious spondylosis;
E. Uncontrolled bleeding or clotting disorder;
F. Malignancy involving the planned injection site;
G. Pregnancy; **or**
H. Refusal of the procedure by the individual or legally authorized representative;
I. ESI will be performed under computed tomography (CT) or fluoroscopic guidance.

<u>Repeat ESI</u>

III. A repeat ESI (caudal, interlaminar, or transforaminal) is considered **medically appropriate** when documentation meets **ALL** the following:

A. Active engagement in non-surgical conservative management with chiropractic care or supervised PT, unless intolerance due to pain is documented;
B. Pain and/or functional impairment persist;
C. Performed for **either** of the following scenarios:

1. For diagnostic injections(s), with/without steroids, when **both** of the following are met:
    a. No more than two (2) injections in total have been performed; **and**
    b. It has been at least 2 weeks between injections; **or**
2. For therapeutic injections, when **all** the following are met:
    a. No more than four (4) injections have been performed per year, per spinal region;
    b. It has been at least 10 weeks between injections;
    c. A minimum of 50% reduction in pain was a result of the previous injection; **and**
    d. Pain relief lasted for a minimum of 10 weeks.

IV. A repeat ESI is considered **not medically necessary** for **ANY** of the following contraindications:

A. Allergy or hypersensitivity to any component of the injectate;
B. Local infection at the planned injection site;
C. Systemic infection;
D. Infectious spondylosis;
E. Uncontrolled bleeding or clotting disorder;
F. Malignancy involving the planned injection site;
G. Pregnancy; **or**
H. Refusal of the procedure by the individual or legally authorized representative.

<u>Selective Nerve Root Block (SNRB)</u>

V. A diagnostic selective nerve root block (SNRB) is considered **medically appropriate** when documentation meets **ALL** the following:

A. Performed at one (1) or more spinal levels;
B. Anesthetic injectate only is used;
C. Performed to assist in establishing a diagnosis of radicular pain (e.g., radiculitis, radiculopathy) when there is no known pain diagnosis;
D. Completed diagnostic evaluation includes **one (1) or more** of the following:
    1. Neurological examination;
    2. Electrodiagnostic testing; **or**
    3. Relevant imaging studies;
E. Documentation of **either** of the following:
    1. Clinical findings are suggestive of nerve root pathology; **or**

2. Performed for preoperative planning.

VI. SNRB is considered **not medically necessary** for **ANY** of the following contraindications:

A. Allergy or hypersensitivity to any component of the injectate;

B. Local infection at the planned injection;

C. Systemic infection;

D. Infectious spondylosis;

E. Uncontrolled bleeding or clotting disorder;

F. Malignancy involving the planned injection site;

G. Pregnancy; **or**

H. Refusal of the procedure by the individual or legally authorized representative.

Initial Facet Joint Injections (FJI) and/or Medial Branch Blocks (MBB)

VII. An initial FJI (cervical, thoracic or lumbar) or MBB are considered **medically appropriate** when the documentation meets **ALL** the following:

A. Pain-related symptoms meet **all** the following:

1. Persistent for a minimum of 12 weeks;
2. Pain causes a functional impairment;
3. Non-radicular (cervical, thoracic or lumbar);

B. A minimum of 6 weeks of conservative management, unless contraindicated, during the previous 6 months failed or was not tolerated, including **both** of the following:

1. Non-pharmacologic management with **either**:
   a. chiropractic care; **or**
   b. supervised physical therapy (PT); **and**
2. Pharmacological management with **either**:
   a. Medication directed at the underlying disease process; **or**
   b. Oral analgesics;

C. The procedure will be performed under computed tomography (CT) or fluoroscopic guidance.

VIII. An initial FJI or MBB is considered **not medically necessary** for **ANY** of the following contraindications:

A. Allergy to any component of the injectate;

B. Uncontrolled bleeding or clotting disorder;

C. Active infection;

D. Pregnancy when ultrasound guidance is not available; **or**

E. History of spinal fusion at the same level.

Repeat FJI/MBB

IX. A repeat FJI or MBB are considered **medically appropriate** when the documentation meets **ALL** the following:

A. Performed at the same level as the initial block;

B. Performed for **either** of the following scenarios:

1. For diagnostic injections(s) when **all** the following are met:

a. No more than two (2) injections per region;

b. A minimum of 70% reduction in pain was a result of the initial injection;

c. A minimum of 6 weeks of conservative management during the previous 6 months failed or was not tolerated, including **BOTH** the following:

i. Non-pharmacologic management with **either**:

a) chiropractic care; **or**

b) supervised physical therapy (PT); **and**

ii. Pharmacological management with **either**:

c) Medication directed at the underlying disease process; **or**

d) Oral analgesics;

2. For therapeutic injections, when **all** the following are met:

a. No more than three (3) injections per region performed in a 12-month period;

b. A minimum of 50% pain relief from the prior injection;

c. Pain relief lasted for a minimum of 3 months; and

d. Active engagement in non-surgical conservative management with chiropractic care or supervised PT, unless intolerance due to pain is documented;

X. A repeat FJI or MBB is considered **not medically necessary** for **ANY** of the following contraindications:

A. Allergy to any component of the injectate;

B. Uncontrolled bleeding or clotting disorder;

C. Active infection;

D. Pregnancy when ultrasound guidance is not available; **or**

E. History of spinal fusion at the same level.

FIJ/MSS as an Alternative to Radiofrequency Ablation/Neurotomy

XI. FJI/MBB as an alternative to radiofrequency ablation/neurotomy is considered **medically appropriate** when documentation meets **ALL** of the following:

A. Significant pain relief (e.g., greater than 50%) was a result of the initial FJI/MBB;

B. Pain relief lasted a minimum of 12 weeks;

C. Radiofrequency denervation/ablation is not appropriate due to **ANY** of the following:

1. Implanted cardiac device (e.g., pacemaker, defibrillator);
2. Prior diagnostic injection positive outcomes support continued injection-based therapy;
3. Continued anticoagulation therapy is required; **or**
4. Young athletes for whom alternative treatment options are preferred based on long-term considerations;

XII. FJI/MBB as an alternative to radiofrequency ablation/neurotomy is considered **not medically necessary** for **ANY** of the following contraindications:

A. Allergy to any component of the injectate;

B. Uncontrolled bleeding or clotting disorder;

C. Active infection;

D. Pregnancy when ultrasound guidance is not available; **or**

E. History of spinal fusion at the same level.

Initial Radiofrequency Neurolysis, Paravertebral Facet Joint/Medial Branch Transection

XIII. Initial radiofrequency neurolysis (denervation/ablation) of a paravertebral facet joint or medial branch transection is considered **medically appropriate** when the documentation meets **ALL** the following:

A. There is no evidence from the clinical assessment, diagnostic evaluation, or imaging studies of an alternative pain generator (e.g., central spinal stenosis, foraminal stenosis, disc herniation, fracture, infection, spinal instrumentation, pseudoarthrosis, or neoplastic disease);

B. Pain-related symptoms meet **all** the following:

1. Persistent for a minimum of 3 months;
2. Pain causes a functional impairment;
3. A minimum of 6 weeks of conservative management during the previous 6 months failed or was not tolerated, including **ALL** of the following:

a. Non-pharmacologic management with **either**:
    i. chiropractic care; **or**
    ii. supervised physical therapy (PT); **and**
b. Pharmacological management with **either**:
    i. Medication directed at the underlying disease process; **or**
    ii. Oral analgesics;

C. No more than two (2) diagnostic facet joint injections/medial branch blocks have been performed;

D. Previous diagnostic facet joint injections/medial branch blocks provided significant reduction in pain or functional improvement for at least the expected duration of the anesthetic utilized; The procedure will be performed under computed tomography (CT), fluoroscopic, or ultrasound guidance.

XIV. Initial radiofrequency neurolysis (denervation/ablation) of a paravertebral facet joint or medial branch transection is considered **not medically necessary** for **ANY** of the following contraindications:

A. Active infection;

B. Coagulopathy;

C. Myopathy, acquired or congenital;

D. Neuromuscular disease, including but not limited to amyotrophic lateral sclerosis (ALS);

E. Pregnancy; **or**

F. Previous spinal fusion at the same level.

<u>Repeat Radiofrequency Neurolysis, Paravertebral Facet Joint/Medial Branch Transection</u>

XV. Repeat radiofrequency joint neurolysis/medial branch transection (denervation/ablations) is considered **medically appropriate** when documentation meets **ALL** the following:

A. No more than two (2) procedures per spinal region during a 12-month period;

B. At least 6 months since the previous denervation/ablation at the same level;

C. Recurrence of pain after previously successful denervation/ablation;

D. Active engagement in non-surgical conservative management with chiropractic care or supervised physical therapy, unless intolerance due to pain is documented.

XVI. Repeat radiofrequency joint neurolysis/medial branch transection (denervation/ablations) is considered **not medically necessary** for **ANY** of the following contraindications:

A. Active infection;

B. Coagulopathy;

C. Myopathy, acquired or congenital;

D. Neuromuscular disease, including but not limited to amyotrophic lateral sclerosis (ALS);

E. Pregnancy; **or**

F. Previous spinal fusion at the same level.

Sacroiliac Joint Injection - Diagnostic

XVII. A diagnostic sacroiliac joint injection is considered **medically appropriate** when documentation meets **ALL** of the following:

A. At least one (1) sacroiliac provocative test is positive;

B. Pain-related symptoms meet **ALL** the following:

1. Unilateral non-radicular pain localized over the sacroiliac joint below the L5 level;
2. Persistent for a minimum of 3 months;
3. A minimum of 6 weeks of conservative management, unless contraindicated, during the previous 6 months failed, including **both** of the following:
    a. Non-pharmacologic management with **either**:
        i. chiropractic care; **or**
        ii. supervised physical therapy (PT); **and**
    b. Pharmacological management includes **either**:
        i. Medication directed at the underlying disease process; or
        ii. Oral analgesics;

C. Injection will be performed under computed tomography (CT) or fluoroscopic guidance.

XVIII. A diagnostic sacroiliac joint injection is considered **not medically necessary** for **ANY** of the following contraindications:

A. Allergy to any component of the injectate;

B. Uncontrolled bleeding or clotting disorder;

C. Active infection; **or**

D. Pregnancy.

Sacroiliac Joint Injection - Therapeutic

XIX. A therapeutic sacroiliac injection for sacroiliac joint pain is considered **medically appropriate** when documentation meets **ALL** the following:

A. A minimum of 50% reduction in pain was a result of the diagnostic injection;

B. Active engagement in non-surgical conservative management with chiropractic care or supervised PT, unless intolerance due to pain is documented;

C. Pain causes a functional impairment.

XX. A therapeutic sacroiliac injection for sacroiliac joint pain is considered **not medically necessary** for **ANY** of the following contraindications:

A. Allergy to any component of the injectate;

B. Uncontrolled bleeding or clotting disorder;

C. Active infection; **or**

D. Pregnancy.

Sacroiliac Joint Injection - Repeat

XXI. Repeat sacroiliac injection(s) are considered **medically appropriate** when documentation meets **ALL** of the following:

A. Active engagement in non-surgical conservative management with chiropractic care or supervised PT, unless intolerance due to pain is documented;

B. Injection(s) will be performed under computed tomography (CT) or fluoroscopic guidance;

C. Performed for **either** of the following scenarios:

1. For diagnostic injections(s) when **both** the following are met:
    a. No more than two (2) injections per region; **and**
    b. The result of the initial injection was less than 75% reduction in pain; **or**
2. For therapeutic injections, when **all** the following are met:
    a. No more than four (4) injections per region performed in a 12-month period;
    b. A minimum of 50% pain relief from the initial injection;
    c. Pain relief lasted for a minimum of two (2) months; **and**
    d. Active engagement in non-surgical conservative management with chiropractic care or supervised PT, unless intolerance due to pain is documented.

XXII. Repeat sacroiliac injection(s) are considered **not medically necessary** for **ANY** of the following contraindications:

A. Allergy to any component of the injectate;

B. Uncontrolled bleeding or clotting disorder;

C. Active infection; **or**

D. Pregnancy.

RELATED POLICIES

Corporate Medical Policy

7.01.124 Intraosseous Basivertebral Nerve Ablation for Safety Net Members

7.01.126 Spine Procedures for Safety Net Members

POLICY GUIDELINE(S)

I. If an individual demonstrates improvement during the initial 6 weeks of PT, an additional 6 weeks of PT should be attempted prior to interventional pain management.

II. Relative contraindications to ESI (caudal, interlaminar, transforminal) include **any** of the following:

   A. Acute spinal cord compression;

   B. Cauda equina syndrome or myelopathy;

   C. Chronic immunosuppression;

   D. Uncontrolled medical comorbidity(ies);

   E. Clinical improvement to conservative management; **or**

   F. For interlaminar ESI only: severe spinal stenosis.

DESCRIPTION

Definitions to support interventional pain management criteria:

- Activities of daily living (ADLs) refer to routine self-care activities required for independent daily functioning, including bathing, dressing, eating, toileting, and transferring between surfaces such as a bed and chair.
- Cauda equina syndrome is a neurologic emergency caused by compression of the lumbosacral nerve roots and may present with bowel or bladder dysfunction, saddle sensory changes, and motor or sensory deficits involving the lower extremities.
- Caudal epidural steroid injection (CESI) is a procedure in which contrast material (when not contraindicated), corticosteroid, and optionally a local anesthetic are introduced into the epidural space through the sacral hiatus under fluoroscopic guidance.
- Compression test is a sacroiliac joint provocation maneuver performed with the individual lying on their side, in which the examiner applies downward (vertical) pressure over the uppermost iliac crest/hip to compress the pelvis and stress the sacroiliac joints, assessing for reproduction of sacroiliac joint pain.
- Conservative management refers to non-surgical treatment strategies used to manage spinal pain and related conditions and may include physical therapy, medication therapy, chiropractic care, and other non-operative interventions.

- Distraction test is a sacroiliac joint provocation maneuver in which outward pressure is applied across the pelvis to place stress on the sacroiliac joints and assess for symptom reproduction.
- Electrodiagnostic testing refers to neurophysiologic studies used to evaluate the function of peripheral nerves, muscles, and related neuromuscular structures.
- Epidural fibrosis refers to scar tissue formation adjacent to a spinal nerve root, most commonly occurring following spinal surgery.
- Epidural steroid injection (ESI) involves administration of a corticosteroid into the epidural space surrounding a spinal nerve root as a diagnostic and/or therapeutic intervention for radicular pain. Epidural injections may be performed using interlaminar, transforaminal, or caudal approaches.
- Flexion, abduction, and external rotation (FABER) Test, also known as Patrick's Test, is a provocative examination maneuver used in the assessment of pathology involving the hip, lumbar spine, or sacroiliac joint.
- Facet joint injections/medial branch blocks refer to the injection of local anesthetic, with or without corticosteroid, into a facet joint or along the medial branch nerves supplying the joint for the evaluation and treatment of facet-mediated pain.
- Failed back surgery syndrome (FBSS) describes persistent or recurrent pain following spinal surgery despite completion of the surgical procedure.
- Fluoroscopy is a real-time X-ray imaging modality that allows visualization of internal structures and procedural instruments during diagnostic and therapeutic interventions.
- Foraminal stenosis refers to narrowing of the neural foramen that may lead to irritation or compression of an exiting spinal nerve root.
- Gaenslen's test is a sacroiliac joint provocation maneuver that places stress across the pelvis and sacroiliac joint to assist in identifying pain arising from that region.
- Glucocorticosteroid refers to a class of medications commonly used for their anti-inflammatory and immunosuppressive properties.
- Immunosuppression refers to reduced immune system function resulting from disease, medication, or therapeutic intervention.
- Interlaminar epidural steroid injection (ILESI) is a procedure in which contrast material (when not contraindicated), corticosteroid, and optionally a local anesthetic are delivered into the epidural space through an interlaminar approach under imaging guidance.
- Log roll test is a physical examination maneuver used primarily to evaluate for pathology arising from the hip joint.
- Medial branch transection, also known as endoscopic rhizotomy, is a surgical or endoscopic division of the medial branch nerves supplying the facet joints for the treatment of facet-mediated pain.
- Myasthenia Gravis is an autoimmune neuromuscular disorder characterized by fluctuating

skeletal muscle weakness resulting from impaired transmission at the neuromuscular junction.

- Myopathy refers to a disorder of muscle tissue characterized primarily by muscle weakness and, in some cases, cramping, stiffness, or pain.
- Nerve root disease, also referred to as radiculopathy, involves irritation or compression of a spinal nerve root that may result in pain, sensory disturbance, and/or motor dysfunction within the affected distribution.
- Neurotomy refers to the intentional interruption or division of a nerve for therapeutic purposes.
- Non-radicular pain refers to pain that is not caused by irritation or compression of a spinal nerve root and generally occurs without objective neurologic findings suggestive of radiculopathy.
- Paravertebral facet joints, also known as zygapophyseal joints or Z-joints, are articulations between adjacent vertebrae that may serve as a source of chronic spinal pain.
- Provocative test refers to a diagnostic maneuver designed to reproduce or exacerbate symptoms associated with a suspected condition.
- Pseudoarthrosis refers to failure of bony fusion following an attempted spinal fusion procedure.
- Radicular means relating to, involving, or arising from a spinal nerve root.
- Radiculitis refers to inflammation or irritation of a spinal nerve root that may result in pain and sensory symptoms.
- Radiculopathy refers to signs and symptoms caused by compression or irritation of a spinal nerve root, including pain, numbness, tingling, and/or weakness.
- Radiofrequency joint denervation/ablation refers to a minimally invasive procedure that uses thermal energy delivered through a radiofrequency probe to disrupt sensory nerve supply to a painful facet joint with the goal of reducing pain.
- Sacral thrust test is a sacroiliac joint provocation maneuver in which pressure is applied over the sacrum to reproduce symptoms arising from the sacroiliac joint.
- Sacroiliac (SI) joint injections involve administration of local anesthetic, with or without corticosteroid, into the sacroiliac joint for diagnostic evaluation and/or treatment of sacroiliac joint-mediated pain.
- Selective nerve root block (SNRB) is a diagnostic procedure in which anesthetic is injected around a specific spinal nerve root under imaging guidance to assist in identifying the symptomatic nerve root and/or for surgical planning.
- Spinal cord compression occurs when pressure on the spinal cord impairs normal neurologic function.
- Spinal instrumentation refers to surgically implanted devices, such as rods, screws, hooks, or wires, used to stabilize and support the spine.
- Spinal stenosis is a condition characterized by narrowing of the spinal canal and/or neural

foramina that may result in compression of neural structures.

- Spondylitis refers to inflammation involving the vertebrae or spinal joints.
- Spondylolisthesis refers to forward displacement of one vertebral body relative to the vertebra below it.
- Thigh thrust test is a sacroiliac joint provocation maneuver in which force is transmitted through the femur to stress the sacroiliac joint and reproduce symptoms.
- Transforaminal epidural steroid injection (TFESI) is a procedure in which contrast material (when not contraindicated), corticosteroid, and optionally a local anesthetic are introduced into the epidural space through the neural foramen under imaging guidance.

SUPPORTIVE LITERATURE

Epidural spinal injection (ESI) is one of several therapies available for people who fail conservative treatment, and is a common modality used for radicular pain and lumbar referred pain with several potentially painful conditions (e.g., neurogenic claudication) associated with degenerative or isthmic spinal stenosis.

Buenaventura et al (2009) conducted a systematic review to evaluate the effectiveness of lumbar TFESIs in managing chronic radicular pain. Of the four randomized, controlled trials evaluating TFESIs, all showed positive results for short-term relief. Two studies were positive for long-term relief; the results for long-term relief were not available for the third study, and the fourth study had negative long-term relief results.

Novak et al (2008) conducted a systematic review to evaluate the evidence in support of guidelines on frequency and timing of epidural steroid injections, to help determine what sort of response should occur to repeat an injection. The review included 11 randomized, controlled trials, one prospective controlled trial, and two prospective cohort studies. The authors concluded that there is limited evidence to suggest guidelines for frequency and timing of epidural steroid injections or to help define an appropriate partial response that would trigger a repeat injection. Research suggests that repeat injections may improve outcomes, but conclusions cannot be made due to methodological limitations of the available evidence. The authors further concluded that there does not appear to be any evidence to support the common practice of a series of injections.

Parr et al (2012) conducted a systematic review evaluating the effect of caudal epidural injections with or without steroids in managing various types of chronic low back and lower extremity pain, produced good evidence for short- and long-term relief of chronic pain secondary to disc herniation or radiculitis with local anesthetic and steroids, and fair relief with local anesthetic only. Further, this systematic review also provided only fair evidence for caudal epidural injections in managing chronic axial or discogenic pain, spinal stenosis, and post-surgery syndrome.

<u>Lumbar Radiculopathy</u>

In a Cochrane review, Oliveira et al (2020) published a systematic review and meta-analysis of 25 placebo-controlled randomized trials (n=2,470) evaluating the efficacy and safety of epidural

corticosteroid injections for lumbosacral radicular pain. Moderate-quality evidence indicated that epidural corticosteroid injections were slightly more effective than placebo in reducing short-term leg pain and short-term disability (95% CI). However, the treatment effects were small and may not be considered clinically important (i.e., mean difference lower than 10%). Epidural corticosteroid injections were not more effective than placebo for reducing leg pain at intermediate or long-term follow-up. Adverse events were mostly minor (e.g., headache, accidental dural puncture, worsening pain), with no significant difference between groups. The authors concluded that the available evidence provides only limited support for the use of epidural corticosteroid injections in lumbosacral radicular pain, as benefits are small and largely confined to the short term.

Verheijen et al (2021) conducted a meta-analysis of 17 RCTs comparing ESI to epidural or nonepidural placebo in patients with sciatica. Studies were eligible for inclusion in the meta-analysis if they provided data on sciatica patients (any level of pain, any duration of symptoms, and any prior therapy). For back pain, ESI was not significantly more effective than epidural placebo at 6 weeks (p=.14), 3 months (p=.95), or 6 months (p=.53). GRADE quality of evidence was moderate at 6 weeks, very low at 3 months, and low at 6 months. When compared to nonepidural placebo, ESI resulted in greater relief of back pain at 3 months (p=.02) but not at 6 weeks or 6 months (quality of evidence: moderate). Based on low-quality evidence, leg pain was significantly improved with ESI compared to epidural placebo at 6 weeks (p<.01) and 3 months (p=.04), but not at 6 months (p=.31). In a sensitivity analysis adjusting for heterogeneity, leg pain was significantly improved with ESI compared to epidural placebo at all time points. Compared to nonepidural placebo, ESI did not significantly improve leg pain at any time point (quality of evidence: low to moderate). Functional status was significantly improved with ESI versus epidural placebo at 6 weeks (p<.01), but between-group differences were not significant at 3 months or 6 months (quality of evidence: moderate at 6 weeks, low at 3 months, and very low at 6 months). Compared to nonepidural placebo, ESI did not significantly improve functional status at any time point (quality of evidence: moderate). The patient population included in this review was not well-defined; therefore, it is unclear whether certain subpopulations may obtain greater benefit from ESI. Other limitations of the review include the relatively small number of studies available (particularly for the back pain outcome analyses and all comparisons between ESI and nonepidural placebo), the unclear clinical importance of the outcomes, and the variation in treatment success definitions across studies.

Cervical Radiculopathy

Cohen et al (2014) reported the results of an RCT that compared ESI, conservative treatment, and a combination of both for patients with cervical radiculopathy. A total of 169 patients were randomized to conservative care (physical therapy plus medications), ESIs, or a combination of both treatments. The primary outcomes were neck and arm pain measured at 1- and 3- months posttreatment. There were no differences noted between ESI and conservative care on any of the outcome measures. The group receiving combination therapy had a greater reduction in arm pain at 1 month compared with the two individual treatments and had a greater success rate at 3 months (56.9% vs. 26.8%, p=.006).

Borton et al (2022) performed a systematic review of cervical transforaminal ESIs for cervical

radiculopathy. The review included six studies (3 RCTs and 3 observational studies; n=443). None of the included studies directly compared cervical transforaminal ESIs with other treatment options or placebo. Short-term (4 to 8 weeks) decreases in pain scores following injection varied greatly both within and between the six studies, and mean reduction in pain scores ranged from 18% to 70%. Four studies reported on longer-term pain relief (> 8 weeks), and mean reduction in pain scores ranged from 33% to 73%; however, there was a significant number of patients lost to follow-up in these studies.

Spinal Stenosis

Schneider et al (2019) published the results of a 3-arm RCT comparing the clinical effectiveness of medical care (n=88), group exercise (n=84), and manual therapy/individualized exercise (n=87) in patients with lumbar spinal stenosis. Treatment in the medical care group consisted of medications and/or ESI provided by a physiatrist. Study limitations include failure to disclose the proportion of patients in the medical care group that received ESI during the course of the study, excluding patients <60 years of age, and no direct reporting of pain outcomes. The primary outcomes were symptoms and physical function as measured by the patient-reported Swiss Spinal Stenosis (SSS) score. The SSS score ranges from 12 to 55 points, with higher scores indicating higher levels of self-reported disability. Analyses at 2 months indicated that manual therapy/individualized exercise demonstrated greater reduction in SSS score compared to medical care or group exercise. The magnitude of the difference in the reduction of SSS score between groups did not reach the level of a minimal clinically important difference of 3.02 points.

Failed Back Surgery Syndrome

The evidence is insufficient to determine that ESI results in an improvement in the net health outcome for individuals with failed back surgery syndrome (FBSS), also known as persistent spinal pain syndrome (PSPS) or post-laminectomy syndrome.

Celenlioglu et al (2022) investigated the efficacy of caudal epidural steroid injection (CESI) versus transforaminal epidural steroid injection (TFESI) in patients with post lumbar surgery syndrome (PLSS). In a prospective, randomized, assessor-blind study, a total of 56 patients (n = 26 CESI group; n = 30 TFESI group) were randomized and assessed at baseline, 1-hour, 3-weeks, and 3-months after the procedure. Treatment success was defined as a ≥ 50% decrease in the Numeric Rating Scale (NRS-11) scores compared to baseline. NRS-11 and modified Oswestry Disability Index (mODI) scores showed a significant decline in both groups at all follow-ups ($p < 0.001$). At 3 weeks, the improvement in the mODI scores was significantly higher in the TFESI group ($p = 0.020$). In all follow-ups, the NRS-11 scores were similar between the groups. At 3 weeks, the rates of patients with a ≥ 50% decrease in NRS-11 scores were 53.8% and 60% in the CESI group and TFESI group, respectively, while these rates were 30% and 26.7%, respectively, at 3 months. Although both CESI and TFESI were effective and safe methods in the treatment of PLSS caused by EF following lumbar discectomy, the study was limited by the lack of a placebo-controlled group and a short follow-up period.

Herpes Zoster Associated Pain (Active and Postherpetic Neuralgia)

A single case report described complete resolution of thoracic postherpetic neuralgia symptoms at 2- and 12-week follow-up after a transforaminal ESI (Mehta 2015); however, case-level evidence is insufficient to draw conclusions about efficacy.

Fujiwara et al (2018) conducted a randomized prospective trial comparing transforaminal (TF) and interlaminar (IL) epidural steroid injection approaches in patients (n=40) with acute-phase shingles. Patients were evaluated at baseline, 1 month, and 3 months using VAS and SF-36 scores. VAS scores at 1- and 3-month follow-up were significantly lower than baseline in both groups, with no significant difference between approaches. SF-36 scores and PHN incidence (defined as VAS >40 at 3 months) were also not significantly different between groups. The study was limited by a small sample size that did not meet power analysis requirements and a short follow-up period. The authors concluded that both IL and TF approaches improved pain scores, but neither demonstrated superiority.

Ghanavatian et al (2019) conducted a retrospective review of 42 patients with PHN managed by ESI at Mayo Clinic campuses from 1997 through 2018. A total of 97% of patients were treated with interlaminar ESI. Patients who reported poor ESI efficacy at 2 weeks had a 94% chance of continued pain at 12 weeks. Conversely, of the 24 patients who reported moderate-to-good pain relief at 2 weeks, 79% had persistent relief at 12 weeks. PHN duration <11 months was predictive of moderate-to-good pain relief at 12 weeks (positive predictive value 55.2%). However, no patient characteristics, concurrent medications, or type of intervention were significantly associated with ESI efficacy. The study was limited by its retrospective design and small sample size.

Choi et al (2020) conducted a prospective, double-blind, randomized controlled trial comparing a single 5 mg epidural dexamethasone dose (group A) with intermittent repeated doses totaling 15 mg (group B) in patients (n=42) with zoster-associated pain (ZAP) beyond the acute phase (30–180 days after rash onset). The primary outcome was change in NRS pain score and the secondary outcome was complete remission of PHN. The percentage of patients with ≥50% pain reduction was not significantly different between groups ($p = 0.110$). However, complete remission of PHN was significantly higher in group B (80.95%) than group A (28.57%, $p = 0.001$). The study was limited by the lack of a placebo control group, small sample size, and exclusion of patients with well-established PHN (>180 days).

Chuang et al (2025) performed a systematic review and meta-analysis of 13 studies (9 RCTs [n=815] and 4 observational studies [n=253]) evaluating various nerve blocks for acute herpes zoster, including paravertebral blocks (PVB), erector spinae plane (ESP) blocks, epidural blocks, and intercostal nerve blocks. The meta-analysis of 6 RCTs showed that nerve blocks significantly reduced VAS pain scores at 4 weeks but not at 12 weeks. PVB and ESP blocks significantly decreased PHN incidence at 3 and 6 months. Notably, the four observational studies comparing epidural or intercostal nerve blocks with other techniques provided only weak evidence for their use, highlighting the need for more high-quality RCTs specifically evaluating epidural approaches for acute herpes zoster.

Ultrasound-Guided ESI

There is limited peer-reviewed literature regarding the overall health benefit of ultrasound guidance

during epidural steroid injections compared to fluoroscopy or CT guidance.

Jang et al (2020) conducted a retrospective comparative review of 122 patients to compare ultrasound (US)-guided selective nerve root block (SNRB; n=44), fluoroscopy (FL)-guided interlaminar cervical epidural steroid injection (IL-CESI; n=41), and FL-guided transforaminal CESI (TF-CESI; n=37) for radicular pain in the lower cervical spine. Neck Disability Index and pain scores improved at 1, 3, and 6 months in all groups, with no significant differences between groups. No intravascular contrast spread was observed in the US-guided group, compared with 2 patients in the FL-guided IL group and 7 in the FL-guided TF group. Despite the advantages of no radiation exposure and real-time visualization of soft tissue structures, the authors acknowledged that ultrasound technique is operator-dependent and cannot independently confirm the spinal level reached by the injectate.

Ahmed et al (2023) performed a meta-analysis of seven randomized controlled trials comparing ultrasonography (USG)-guided versus conventional fluoroscopy (FL)-guided ESIs for radiculopathy. There was no statistically significant difference in pain reduction between groups at the lumbosacral level at 1 month or 3 months. Functional improvement was also comparable between groups. USG guidance was associated with a significantly lower risk of inadvertent vascular puncture (OR 0.21; 95% CI 0.07–0.64) and shorter procedure time compared to FL guidance. There was no significant difference in the need for repeat ESIs between groups. Study limitations include heterogeneity due to inclusion of both cervical and lumbosacral levels, different epidural approaches, and different steroids used. The authors concluded that USG-guided ESIs are noninferior to FL-guided ESIs in terms of pain reduction and functional improvement.

Kimura et al (2023) conducted a systematic review and meta-analysis of 8 RCTs (n=962) to compare US-guided versus FL- or CT-guided spinal nerve injections. There was little to no difference in pain reduction or functional disability between groups. US guidance probably reduced major adverse events (0.7% vs 6.5%) and minor adverse events (2.1% vs 4.2%), and significantly reduced procedure time (MD −4.19 min; 95% CI −5.09 to −3.30). The authors concluded that US-guided injections remained effective while reducing adverse events compared to conventional guidance.

Injectates – Biologics (e.g., Platelet Rich Plasma, Stem Cells, Amniotic Fluid)

Sanapati et al (2018) conducted a systematic review and single-arm meta-analysis of the effectiveness of platelet-rich plasma (PRP) and mesenchymal stem cell (MSC) injections in managing low back and lower extremity pain. Twenty-one studies met inclusion criteria (12 lumbar disc injections, 5 epidural, 3 lumbar facet joint, and 3 sacroiliac joint studies). Disc injections of PRP and MSCs showed Level III evidence, while epidural, facet joint, and sacroiliac joint injections demonstrated Level IV evidence. The authors concluded that MSCs and PRP may be effective in managing discogenic low back pain, radicular pain, facet joint pain, and sacroiliac joint pain, but the evidence lacked high-quality randomized controlled trials.

Wang and Zhang (2025) conducted a systematic review and meta-analysis of 7 studies (4 RCTs and 3 prospective studies; n=416) comparing epidural PRP versus corticosteroid injection for lumbar radicular pain. Corticosteroids significantly reduced Oswestry Disability Index (ODI) scores at 4 weeks

(p = 0.0008), with no significant differences in VAS or ODI scores between groups at other time points. Complication rates were similar, though incomplete reporting may underestimate risks. The authors concluded that PRP did not demonstrate superior improvements over corticosteroid injections for lumbar radicular pain, while corticosteroids showed significant short-term functional improvement. The review was limited by low study quality and heterogeneity in PRP preparation methods.

Generally, the outcomes from clinical studies reflect that a diagnostic facet joint injection may assist in determining whether specific interventions targeting the facet joint are indicated.

Manchikanti et al (2015) stated that despite interventional procedures being common as treatment strategies for facet joint pathology, there is a paucity of literature investigating these therapeutic approaches. A systematic review and best evidence synthesis of the effectiveness of therapeutic facet joint interventions in managing chronic spinal pain was conducted to evaluate and update the clinical utility of therapeutic lumbar, cervical, and thoracic facet joint interventions in managing chronic spinal pain. A total of 21 randomized controlled trials (RCTs) and 5 observational studies were assessed. The limitations of this systematic review include an overall paucity of high-quality studies and the lack of investigations related to thoracic facet joint injections. Based on the present assessment for the management of spinal facet joint pain, the evidence for long-term improvement is Level II for therapeutic facet joint nerve blocks in the cervical, thoracic, and lumbar spine.

Wardhana et al (2022) acknowledge that a few studies have explored the effectiveness of facet interventions for chronic lumbar pain, but there has been no clear consensus of which procedures are more superior. In a meta-analysis, this study aimed to compare the effectiveness of corticosteroid injection (CI) and radiofrequency (RF) ablation for the treatment of lumbar facet joint (LFJ) pain. In total, 7 studies (n=552 patients) were included in the analysis. The corticosteroid agents were methylprednisolone in 4 trials, betamethasone in 2 trials, and dexamethasone in 1 trial. Pulsed RF was performed in 4 trials, whereas continuous RF was performed in 3 trials. Treatment with CI was associated with higher pain intensity score than RF ablation (3 trials; p < 0.00001), with substantial heterogeneity. Pain intensity scores at 6 months were significantly higher in patients treated with CI than RF ablation (7 trials, p = 0.0002), with substantial heterogeneity. The estimated effect of CI on pain intensity score at 12 months when CI was compared to RF ablation showed a statistically insignificant increase (p = 0.08), with substantial heterogeneity. Overall, the authors concluded that the pooled analysis from limited trials showed a benefit of RF to the improvement of pain intensity and functional disability when comparing RF with CI for the treatment of LFJ pain.

Pasuhirunnikorn et al (2023) evaluated the effect of prolonged concordant response and functional clinical improvement between lidocaine and bupivacaine for cervical medial branch block (CMBB) in chronic cervical facet syndrome. Sixty-two patients diagnosed with chronic cervical facet syndrome were randomized into either lidocaine or bupivacaine groups. The patients, pain assessor, and pain specialist were blinded. The therapeutic CMBB was performed under ultrasound guidance. Either 2% lidocaine or 0.5% bupivacaine with a volume of 0.5-1 milliliter (mL) per level was injected according to the patient's pain symptoms. The primary outcome was the duration of pain reduction by at least 50%. The Numerical Rating Scale (NRS) of 0-10 and the Neck Disability Index questionnaire were recorded. There was no significant difference in the duration of 50% and 75% pain reduction and

Neck Disability Index between the lidocaine and bupivacaine groups. Lidocaine provided significant pain reduction up to 16 weeks ($P < 0.05$) and significant improvement in neck functional outcomes up to 8 weeks ($P < 0.01$) compared to the baseline. Bupivacaine yielded significant pain alleviation for up to 8 weeks for pain upon neck mobilization ($P < 0.05$) and demonstrated notable improvement in neck function up to 4 weeks ($P < 0.01$) compared to the baseline. CMBB using lidocaine or bupivacaine provided clinical benefits in prolonged analgesic effect and improving neck functions for chronic cervical facet syndrome. Lidocaine illustrated better performance and could be considered a local anesthetic of choice regarding the prolonged concordance response.

Manchikanti et al (2024) evaluated the effectiveness of facet joint nerve blocks as a therapeutic modality in managing chronic axial spinal pain of facet joint origin by conducting a systematic review and meta-analysis of randomized controlled trials (RCTs) and observational studies. The primary outcome measure was the proportion of patients with significant relief and functional improvement of greater than 50% of at least 3 months. Duration of relief was categorized as short-term (less than 6 months) and long-term (greater than 6 months). Despite the availability of multiple studies, the paucity of literature is considered as the major drawback. Based on the present systematic review and meta-analysis with 9 RCTs and 12 non-randomized studies, the evidence is Level II with moderate to strong recommendation for therapeutic facet joint nerve blocks in managing spinal facet joint pain.

PROFESSIONAL GUIDELINE(S)

Facet Joint Interventions for Management of Chronic Spinal Pain

In 2020, the American Society of Interventional Pain Physicians (ASIPP) published guidelines on facet joint interventions for management of chronic spinal pain (Manchikanti 2020).

- Facet joint nerve blocks for diagnosis are recommended with moderate to strong strength for the lumbar spine (evidence level I–II), moderate strength for the cervical spine (evidence level II), and moderate strength for the thoracic spine (evidence level II), using a criterion standard of ≥80% pain relief with dual comparative blocks.
- Radiofrequency ablation for treatment is recommended with moderate strength for the lumbar and cervical spine (evidence level II) and weak to moderate strength for the thoracic spine (evidence level III).
- Facet joint nerve blocks are recommended for treatment of pain in the lumbar spine (moderate strength recommendation; evidence level II), cervical spine (moderate strength recommendation; evidence level II), and thoracic spine (weak to moderate strength recommendation; evidence level III).
- Intra-articular injections received a weak recommendation with lower levels of evidence (level III–V across spinal regions).

Sacroiliac Joint – Ablation and Injection

In 2020, North American Spine Society (NASS) acknowledge the limited available data and that the optimal procedural technique has not been established. However, based on this limited data, NASS indicates it is reasonable to offer coverage for thermal radiofrequency neurotomy at the L5 dorsal ramus and S1-S3 sacral lateral branches for SIJ pain. NASS does not include recommendation details for other ablative techniques (e.g., pulsed RF, laser, cooled RF, cryoablation).

The American Society of Pain and Neuroscience (ASPN) Best Practice Guideline for the Treatment of Sacroiliac Disorders (Sayed 2024) recommends RFA of the lateral branches of the S1-S3 dorsal rami along with the L5 dorsal rami (and possibly L4) after an appropriate trial of conservative care and appropriate response to diagnostic blockade. Dual diagnostic blockade of the L5 dorsal ramus and S1-S3 sacral lateral branches with ≥50% improvement in pain and function is the preferred strategy prior to neuroablative procedures. The ASPN notes that rarer modalities such as intra-articular chemical neurolysis and cryoablation have low-quality evidence supporting mild efficacy with limitations due to adverse effect profile.

In 2025, the American Academy of Pain Medicine (AAPM) and American Society of Regional Anesthesia & Pain Medicine (ASRA-PM) issued multispecialty consensus practice guidelines on SIJ complex pain (McCormick 2025), developed by an international working group, and endorsed by 21 organizations. The consensus found strong evidence for sacral lateral branch RFA to provide relief for at least 6 months in individuals with extra-articular pathology. The guidelines recommend targeting S1-S3 lateral branches in all patients (Grade A, high certainty), with consideration of the L5 dorsal ramus and S4 lateral branch based on individual anatomy (Grade B, moderate certainty). Stronger evidence supports larger lesions or more aggressive lesioning strategies over less stringent techniques. The evidence for cryoablation was found to be very limited.

For radicular pain, the North American Spine Society (NASS) (2020) finds that there is sufficient literature to suggest that a trial of ESIs for radicular pain caused by conditions other than disc herniation is appropriate prior to considering surgical intervention. NASS cites multiple randomized-controlled trials (RCTs) that demonstrate lumbar epidural steroid injections (LESIs) are effective in the treatment of lumbar radiculitis caused by disc herniation. Similarly, citing that several conditions may cause cervical radicular pain, with literature regarding interlaminar (IL) ESIs demonstrating durable improvements in pain and disability for 12 and 24 months for a variety of cervical pathologic conditions. The literature on cervical transforaminal (TF) ESIs is limited to observational studies including reduction in surgical intervention has been demonstrated, and the biochemical pathology involved is likely similar to lumbar radicular etiologies.

For lumbar referred pain, NASS (2020) finds that the literature suggests LESIs are effective in reducing pain in this patient population. It is noted that this treatment seems to be less effective in this group than in patients with herniated discs. In addition, data show that LESI is equivalent to epidural local anesthetic likely due to the suppression of neurogenic inflammation by the local anesthetic. Based on these data, it is felt that a trial of LESIs is reasonable prior to the consideration of surgical intervention.

NASS' (2020) evidence-based clinical guidelines for diagnosis and treatment of low back pain reported that there is insufficient evidence to make a recommendation for or against the use of

caudal or interlaminar epidural steroid injections in patient with low back pain (Grade I).

The American Society of Interventional Pain Physicians (ASIPP) published comprehensive evidenced-based guidelines for facet joint interventions in the management of chronic spinal pain (Manchikanti 2020). Patients testing positive for facet joint pain may undergo either therapeutic facet joint nerve blocks or radiofrequency neurotomy based on patients' preferences, values, and physician expertise. Once facet joint pain is excluded, the patient may be treated with epidural injections.

The American Society of Interventional Pain Physicians (ASIPP) published an updated guideline on the use of epidural injections in the management of chronic spinal pain (Manchikanti 2021). The following recommendations were made

- For patients with disc herniation:
    - The evidence is Level I for caudal epidural injections, lumbar interlaminar epidural injections, lumbar transforaminal epidural injections, and cervical interlaminar epidural injections with strong recommendation for long-term effectiveness.
    - For thoracic disc herniation, based on one relevant, high-quality RCT of thoracic epidural with fluoroscopic guidance, with or without steroids, the evidence is Level II with moderate to strong recommendation for long-term effectiveness.
- For patients with spinal stenosis:
    - Based on one high-quality RCT in each category the evidence is Level III to II for fluoroscopically guided caudal epidural injections with moderate to strong recommendation and Level II for fluoroscopically guided lumbar and cervical interlaminar epidural injections with moderate to strong recommendation for long-term effectiveness.
    - The evidence for lumbar transforaminal epidural injections is Level IV to III with moderate recommendation with fluoroscopically guided lumbar transforaminal epidural injections for long-term improvement.
- For patients with axial discogenic pain, the evidence for axial discogenic pain without facet joint pain or sacroiliac joint pain in the lumbar and cervical spine with fluoroscopically guided caudal, lumbar and cervical interlaminar epidural injections, based on one relevant high quality RCT in each category is Level II with moderate to strong recommendation for long-term improvement, with or without steroids.
- For acute proven disc herniation with radiculitis with disabling pain or to avoid surgical intervention, herpes zoster, post herpetic neuralgia, CRPS I and II, epidural injections may be performed at physician discretion without additional pain duration or conservative management requirements.

A 2022 American Society of Pain and Neuroscience (ASPN) guideline provides recommendations for the use of epidural steroid injections in the treatment of low back pain (Sayed 2022). Grade A consensus recommendations include:

- Interlaminar epidural injections for treatment of low back and radicular pain originating from disc disease, spinal stenosis and for chronic back/leg pain after surgical intervention.
- Transforaminal epidural injections for treatment of low back and radicular pain originating from disc disease, spinal stenosis and for chronic back/leg pain after surgical intervention.
- Caudal epidural injections for treatment of low back and radicular pain originating from disc disease, spinal stenosis and for chronic back/leg pain after surgical intervention when interlaminar or transforaminal approaches are not feasible
- Use of either steroid or local anesthetic or the two classes of medication in combination for use in epidural injections for treatment of low back and radicular pain originating from disc disease, spinal stenosis and for chronic back/leg pain after surgical intervention.

In 2022, ASPN provided updated consensus guidance regarding best practices for minimally invasive lumbar spinal stenosis treatment (MIST) (Deer 2022). The guidelines note that most trials, on lumbar ESI, have demonstrated efficacy but there is considerable variability regarding epidural technique, medication, dosage, and duration of improvement. As a result, treatment efficacy for the modality has been difficult to determine, as foundational studies in support of the procedure come from different eras representing the evolution of evidence-based medicine and evidence-based study standards.

- Epidural steroid injections are recommended in the algorithm for the treatment of symptomatic lumbar spinal stenosis. Grade B; Level of certainty high; Level of evidence I-A)
- Epidural steroid injections may be repeated when a patient has significant temporary improvement in symptoms. Be aware that the number and frequency of injections may be limited by insurance and payer rules and regulations. Grade B; Level of certainty moderate; Level of evidence I-B).

In 2025, the American Academy of Neurology (AAN) Guidelines Subcommittee conducted a systematic review of 90 RCTs on the efficacy of epidural steroids for cervical and lumbar radicular pain and spinal stenosis published between January 2005 and January 2021 (Armon 2025). The review affirms limited efficacy of ESIs in reducing pain and disability in cervical and lumbar radiculopathies and possibly in lumbar spinal stenosis, largely in the short term. The panel made the following conclusions:

- For patients with cervical or lumbar radiculopathy, ESIs probably reduce short-term disability (moderate confidence).
- For patients with lumbar spinal stenosis, ESIs possibly reduce short-term disability (low confidence, confidence downgraded for heterogeneity). There were no studies evaluating ESIs in cervical spinal stenosis.
- For patients with cervical or lumbar radiculopathy, ESIs possibly decrease long-term disability (low confidence).

- For patients with lumbar spinal stenosis, ESIs possibly reduce long-term disability (low confidence). There were no studies evaluating cervical stenosis.
- For patients with cervical or lumbar radiculopathy, ESIs probably provide short-term pain reduction (moderate confidence).
- For patients with lumbar spinal stenosis, ESIs probably do not provide short-term pain reduction (moderate confidence). No studies were available for cervical stenosis.
- For patients with cervical or lumbar spinal radiculopathy, there is insufficient evidence to determine whether ESIs provide long-term pain reduction (very low confidence).
- For patients with lumbar spinal stenosis, there is insufficient evidence to determine whether ESIs reduce long-term pain (very low confidence). There were no studies evaluating cervical stenosis.
- Epidural steroid injections are possibly equally effective in patients with lumbar and cervical disease (low confidence, anchored by imprecision), considering that there is only 1 RCT meeting inclusion criteria for cervical radiculopathy.
- There is no significant difference between interlaminar, transforaminal, and caudal ESIs in the outcomes of short-term disability or pain or long-term disability or pain.

Ultrasound Guidance

In 2020, the North American Spine Society (NASS) published coverage policy recommendations for epidural steroid injections & selective spinal nerve blocks which indicates there is insufficient safety and efficacy data to support ultrasound guidance for any approach delivering ESI.

Injectates – Biologics (e.g., Platelet Rich Plasma, Stem Cells, Amniotic Fluid)

The American Society of Pain and Neuroscience (ASPN) identified the educational need for an evidence-based guideline on regenerative medicine therapy for chronic pain and convened a multispecialty working group to evaluate the evidence (D'Souza 2024). The expert panel made the following relevant statements:

- Consensus Point 29. While epidural injections with autologous-conditioned serum (ACS) may improve radicular pain symptoms, some evidence suggests that it is not superior to corticosteroid injection (Level I, Grade C).
- Consensus Point 30. Epidural injections with PRP or other PRP-related products may alleviate radicular pain symptoms in radiculopathy, although studies had a high risk for bias (Level I, Grade C).
- Consensus Point 34. PRP injection at the site of pain for post-herpetic neuralgia as an adjunct to oral neuropathic analgesics may be associated with improved pain intensity compared to medications alone (Level II-2, Grade C).

In 2025, the American Society of Interventional Pain Physicians (ASIPP) published comprehensive evidence-based guidelines for regenerative therapies in the management of chronic low back pain (Manchikanti 2025). The panel made the following relevant statements:

- Epidural injections with PRP are supported by Level III (fair) evidence, with a moderate consensus-based clinical recommendation.
- Intradiscal injections with PRP are supported by Level III (fair) evidence, with a moderate consensus-based clinical recommendation.
- Intradiscal injections with bone marrow aspirate concentrate (BMAC) are supported by Level III (fair) evidence, with a moderate consensus-based clinical recommendation.
- Facet joint injections with PRP and MSCs are supported by Level IV (limited) evidence, with a moderate consensus-based clinical recommendation.

Sacroiliac joint injections with PRP are supported by Level IV (limited) evidence, with a low consensus-based clinical recommendation.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates devices and instruments used during interventional pain procedures as medical devices. All devices and instruments including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Sept 12]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls-and-early-alerts [accessed 2026 Sept 12]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Epidural Steroid Injection	
62320	Injection(s), of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; without imaging guidance

Code	Description
62321	Injection(s), of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, cervical or thoracic; with imaging guidance (i.e., fluoroscopy or CT)
62322	Injection(s), of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural orsubarachnoid, lumbar or sacral (caudal); without imaging guidance
62323	Injection(s), of diagnostic or therapeutic substance(s) (e.g., anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, interlaminar epidural or subarachnoid, lumbar or sacral (caudal); with imaging guidance (i.e., fluoroscopy or CT)
64479	Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), cervical or thoracic, single level
64483	Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), lumbar or sacral, single level
Facet Joint Injections / Medial Branch Blocks	
64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
0213T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, cervical or thoracic; single level
0216T	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with ultrasound guidance, lumbar or sacral; single level
Paravertebral facet joint radiofrequency neurolysis/medial branch transection	
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint

Code	Description
Sacroiliac Joint Injection	
27096	Injection procedure for sacroiliac joint, anesthetic/steroid, with image guidance (fluoroscopy or CT) including arthrography when performed
64451	Injection(s), anesthetic agent(s) and/or steroid; nerves innervating the sacroiliac joint, with image guidance (i.e., fluoroscopy or computed tomography)
G0260	Injection procedure for sacroiliac joint; provision of anesthetic, steroid and/or other therapeutic agent, with or without arthrography

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

Bansal A, et al. Current updates in image-guided musculoskeletal interventions. J Clin Orthop Trauma. 2021;22:101601.

Basi HK, et al. Spine injections. In: Steinmetz MP, Berven SH, Benzel EC, editors. Benzel's spine surgery. 5th ed. Philadelphia (PA): Elsevier; 2022. p. 668-683.e1.

Bodor M, et al. Ultrasound-guided cervical facet joint injections. Spine J. 2022;22(6):983-992.

Chou R, et al. Interventional treatments for acute and chronic pain: systematic review. Comparative Effectiveness Review No. 247. Rockville (MD): Agency for Healthcare Research and Quality; 2021.

Cohen SP, et al. Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group. Reg Anesth Pain Med. 2020;45(6):424-467

Cohen SP, et al. Facet pain: pathogenesis, diagnosis, and treatment. In: Benzon H, editor. Practical management of pain. 6th ed. Philadelphia (PA): Elsevier; 2023. p. 432-452

DePalma MJ, et al. Common neck problems. In: Cifu DX, editor. Braddom's physical medicine and rehabilitation. 6th ed. Philadelphia (PA): Elsevier; 2021. p. 627-650.e616

Filippiadis D, et al. Percutaneous imaging-guided techniques for the treatment of benign neuropathic

pain. Diagn Interv Imaging. 2021;102(1):11-18.

Fornari M, et al. Conservative treatment and percutaneous pain relief techniques in patients with lumbar spinal stenosis: WFNS Spine Committee recommendations. World Neurosurg X. 2020;7:100079.

Gardocki RJ, et al. Degenerative disorders of the cervical spine. In: Azar FM, Beaty JH, editors. Campbell's operative orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1682-1718.e5.

Gardocki RJ, et al. Degenerative disorders of the thoracic and lumbar spine. In: Azar FM, Beaty JH, editors. Campbell's operative orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1719-1801.e9.

Gill B, et al. Radiofrequency ablation for zygapophyseal joint pain. Phys Med Rehabil Clin N Am. 2022;33(2):233-249.

Inman RD, et al. Spondyloarthritis. In: Goldman L, Schafer AI, editors. Goldman-Cecil medicine. 27th ed. Philadelphia (PA): Elsevier; 2024. p. 1760-1767.e1.

Jayapaul P, et al. Efficacy of transforaminal epidural steroid injection in patients with lumbar radiculopathy. Interdiscip Neurosurg. 2020;21:100706.

Khalid H, et al. Image-guided cervical injections with most updated techniques and society recommendations. Adv Clin Radiol. 2022;4(1):171-178.

Kose SG, et al. Ultrasound-guided caudal epidural pulsed radiofrequency for the treatment of failed back surgery syndrome: results of a prospective clinical study. Interv Pain Med. 2022;1(4):100145.

Ladd B, et al. Sacroiliac joint pain. In: Steinmetz MP, Berven SH, Benzel EC, editors. Benzel's spine surgery. 5th ed. Philadelphia (PA): Elsevier; 2022. p. 1205-1213.e2.

MacVicar J, et al. Appropriate use criteria for fluoroscopically guided diagnostic and therapeutic sacroiliac interventions: results from the Spine Intervention Society convened multispecialty collaborative. Pain Med. 2017;18(11):2081-2095.

Manchikanti L, et al. Comprehensive evidence-based guidelines for facet joint interventions in the management of chronic spinal pain: American Society of Interventional Pain Physicians (ASIPP) guidelines facet joint interventions 2020 Guidelines. Pain Physician. May 2020;23(3S):S1-S127.

Manchikanti L, et al. Epidural interventions in the management of chronic spinal pain: American Society of Interventional Pain Physicians (ASIPP) comprehensive evidence-based guidelines. Pain Physician. 2021;24(S1):S27-S208.

Nagpal AS, et al. Systematic review of the effectiveness of caudal epidural steroid injections in the treatment of chronic low back or radicular pain. Interv Pain Med. 2022;1(4):100149.

Nelson AM, et al. Interlaminar and transforaminal therapeutic epidural injections. In: Benzon H, editor. Practical management of pain. 6th ed. Philadelphia (PA): Elsevier; 2023. p. 874-891.

Newman DP, et al. Sacroiliac joint dysfunction: diagnosis and treatment. Am Fam Physician. 2022;105(3):239-245.

North American Spine Society. Evidence-based clinical guidelines for multidisciplinary spine care: diagnosis and treatment of low back pain. Burr Ridge (IL): North American Spine Society; 2020. Available from: https://www.spine.org/Research/Clinical-Guidelines [accessed 2026 Sep 10]

Reitman CA, et al. Appropriate use criteria for degenerative lumbar spondylolisthesis. Burr Ridge (IL): North American Spine Society; 2020. Available from: https://www.spine.org/Research-Clinical-Care/Quality-Improvement/Appropriate-Use-Criteria [accessed 2026 Sep 10]

Sayed D, et al. American Society of Pain and Neuroscience best practice (ASPN) guideline for the treatment of sacroiliac disorders. J Pain Res. 2024 May 3;17:1601-1638.

Sherrier M, et al. Ultrasound basics. In: Williams CJ, Sussman WL, Pitts J, editors. Atlas of interventional orthopedics procedures. Philadelphia (PA): Elsevier; 2023. p. 14-30.

Soar H, et al. Lumbar radicular pain. BJA Educ. 2022;22(9):343-349.

Verheijen E, et al. Epidural steroid injections are only superior on the short term compared to epidural placebo injections for lumbar radiculopathy. Brain Spine. 2021;1:100187.

Viswanathan VK, et al. Role of transforaminal epidural injections or selective nerve root blocks in the management of lumbar radicular syndrome: a narrative, evidence-based review. J Clin Orthop Trauma. 2020;11(5):802-809.

Walsh T, et al. Radiofrequency techniques for chronic pain. BJA Educ. 2022;22(12):474-483.

Walston Z, et al. Importance of early improvement in the treatment of low back pain with physical therapy. Spine (Phila Pa 1976). 2020;45(8):534-540.

William J, et al. Epidural steroid injections. Phys Med Rehabil Clin N Am. 2022;33(2):215-231.

Xu Y, et al. Management of pain by percutaneous anesthetic injections and neurolysis. In: Winn HR, editor. Youmans & Winn neurological surgery. 8th ed. Philadelphia (PA): Elsevier; 2023. p. 1494-1504.e3.

Yang AJ, et al. Sacroiliac joint interventions. Phys Med Rehabil Clin N Am. 2022;33(2):251-265.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Facet Joint Interventions for Pain Management (LCD L35936) [accessed 2026 Sep 10]

Epidural Steroid Injections for Pain Management (LCD L39036) [accessed 2026 Sep 10]

Sacroiliac Joint Injections and Procedures (LCD L39455) [accessed 2026 Sep 10]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.

- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

MEDICAL POLICY

Medical Policy Title	**Intraocular Lens (IOL) Implants**
Policy Number	**9.01.14**
Current Effective Date	**August 1, 2026**
Next Review Date	**October 2027**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. The use of a monofocal (spherical or aspheric) intraocular lens (IOL) as replacement of the natural crystalline lens of the eye following cataract extraction is considered **medically appropriate.**

II. The use of a multifocal IOL, an astigmatism-correcting lens, or an accommodating/trifocal IOL following cataract extraction is considered **not medically necessary**, as no superior medical benefit for these lenses has been demonstrated over the monofocal IOL, other than decreasing the need for corrective eye wear.

RELATED POLICIES

Corporate Medical Policy:
Durable Medical Equipment, Prosthetics/Orthotics, & Medical Supplies, 1370/20.000509

Payment Policies:
Refraction & Vision Services by Eye Care Specialists, 1550/20.000217
Vision Hardware and Contact Lenses Services, 1550/20.000202

POLICY GUIDELINE(S)

In a manner similar to the Centers for Medicare and Medicaid Services (CMS), individuals may choose to receive an astigmatism-correcting, multifocal or accommodating IOL (please refer to the CMS synopsis at the end of this policy). Individuals must sign a beneficiary notice waiver and agree to assume liability for the additional expense of the multifocal or accommodating lens. Reimbursement will be provided for only the cost of a standard or monofocal IOL. Individuals should be apprised of this option by their eye surgeon prior to the cataract extraction surgery.

DESCRIPTION

The eye functions much like a camera with two lenses. The first lens is the cornea, a clear membrane that covers the front of the eye. The second lens is the eye's natural crystalline lens, which is located behind the pupil. The cornea is responsible for about 70 percent of the eye's focusing power, while the natural lens "fine tunes" the image before it is focused on the retina at the back of the eye. The natural lens accomplishes this fine-tuning function by changing shape to accommodate both near objects and those that are further away. Ciliary muscles and zonules are attached to the lens and are

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responsible for its ability to change shape. A cataract is a hardening and opacification of the normally transparent crystalline lens within the eye. Cataract formation usually occurs as part of the aging process but may also be congenital in nature. Rarely, a cataract may form when related to trauma or inflammation of the eye or may also result from the use of some medications. Cataracts may result in progressive loss of vision with the degree of loss depending on the location, size, and density of the cataract. Cataract surgery is indicated when the visual function no longer meets the individual's needs and there is a reasonable likelihood of vision improvement with the procedure. The current cataract procedure of choice is an extracapsular technique (removes only the lens) with the implantation of an intraocular lens.

IOLs are used to replace the natural lens and restore the optical focusing power of the eye. The more common replacement lenses include monofocal, multifocal or accommodating IOLs.

Monofocal IOLs are the current standard of treatment. This type of IOL usually has a fixed focusing power, which provides good distance vision and sometimes intermediate vision, but does not correct the individuals near vision, because the full accommodating ability of the eye is lost. Thus, the placement of a monofocal IOL usually requires corrective lenses or eyeglasses after surgery for reading and near-vision tasks. While a traditional, fixed monofocal IOL is spherical (the front surface is uniformly curved), an aspheric monofocal IOL is slightly flatter in the periphery, allowing for a better contrast sensitivity and a reduction in visual aberrations. The advent of aspheric IOLs has enhanced the quality of visual outcome for monofocal lenses.

Multifocal IOLs are designed to provide distance and near vision and are referred to as pseudoaccommodative lenses or dynamic lenses. The multifocal IOL structure allows light rays to be focused from both distance and near. This type of lens does not restore good intermediate vision, but the need for eyeglasses for near vision correction appears to be much less with the use of multifocal IOLs, compared to the monofocal IOL. Reports of increased glare, halos at night, variable loss of clarity, and low-contrast acuity have been reported by individuals with the use of multifocal IOLs, creating patient dissatisfaction with the multifocal IOL variety.

Accommodating or trifocal IOLs are designed to provide good distance, intermediate, and near vision. The accommodating IOL has hinges at both ends, to facilitate forward and backward movement, and interacts with the eye's ciliary muscles and zonules, allowing variable-focus capability. This type of lens allows individuals to see a continuous range of vision and greatly reduces the need for post-operative corrective lenses. Multifocal and accommodating IOLs are sometimes referred to as presbyopia correcting IOLs.

Astigmatism-correcting IOLs, also known as toric IOLs, provide correction or reduction of pre-existing astigmatism (astigmatism that was present before cataract surgery) by incorporating a special curvature into the IOL. Prior to the advent of toric IOLs, pre-existing astigmatism could only be corrected by making limbal relaxing incisions into the cornea during cataract surgery to change its curvature, or by wearing astigmatism-correcting eyeglasses after surgery.

SUPPORTIVE LITERATURE

A Cochrane review (Leyland 2003, 2006) comparing multifocal to monofocal lenses post-cataract surgery, found no statistical difference between the use of these IOLs relative to best-corrected

visual acuity, although unaided near vision was improved with the use of multifocal lenses. Review of the literature found no studies to support that the pseudo-accommodating or accommodating lens technology is superior to standard-use monofocal IOLs. The long-term stability of the accommodative effect of these lenses is unknown, and some individuals may still require corrective lenses after the multifocal or accommodative lenses are placed.

A 2012 update of the Cochrane review by Calladine and colleagues noted that there was moderate quality evidence that similar distance acuity is achieved with both types of lenses. There was also evidence that people with multifocal lenses had better near vision, but methodological and statistical heterogeneity meant that they did not calculate a pooled estimate for effect on near vision. Total freedom from use of glasses was achieved more frequently with multifocal than monofocal IOLs. Adverse subjective visual phenomena, particularly haloes, or rings around lights, were more prevalent and more troublesome in participants with the multifocal IOL, and there was evidence of reduced contrast sensitivity with the multifocal lenses. They concluded that multifocal IOLs are effective at improving near vision relative to monofocal IOLs. Whether that improvement outweighs the adverse effects of multifocal IOLs will vary between individuals. Motivation to achieve spectacle independence is likely to be the deciding factor.

de Silva et al (2016) updated the Cochrane review of multifocal versus monofocal IOL after cataract extraction. Their analysis included 20 trials that included data on 2,061 individuals (3,194 eyes). These trials were conducted in Europe (13), China (three), USA (one), Middle East (one), India (one) and one multicenter study in Europe and the USA. Most of these trials compared multifocal with monofocal lenses; two trials compared multifocal lenses with monovision. There was considerable variety in the make and model of lenses implanted. There was moderate-certainty evidence that the distance acuity achieved with multifocal lenses was not different to that achieved with monofocal lenses (eyes = 682; studies = 8). Individuals receiving multifocal lenses may achieve better near vision (eyes = 782; studies = 8). The authors noted this to be low-certainty evidence because of risk of bias in the included studies and high heterogeneity. Individuals receiving multifocal lenses may be less spectacle dependent (eyes = 1000; studies = 10). The authors again noted this to be low-certainty evidence because of risk of bias and evidence of publication bias. Adverse subjective visual phenomena were more prevalent and more troublesome in participants with a multifocal IOL compared with monofocals (glare, eyes = 544; studies = 7, low-certainty evidence and haloes, eyes = 662; studies = 7; moderate-certainty evidence). In one study, the investigators noted that more people in the multifocal group underwent IOL exchange in the first year after surgery (6 participants with multifocal vs 0 participants with monovision). The authors concluded multifocal IOLs are effective at improving near vision relative to monofocal IOLs although there is uncertainty as to the size of the effect. Whether that improvement outweighs the adverse effects of multifocal IOLs, such as glare and haloes, will vary between people. Motivation to achieve spectacle independence is likely to be the deciding factor.

PROFESSIONAL GUIDELINE(S)

The American Academy of Ophthalmology 2022 preferred practice pattern (Miller) regarding care for cataracts in the adult eye states the use of presbyopia correcting IOLs may improve a patient's quality of life by improving near and intermediate vision and decreasing the need for corrective

eyewear after cataract surgery, though patient selection is critical. Patients should be informed of the potential compromise in quality of vision associated with the various choices. These patients were found to have more glare, halos, and reduced contrast sensitivity than patient with monofocal IOLs (good, strong quality of evidence). Intraocular lens implantation is the method of choice for correcting aphakia, unless there are specific contraindications. Posterior chamber IOL implantation inside the capsular bag is the optimal method for most cases. Cataract surgeons can choose from a wide variety of posterior chamber IOL styles and materials to find an appropriate lens to match their patients' needs. Intraocular lens optic size, shape, haptic configuration, optic edge design, optic and haptic materials, and chromophore content are engineered with a variety of characteristics. Foldable IOLs are commonly used because of their ability to fit through small incisions, and they have largely replaced rigid polymethyl methacrylate (PMMA) posterior chamber IOLs. Foldable IOLs can be made from silicone, hydrophilic acrylic, and hydrophobic acrylic. All foldable IOL materials are associated with minimal giant-cell foreign-body reaction. Surgeons should be familiar with the unique positive and negative features of each IOL type with regard to material, design, and insertion system.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates intraocular lenses as medical devices. All intraocular lenses including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Sep 10]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
66982	Extracapsular cataract removal with insertion of intraocular lens prosthesis (one-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation
66983	Intracapsular cataract extraction with insertion of intraocular lens prosthesis (one-stage procedure)

Code	Description
66984	Extracapsular cataract removal with insertion of intraocular lens prosthesis (one-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation
66985	Insertion of intraocular lens prosthesis (secondary implant), not associated with concurrent cataract removal
66986	Exchange of intraocular lens
66987	Extracapsular cataract removal with insertion of intraocular lens prosthesis (one-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with endoscopic cyclophotocoagulation
66988	Extracapsular cataract removal with insertion of intraocular lens prosthesis (one-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); with endoscopic cyclophotocoagulation
66989	Extracapsular cataract removal with insertion of intraocular lens prosthesis (one-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more
66991	Extracapsular cataract removal with insertion of intraocular lens prosthesis (one-stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification); with insertion of intraocular (ego, trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more

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HCPCS Codes

Code	Description
C1780	Lens, intraocular (new technology)
V2630	Anterior chamber intraocular lens
V2631	Iris supported intraocular lens
V2632	Posterior chamber intraocular lens

Code	Description
V2787 (NMN)	Astigmatism correcting function of intraocular lens
V2788 (NMN)	Presbyopia correcting function of intraocular lens

ICD10 Codes

Code	Description
E08.36	Diabetes mellitus due to underlying condition with diabetic cataract
E09.36	Drug or chemical induced diabetes mellitus with diabetic cataract
E10.36	Type 1 diabetes mellitus with diabetic cataract
E11.36	Type 2 diabetes mellitus with diabetic cataract
E13.36	Other specified diabetes mellitus with diabetic cataract
H25.011-H25.9	Age-related cataract (code range)
H26.001-H26.09	Infantile and juvenile cataract (code range)
H26.101-H26.139	Traumatic cataract (code range)
H26.20	Unspecified complicated cataract
H26.211-H26.219	Cataract with neovascularization (code range)
H26.221-H26.229	Cataract secondary to ocular disorders (degenerative) (inflammatory), (code range)
H26.231-H26.239	Glaucomatous flecks (subcapsular), (code range)
H26.30-H26.33	Drug-induced cataract (code range)
H26.40	Unspecified secondary cataract
H26.411-H26.419	Soemmerring's ring (code range)
H26.491-H26.499	Other secondary cataract (code range)
H26.8	Other specified cataract

Code	Description
H26.9	Unspecified cataract
H28	Cataract in diseases classified elsewhere
Z96.1	Presence of intraocular lens

REFERENCES

Al-Mohtaseb Z, et al. Toric monofocal intraocular lenses for the correction of astigmatism during cataract surgery: A Report by the American Academy of Ophthalmology. Ophthalmology 2024 Mar;131(3):383-392.

Ang, RE. Comparison of tolerance to induced astigmatism in pseudophakic eyes implanted with small aperture, trifocal, or monofocal intraocular lenses. Clinical Ophthalmology. 2019;13: 905–911.

Auffarth GU, et al. Clinical evaluation of a new monofocal IOL with enhanced intermediate function in patients with cataract. J Cataract Refract Surg. 2021 Feb; 47:184-191.

Buzzonetti L, et al. Comparative analysis of visual outcomes of multifocal and monofocal intraocular lenses in congenital cataract surgery. J Cataract Refract Surg. 2022 Jan; 48(1): 56-60.

Calladine D, et al. Multifocal versus monofocal intraocular lenses after cataract extraction. Cochrane Database Syst Rev. 2012 Sep;9:CD003169.

Chang JSM, et al. Monovision with a bifocal diffractive multifocal intraocular lens in presbyopic patients: A prospective, observational case series. Am J Ophthalmol. 2020;212:105-115.

de Silva SR, et al. Multifocal versus monofocal intraocular lenses after cataract extraction. Cochrane Database of Systematic Reviews 2016 Dec 12,12:CD003169.

Fernández J, et al. Systematic review of potential causes of intraocular lens opacification. Clin Experiment Ophthalmol. 2020;48:89-97.

Giglio R, et al. Visual outcomes and patient satisfaction after bilateral implantation of an enhanced monofocal intraocular lens: a single-masked prospective randomized study. Int Ophthalmol. 2024 Feb;44(1):112.

Guarro M, et al. Visual disturbances produced after the implantation of 3 EDOF intraocular lenses vs 1 monofocal intraocular lens. J Cataract Refract Surg. 2022 Dec;48(12):1354-1359.

Lambert SR, et al. Long-term effect of intraocular lens vs contact lens correction on visual acuity after cataract surgery during infancy: A randomized clinical trial. JAMA Ophthalmol. 2020 Apr; 138(4): 365-372.

Leyland M, Zinicola E. Multifocal versus monofocal intraocular lenses after cataract extraction. Cochrane Database of Systematic Reviews. 2003 Jan 20,1:CD003169.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Leyland M, Pringle E. Multifocal versus monofocal intraocular lenses after cataract extraction. Cochrane Database of Systematic Reviews. 2006 Oct 18,4:CD003169.

Miller KM, et al; American Academy of Ophthalmology Preferred Practice Pattern Cataract/Anterior Segment Panel. Cataract in the Adult Eye Preferred Practice Pattern. Ophthalmology. 2022 Jan;129(1):P1-P126.

Moshirfar M, et al. Astigmatic correction with implantation of a light adjustable vs monofocal lens: a single site analysis of a randomized controlled trial. Int J Ophthalmol. 2019;12(7):1101-1107.

Paik DW, et al. Comparing the visual outcome, visual quality, and satisfaction among three types of multi-focal intraocular lenses. Scientific Reports. 2020 Sept; 10:1-10.

Schallhorn J, et al. Multifocal and accommodating intraocular lenses for the treatment of presbyopia a report by the American Academy of Ophthalmology. Ophthalmic Technology Assessment. Ophth. 2021 Oct; 28(10): 1469-1482.

Shin DE, et al. Comparative analysis of a presbyopia-correcting intraocular lens that combines extended depth-of-focus and bifocal profiles with a standard monofocal intraocular lens. BMC Ophthalmol. 2022 Jul; 22(1): 302.

Sridhar U, Tripathy K. Monofocal Intraocular Lenses. [Updated 2023 Aug 23]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan- [accessed 2025 Sep 10]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK580484/

SEARCH TERMS

Accommodating, Aspheric, Astigmatism-correcting, Crystalens, dynamic, Monofocal, Multifocal, pseudoaccommodating, toric.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Intraocular Lenses (IOLs) (NCD 80.12) [accessed 2025 Sep 10]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 12/97

Revised: 10/98, 05/99, 09/99, 06/00, 09/00, 04/01, 11/02, 09/03, 09/04, 01/05, 09/05, 06/06, 11/06, 06/06, 11/06, 3/07, 5/07, 03/08, 05/08, 07/08, 07/09, 07/10, 07/13, 01/14, 07/14, 09/14, 07/15, 09/15, 07/16, 07/17, 01/18, 07/18, 07/20, 5/22, 7/23, 11/23, 7/24, 1/25, 7/25, 7/26

Reviewed: 07/11, 7/19, 7/21, 7/22, 11/25

Date	Summary of Changes
11/1/2026	• Transitioned Contact Lenses, Intraocular Lenses & Eyeglasses for Medical Purposes policy, 1370/20.000164 to Lifetime Healthcare Companies policy template.
5/1/2025 *No change to effective date of policy	• Under Policy Considerations, clarified that fitting/fabrication of prosthetic eye is also included in the reimbursement of the prosthetic.
5/1/2025	• In the Policy Considerations section, added misc code 92499 to information regarding fittings.
8/1/2024	• Added ICD code H59.099 to table in Position Statement as allowable under cataract extraction surgery.
3/1/2024	• Added information for the PROSE device.
8/1/2023	• Updated diagnosis codes for endothelial corneal dystrophy in the Gas Permeable Scleral Contact Lens section.
6/1/22	• Removed “per lifetime” limit for cataract surgery and added “per cataract surgery.”
11/1/20	• Added V2780 (Oversized lenses) to Medicare Advantage section. • Removed reference to $160 max.

Proprietary Information of Capital District Physicians’ Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians’ Healthcare Network, Inc.

MEDICAL POLICY

Medical Policy Title	**Intraosseous Basivertebral Nerve Ablation for Child Health Plus (CHP), and Essential Plan (EP) Members**
Policy Number	**7.01.124**
Current Effective Date	**January 1, 2027**
Next Review Date	**September 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Thermal ablation of the intraosseous basivertebral nerve (BVN) is considered **medically appropriate** when documentation meets **ALL** the following:

A. Individual is 18 years of age or older;

B. Chronic low back pain for a minimum of 6 months;

C. Pain failed to adequately improve, or was not tolerated, despite a minimum of 6 months of conservative treatment that includes **BOTH** of the following:

1. Non-pharmacologic management includes **ANY** of the following:

a. Acupuncture;

b. Chiropractic treatment;

c. Cognitive behavioral therapy; **or**

d. Supervised physical therapy (PT); **and**

2. Pharmacologic management includes **ANY** of the following:

a. Interventional pain management with epidural steroid injections (ESI) or facet-based interventions;

b. Nonsteroidal anti-inflammatory drugs (NSAIDs); **or**

c. Oral analgesic therapy;

D. Clinical presentation is consistent with vertebrogenic pain (e.g., persistent low back pain, deep midline pain, pain aggravated by bending, prolonged standing, or sitting);

E. Modic Type 1 and/or Type II endplate changes at least one (1) vertebral level from L3 to S1 documented on magnetic resonance imaging (MRI) within the previous 12 months;

F. Pain presentation includes **BOTH** of the following:

1. Axial low back pain as the primary symptom; **and**

2. Pain causes functional impairment (e.g., reduced mobility, impaired activities of daily living);

G. The procedure will be performed using fluoroscopic or computed tomography (CT) guidance.

II. Thermal ablation of the intraosseous basivertebral nerve (BVN) is contraindicated and **not medically necessary** for **ANY** of the following:

A. Active infection, local or systemic;

B. Bleeding or clotting disorder;

C. Compromised bone integrity with **any** of the following diagnoses:

1. osteoporosis (T-score ≤ -2.5);
2. spinal malignancy;
3. trauma/compression fracture involving the intended treatment level; **or**
4. vertebral fragility fracture;

D. History of basivertebral nerve ablation at the requested vertebral level;

E. History of spinal surgery at the requested vertebral level;

F. Imaging evidence (MRI, CT, X-ray) identifies an alternative cause of low back pain symptoms (e.g., degenerative scoliosis, disc herniation, lumbar stenosis, spondylolisthesis);

G. Implanted electronic devices (e.g., pacemaker, defibrillator, neurostimulator);

H. Modic Type 3 (sclerotic) endplate changes;

I. Pain localized to the anterior column/midline, with other pain generators (discogenic, facet, radicular, sacroiliac) reasonably ruled out;

J. Pregnancy;

K. Primary presenting symptoms include **any** of the following:

1. lumbar radiculopathy;
2. nerve compression/impingement (e.g., stenosis);
3. neurogenic claudication; **or**
4. radicular pain;

L. Severe cardiac or pulmonary impairment;

M. Skeletal immaturity (younger than 18 years of age).

RELATED POLICIES

Corporate Medical Policy

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Intraosseous basivertebral nerve ablation (BVNA) is a minimally invasive, image-guided procedure used to treat chronic vertebrogenic low back pain. Vertebrogenic pain is thought to originate from damaged vertebral endplates and is transmitted to the central nervous system through the basivertebral nerve (BVN), an intraosseous nerve that courses within the vertebral body. Endplate damage is commonly associated with Modic Type 1 and/or Type 2 changes seen on MRI.

During the procedure, a bipolar radiofrequency probe is advanced percutaneously through a transpedicular approach into the vertebral body under fluoroscopic guidance. Radiofrequency energy is then applied to the basivertebral nerve within the inner, spongy (cancellous) bone of the vertebral body, thermally ablating the nerve to interrupt the transmission of pain signals from the affected endplates. The vertebral body itself and its structural integrity are preserved.

BVNA is generally considered for skeletally mature patients with chronic axial low back pain of at least six months' duration who have not adequately improved with conservative (nonsurgical) management and who demonstrate Modic Type 1 and/or Type 2 endplate changes at one or more levels from L3 through S1 on MRI. The goal of treatment is durable reduction in pain and improvement in function.

Supporting definitions:

- Activities of daily living (ADLs) refer to basic self-care tasks that individuals perform to maintain their well-being and live independently. These tasks include bathing or showering; dressing; eating; toileting; transferring (getting in and out of bed or chair).
- Computed tomography (CT) is an imaging test that uses X-rays to computer analysis to generate cross sectional images of the internal structures of the body that can be displayed in multiple planes.
- Conservative management is an approach to treating back pain, neck pain and related spinal conditions utilizing non-surgical treatment options, such as physical therapy, medication and injections.
- Fluoroscopy is a study of moving body structures, similar to an X-ray "movie." A continuous X-ray beam is passed through the body part being examined and is transmitted to a TV-like monitor so that the body part and its motion can be seen in detail. Fluoroscopy, as an imaging tool, enables physicians to look at many body systems, including the skeletal, digestive, urinary, respiratory, and reproductive systems.

- Magnetic resonance imaging (MRI) uses a strong magnetic field and radiofrequency pulses to energize hydrogen protons in body tissues, then constructs images from the different signals emitted as those protons return toward equilibrium.
- Modic changes are magnetic resonance imaging (MRI) signal changes related to spinal degeneration in the vertebral endplate and adjacent bone marrow, also described as reactive vertebral body changes within the cancellous bone adjacent to the vertebral end plates.
    - Type I: Reflects marrow edema and inflammation
    - Type II: Fatty replacement of bone marrow
    - Type III: Subchondral or bony sclerosis
- Neurogenic claudication is the symptom pattern typically associated with lumbar spinal stenosis in which lower-extremity, buttock, or back pain, numbness, weakness, or paresthesias are brought on by standing or walking and relieved by sitting or spinal flexion, often termed pseudoclaudication.
- Osteoporosis is a skeletal disorder characterized by compromised bone strength, often described as low bone mass with microarchitectural deterioration, that increases bone fragility and fracture risk. Defined as a T-score of -2.5 or lower compared with a young adult reference mean in postmenopausal women and in men aged 50 years or older.
- Vertebrogenic pain refers to chronic low back pain arising from damaged vertebral endplates and transmitted through the basivertebral nerve. MRI evidence of Modic Type 1 or Type 2 changes is commonly present.

SUPPORTIVE LITERATURE

The published evidence supports intraosseous basivertebral nerve ablation (BVNA) as an effective, durable treatment for vertebrogenic chronic low back pain in appropriately selected patients with Modic type 1 or 2 endplate changes at L3–S1.

PROFESSIONAL GUIDELINE(S)

In 2022, the International Society for the Advancement of Spine Surgery (ISASS) (Lorio 2022) recognized intraosseous BVN ablation as a safe, predictable, and durable treatment for chronic axial vertebrogenic low back pain identified by established clinical criteria and Modic type 1 and/or type 2 changes on MRI. The recommendation rests on Level I evidence with a systematic review and two randomized controlled trials showing statistically significant reductions in pain and improvements in function, with benefit maintained beyond 5 years after a single treatment.

In 2022, the American Society of Pain and Neuroscience (ASPN) published best practice guidelines for the diagnosis and treatment of vertebrogenic pain with BVN ablation (Sayed 2022). A multidisciplinary concluded that moderate-to-high quality evidence supports BVNA for improving pain, function, and quality of life, reducing opioid use, and achieving high patient satisfaction, with

clinically meaningful and statistically significant superiority over standard care in carefully selected patients.

The 2023 North American Spine Society (NASS) Basivertebral Nerve (BVN) Ablation Coverage Recommendations supports percutaneous interosseous radiofrequency ablation of the BVN for individuals who are:

- Skeletally mature with chronic low back pain for at least 6 months;
- Inadequately improved despite nonsurgical management;
- Have Type 1 or Type 2 Modic changes at endplates between L3 and S1.

NASS notes a growing evidence base that damage to innervated vertebral endplates produces vertebrogenic back pain transmitted via the BVN, with percutaneous intraosseous radiofrequency ablation emerging as an interventional option. NASS does not support transforaminal epiduroscopic BVN laser ablation, citing only a single promising case series and the need for further study.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates radiofrequency generators as medical devices. All radiofrequency generators including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Sep 12]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: https://www.fda.gov/medical-devices/medical-device safety/medical-device-recalls-and-early-alerts [accessed 2026 Sep 12]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
64628	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; first 2 vertebral bodies, lumbar or sacral

Code	Description
64629	Thermal destruction of intraosseous basivertebral nerve, including all imaging guidance; each additional vertebral body, lumbar or sacral (List separately in addition to code for primary procedure)

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
M42.16	Adult osteochondrosis of spine, lumbar region
M42.17	Adult osteochondrosis of spine, lumbosacral region
M51.36	Other intervertebral disc degeneration, lumbar region
M51.360	Other intervertebral disc degeneration, lumbar region, unspecified pain status
M51.37	Other intervertebral disc degeneration, lumbosacral region
M51.370	Other intervertebral disc degeneration, lumbosacral region, unspecified pain status
M54.50	Low back pain, unspecified
M54.51	Vertebrogenic low back pain
M54.59	Other low back pain

REFERENCES

Conger A, et al. The effectiveness of intraosseous basivertebral nerve radiofrequency ablation for the treatment of vertebrogenic low back pain: an updated systematic review with single-arm meta-analysis. Pain Med. 2022;2(12):S50-S62.

Ehsanian R, et al. Patient selection, clinical outcomes, associated healthcare utilization, and cost-effectiveness of basivertebral nerve ablation for the treatment of vertebrogenic low back pain: a narrative review. N Am Spine Soc J. 2025;24:100788.

Koreckij T, et al. Prospective, randomized, multicenter study of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain: 24-month treatment arm results. N Am Spine Soc J. 2021;8:100089.

Lorio M, et al. ISASS policy statement 2022: literature review of intraosseous basivertebral nerve ablation. Int J Spine Surg. 2022;16(3):1084-1094.

North American Spine Society (NASS) [Internet]. Coverage policy recommendations. Basivertebral Nerve Ablation. 2023 Feb [accessed 2026 Sep 12]. Available from: https://www.spine.org/coverage

Sayed D, et al. Best practice guidelines on the diagnosis and treatment of vertebrogenic pain with basivertebral nerve ablation from the American Society of Pain and Neuroscience. J Pain Res. 2022;15:2801-2819.

Schnapp W, et al. Basivertebral nerve ablation for the treatment of chronic low back pain in a community practice setting: 6-month follow-up. N Am Spine Soc J. 2023;14:100201.

Schnapp W, et al. Basivertebral nerve ablation for the treatment of chronic low back pain with Modic changes in a community practice setting: 12-month follow-up. N Am Spine Soc J. 2024;18:100383.

Smuck M, et al. A cost-effectiveness analysis of intraosseous basivertebral nerve ablation for the treatment of chronic low back pain. Spine J. 2025;25(2):201-210.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Thermal Destruction of the Intraosseous Basivertebral Nerve (BVN) for Vertebrogenic Lower Back Pain (LCD L40302) [accessed 2026 Sep 12]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

Policy/Procedure Name: Kebilidi (eladocagene exuparvovec-tneq) **Control Number: 1350/20.000547**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Aromatic l-amino acid decarboxylase (AADC) deficiency is an extremely rare autosomal recessive genetic disorder. AADC deficiency can be caused by more than 580 changes (variants) in a gene called *DDC* (which stands for DOPA decarboxylase, another name for AADC). AADC catalyzes chemical reactions responsible for the synthesis of neurotransmitters, including epinephrine, norepinephrine, dopamine, and serotonin. Affected individuals can appear normal at birth, but most will develop symptoms during the first months of life. Symptoms can include abnormal eye movements, movement disorders (especially dystonia) and autonomic dysfunction (excessive sweating, temperature instability, drooping eyelids (ptosis), nasal congestion and hypoglycemic episodes. Sleep and mood disturbances are also common. Fewer than 350 patients have been reported in the medical literature. Half of these patients are Asian individuals, and a fifth are people with Taiwanese ancestry. Males and females seem to be equally affected. The estimated prevalence in the U.S. based on cerebrospinal fluid (CSF) analysis and genetic testing is roughly 1-2:1,000,000 live newborns.

Diagnosis is based on a complete clinical evaluation and high index of suspicion. Lab diagnosis includes lumbar puncture analyzing metabolites, metabolite 3-O-methyl-dopa (3OMD) in plasma or dried blood spots, which is increased in patients with the disease, measurement of the AADC enzyme activity in the blood, and genetic testing identifying pathogenic variants in the DDC gene.

There is limited scientific evidence for the efficacy of most treatment options due to the rarity of AADC deficiency, and medications are used to help manage the symptoms of the disease. Treatments include dopamine agonists, MAO-B inhibitors, and pyridoxine. Other medications may be used depending on the patient's symptoms.

On November 14, 2024, Kebilidi (eladocagene exuparvovec-tneq) was approved under the accelerated pathway in the United States indicated for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency. Kebilidi had already been approved in Europe, the U.K., Israel, Brazil, and Taiwan as Upstaza, albeit in a more narrowed patient population. Kebilidi is an adeno-associated virus (AAV) vector-based gene therapy administered as four intraputaminal infusions in a single stereotactic neurosurgical procedure. The SmartFlow Neuro Cannula is currently the only FDA authorized device indicated for use to administer Kebilidi.

The safety and effectiveness of Kebilidi were demonstrated in an open-label, single-arm clinical study in 13 pediatric patients with confirmed diagnosis of AADC deficiency. At the start of the study, twelve of the 13 patients had the severe phenotype of AADC deficiency, defined as having no motor milestone achievement at baseline, and no clinical response to standard of care therapies. and decreased AADC activity in the plasma. Patients treated with Kebilidi were compared to untreated patients (natural history). Motor milestone assessments were completed for 12 of the 13 patients at week 48 after receiving the treatment (one patient dropped out of the study prior to Week 48). Eight (67%) of the 12 treated patients achieved a new gross motor milestone at week 48: 3 patients achieved full head control, two patients achieved sitting with or without assistance, two patients achieved walking backwards and the patient with the "variant" severe phenotype was able to sit unassisted. The two patients who achieved walking backwards at week 48 were treated before two years of age. The four patients who were unable to achieve new gross motor milestones at week 48 were treated between the ages of 2.8 and 10.8 years. In comparison, none of the 43 untreated patients with the severe phenotype had documented motor milestone achievement at last assessment at a median age of 7.2 years (range 2 to 19 years).

The most common adverse reactions (≥ 15%) of Kebilidi are dyskinesia, pyrexia, hypotension, anemia, salivary hypersecretion, insomnia, low levels of potassium, phosphate, and/or magnesium, and procedural complications such as respiratory and cardiac arrest. It is also contraindicated in patients who have not achieved skull maturity assessed by neuroimaging.

Summary

Effective Date of Policy:	5/28/2026
Indications	Treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency
ICD10 Diagnosis Codes	E70.81
Availability	single-dose 2 mL vial (each mL of suspension contains a nominal concentration of 5.6×10^{11} vg of eladocagene exuparvovec-tneq)
Duration	Approval will be provided for 6 months to allow sufficient time for administration

Required Criteria for Approval

1. Kebilidi must be prescribed by or in consultation with a neurologist or metabolic specialist with expertise in aromatic L-amino acid decarboxylase (AADC) deficiency or neurotransmitter disorders **AND**
2. The procedure must be performed by a neurosurgeon trained in stereotactic neurosurgery
    a. The neurosurgeon performing the procedure must confirm, using neuroimaging (CT or MRI), that the patient has achieved skull maturity **AND**
3. Attestation that the administering facility has the following capabilities is required:
    a. Stereotactic neurosurgical capability (including MR-guided or frame-based systems)
    b. Pediatric neuroanesthesia support
    c. Inpatient neurology and neurosurgical postoperative care
4. The patient must be between 16-months and 10-years of age **AND**
5. The patient must have a diagnosis of aromatic L-amino acid decarboxylase (AADC) deficiency confirmed by ALL of the following:
    a. Molecular genetic testing confirming biallelic pathogenic or likely pathogenic variants in the DDC gene
    b. Biochemical confirmation of disease that includes at least ONE of the following:
        i. Elevated plasma 3-O-methyldopa (3-OMD) **OR**
        ii. Reduced cerebrospinal fluid (CSF) homovanillic acid (HVA) OR 5-hydroxyindoleacetic acid (5-HIAA)
    c. Attestation from the treating specialist that the patient's clinical presentation is consistent with AADC deficiency (e.g., hypotonia, oculogyric crises, movement disorder, developmental delay with onset in infancy) **AND**
6. The patient must have a severe phenotype of AADC deficiency, defined as the inability to achieve **ANY** of the following motor milestones independently: sitting, standing, or walking (with or without assistive device). Documentation of a motor function assessment (e.g., PDMS-2, Bayley-III) within 6 months of the request must be submitted **AND**
7. The patient must not have:
    a. Significant brain structure abnormality on neuroimaging that would preclude safe stereotactic neurosurgery or compromise expected efficacy.
    b. Anti-AAV2 neutralizing antibody titer >1:1200 or ELISA OD >1
    c. Confirmed diagnosis of pyridoxine 5'-phosphate oxidase (PNPO) deficiency or tetrahydrobiopterin (BH4) deficiency
8. Kebilidi is indicated for a one-time, single-dose intraputaminal use only and therefore will not be authorized for retreatment. Retreatment will be considered Experimental/Investigational when any FDA approved gene therapy, or any other gene therapy under investigation, has been previously administered
9. The recommended dose of Kebilidi is four 0.08 mL (0.45×10^{11} vg) intraputaminal infusions in a single stereotactic neurosurgical procedure. Please refer to Kebilidi FDA-approve prescribing information for complete dosage and administration instructions.
10. Kebilidi (eladocagene exuparvovec-tneq) is considered investigational when the above criteria are not met.
11. Kebilidi (eladocagene exuparvovec-tneq is considered investigational for all other indications.
12. Authorization will be granted for 6 months from the date of approval to allow sufficient time for pre-procedural workup, scheduling, and administration.
    a. If treatment is not administered within the 6-month authorization window, a new prior authorization request is required with updated clinical documentation, including repeat anti-AAV2 antibody testing.

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.
- Physician acknowledges that CDPHP will request documentation, not more frequently than biannually, of follow-up patient assessments such as gross motor milestone achievement, as well as documentation of relevant clinical status while the patient is under the care of the physician.
- Unless otherwise indicated within drug specific criteria, the drugs listed in this policy are administered by a health care professional and therefore are covered under the medical benefit.
- Utilization Management are contract dependent. Refer to specific contract/benefit language for exclusions.
    - Coverage criteria may be dependent on the contract renewal date.
    - Coverage of drugs listed in this policy are contract dependent.
    - Not all contracts/benefits allow coverage of health care professional administered drugs as part of their pharmacy benefit
    - Not all contracts/benefits cover all medical infusible drugs.

- Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging, and other objective or subjective measures of clinical benefit. For recertification, continued approval requires documentation demonstrating that the requested product is providing ongoing benefit to the patient, evidenced by improvement or stability in the disease state or condition, and that continued use remains medically necessary. Ongoing use of the requested product must continue to align with the current policy's preferred formulary. Recertification reviews may result in a requirement to trial more cost-effective treatment alternatives as they become available (e.g., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must remain consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
- For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Uses of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
- All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
- Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
- This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
- For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.
- The following applies to all gene and cellular therapies unless otherwise specified within the drug-specific coverage criteria:
    - Administration, Retreatment, and Treatment with Additional or Other Gene/Cellular Therapies
        - One-Time Administration
            - Most gene and cellular therapies, whether autologous, allogeneic ("off-the-shelf"), or in vivo gene-transfer therapies, are designed and studied as one-time treatments.
            - Repeat dosing, reinfusion, or sequential therapy with other gene or cellular products has not been established as safe, effective, or clinically appropriate.
    - Retreatment/Repeat Administration
        - Retreatment with the same gene or cellular therapy product is considered experimental and investigational because:
            - Clinical trials evaluated these therapies as single-administration interventions
            - Safety, efficacy, and durability of a second administration have not been established
            - Risks of immune activation, insertional mutagenesis, or vector immunity may be increased with repeat dosing
    - Treatment with an Additional or Other Gene/Cellular Therapy
        - Treatment with an additional or different gene or cellular therapy after prior exposure to any gene or cellular therapy is currently considered experimental and investigational as there is lack of evidence demonstrating the following:
            - Anticipated clinical benefit beyond available standard therapies
            - Safety of sequential administration
            - Justification for selecting a second gene/cellular intervention after a prior one
        - This includes, but is not limited to:
            - Switching between CAR-T products (e.g., CD19 → CD19 or CD19 → BCMA)
            - Switching between autologous and allogeneic cellular therapies
            - Sequential use of CAR-T, TCR-T, NK-cell therapies, or other genetically engineered cell therapies
            - Receiving a gene therapy after previous gene or cellular therapy exposure

- Receiving an in vivo gene therapy following any prior vector-based therapy

- Prior Gene/Cell Therapy Exposure
  - An individual is generally not eligible for additional gene or cellular therapy if they have previously received:
    - Any autologous cellular therapy (e.g., CAR-T, TCR-T, TIL),
    - Any allogeneic genetically modified cellular therapy,
    - Any in vivo gene therapy (e.g., AAV, lentiviral vector)
    - Any ex vivo gene-modified cell product
    - Are being considered for any other gene or cellular therapy without documented evidence supporting safety and anticipated benefit.
- Coverage Determination
  - Absent peer-reviewed evidence demonstrating safety and benefit, retreatment or sequential therapy is considered investigational and will not be covered.

References

		Updated	Accessed
	Aromatic L-Amino Acid Decarboxylase Deficiency. National Organization for Rare Disorders. Available at: https://rarediseases.org/rare-diseases/aromatic-l-amino-acid-decarboxylase-deficiency/	11/2024	11/2024
	A Study of SmartFlow Magnetic Resonance (MR) Compatible Ventricular Cannula for Administering Eladocagene Exuparvovec to Pediatric Participants. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/study/NCT04903288	11/2024	11/2024
	Kebilidi [prescribing information]. PTC Therapeutics, Inc. Warren, NJ.	11/2024	9/2025

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted in above application.
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 5/28/2026

New: 12/2024

Revised	Reviewed
12/2025, 5/2026	

Revision Date	Changes Made
12/2025	Removed age criteria Removed exclusion criteria section Updated approval duration to 6 months to allow adequate time for administration
5/2026	Made applicable to Medicare LOB Added attestation for administering facility Added policy guidance to considerations

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Policy/Procedure Name: Ketamine solution for injection **Control Number: 1350/20.000430**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care for enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Ketamine is a rapid-acting general anesthetic producing an anesthetic state characterized by profound analgesia, normal pharyngeal-laryngeal reflexes, normal or slightly enhanced skeletal muscle tone, cardiovascular and respiratory stimulation, and occasionally a transient and minimal respiratory depression. The mechanism of action is primarily due to antagonism of NMDA receptors in the central nervous system. Ketamine has been approved by the U.S. Food and Drug Administration (FDA) for diagnostic and surgical procedures that do not require skeletal muscle relaxation, for the induction of anesthesia prior to the administration of other general anesthetic agents, and to supplement low-potency agents such as nitrous oxide.[1] Ketamine for the treatment of psychiatric disorders and/or pain is an off-label use and considered experimental and investigational at this time. Refer to policy: Experimental, Investigational & Non-Standard Treatments/Clinical Trials, Control Number, 1370/20.000152.

Psychiatric disorders

While preliminary studies demonstrate short-term outcomes with ketamine infusions in patients suffering from treatment resistant depression, there is insufficient long-term data to support its use at this time. Studies available currently are moderate in size, short in duration, low in design quality, and had limited or no follow-up to assess the duration of treatment effects. More studies are needed to demonstrate safety and efficacy before ketamine can be considered an appropriate or medically necessary treatment for psychiatric and/or pain disorders. Additionally, consideration must be given as ketamine has abuse potential and it is associated with psychological side effects such as dissociative or psychotomimetic effects.[2]

The American Psychiatric Association (APA) guidelines for the treatment of posttraumatic stress disorder, bipolar disorder, obsessive-compulsive disorder, and major depressive disorder have not been updated within the last decade and do not address ketamine. In 2017, the American Psychiatric Association (APA) published an evidence review and consensus opinion of the use of ketamine in treatment-resistant depression. The APA noted that "while ketamine may be beneficial to some patients with mood disorders, it is important to consider the limitations of the available data and the potential risk associated with the drug when considering treatment options. Risks include suicidal ideation and potential for substance abuse.[3]

Due to the lack of established clinical value, CDPHP considers ketamine to be experimental and investigational for psychiatric disorders.

Esketamine is the S-enantiomer of ketamine, which binds with greater affinity to the N-methyl D-aspartate (NMDA) receptor and enhances glutamine release in the brain. Spravato (esketamine) is Food and Drug Administration (FDA) an approved therapy in conjunction with an oral antidepressant for treatment resistance depression and depressive symptoms in adults with major depressive disorder with acute suicidal ideation or behavior. The onset of action is 20 to 40 minutes. Due to risks for serious adverse outcomes resulting from sedation, dissociation, and abuse and misuse, Spravato is available only through a restricted Risk Evaluation and Mitigation Strategy (REMS) program.[4] Refer to policy: Spravato (esketamine) Control Number: 1350/20.000370.

Pain conditions

A review of clinical literature for the use of ketamine infusions for chronic pain reveal that there is limited evidence that suggests ketamine may provide temporary relief to some chronic pain patients. However, there is insufficient evidence to advocate the routine use of this treatment for patients with chronic pain. Of particular concern are the significant adverse effects on the central and peripheral nervous system. Little data is available concerning appropriate dosing and long-term administration. The overall health benefit of ketamine infusions for chronic pain cannot be determined due to the limited evidence and severity of side effects. Additional clinical trials are needed to evaluate the long-term safety and efficacy before its use can be considered clinically appropriate.[5]

In 2018, the American Society of Regional Anesthesia and Pain Medicine, the American Academy of Pain Medicine, and the American Society of Anesthesiologists issued a joint consensus guideline on the use of intravenous ketamine for treatment of chronic pain. The authors found:

- Weak evidence supporting use of IV ketamine for short-term improvement in patients with spinal cord injury pain
- Moderate evidence supporting use of IV ketamine for improvement in patients with Complex Regional Pain Syndrome (CRPS) up to 12 weeks

- Weak or no evidence for immediate improvement with IV ketamine use for other pain conditions, including mixed neuropathic pain, fibromyalgia, cancer pain, ischemic pain, headache, and spinal pain

Of note, the authors footnote this paper indicating that the document has neither been presented to nor approved by either the American Society of Anesthesiologists Board of Directors or House of Delegates and therefore is not an official or approved statement or policy of the Society.[6]

Due to the lack of established clinical value, CDPHP considers ketamine to be experimental and investigational for pain conditions.

Summary	
Effective Date of Policy:	12/8/2021
Indications	FDA approved indication: • diagnostic and surgical procedures that do not require skeletal muscle relaxation, • the induction of anesthesia prior to the administration of other general anesthetic agents, and • supplement low-potency agents such as nitrous oxide
Availability	Multiple concentrations J3490
Duration	Not applicable
Coverage	Ketamine may be covered for FDA-approved indications according to provider contract terms Outpatient use of ketamine will not be covered for off-label use

References

		Accessed
1	Ketamine [prescribing information]. Lake Forest, IL; Hospira, Inc.; July 2022.	03/2024
2	Hayes Medical Technology Directory. Ketamine as Primary Therapy for Treatment-Resistant Unipolar Depression or Posttraumatic Stress Disorder. November 21, 2017.	11/2021
3	Sanacora G, Frye MA, McDonald W, et al. A consensus statement on the use of ketamine in the treatment of mood disorders. *JAMA Psychiatry.* 2017;74(4):399-405.	11/2021
4	SPRAVATO™ (esketamine) nasal spray, CIII [prescribing information]. Titusville, NJ: Janssen Pharmaceutical Companies; 2020.	11/2021
5	Hayes Health Technology Assessment. Intravenous Ketamine for Chronic Nonmalignant Paid. March 18, 2021.	11/2021
6	Cohen SP, Bhatia A, Buvanendran A, et al. Consensus guidelines on the use of intravenous ketamine infusions for chronic pain from the American Society of Regional Anesthesia and Pain Medicine, the American Academy of Pain Medicine, and the American Society of Anesthesiologists. Regional Anesthesia and Pain Medicine 2018 45 (5) 521-546.	11/2021
7	McIntyre RS, Carvalho IP, Lenanna L, et al. The effect of intravenous, intranasal, and oral ketamine in mood disorders: a meta-analysis. Journal of Affective Disorders. 2020;276(1):576-584.	5/2023

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 8/13/2026

Policy History

Date	Note
12/2021	New policy
6/2023, 6/2024, 6/2025, 8/2026	Reviewed, no changes

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MEDICAL POLICY

Medical Policy Title	**Kidney Transplantation**
Policy Number	**07.02.04**
Current Effective Date	**July 1, 2026**
Next Review Date	**April 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Kidney transplants are **medically appropriate** for candidates with documented progressive end stage renal disease (ESRD) when **EITHER** of the following indications are present:

   A. A measured (actual urinary collection) creatinine clearance level or calculated glomerular filtration rate (GFR) (or another reliable formula) less than or equal to 20ml/min; **or**

   B. The initiation of dialysis.

II. Kidney retransplants after a failed primary kidney transplant are considered **medically necessary** when the criteria in Policy Statement I are met.

III. The following conditions are absolute contraindications to kidney transplantation:

   A. Presence of malignancy (other than non-melanoma skin cancers), unless malignancy has been completely resected, or unless (upon medical review) it is determined that malignancy has been treated with a small likelihood of recurrence and acceptable future risks;

   B. Ongoing or recurring infections that are not effectively treated;

   C. Serious cardiac or pulmonary, other ongoing comorbid conditions that create an inability to tolerate transplant surgery;

   D. Demonstrated non-adherence to medical recommendations, which places the organ at risk.

IV. Kidney transplantation is considered a relative contraindication in human immunodeficiency virus (HIV) positive individuals, unless **ALL** of the following criteria are met:

   A. Cluster of Differentiation 4 (CD4) count greater than 200 cells/mm^3;

   B. Undetectable HIV-1 ribonucleic acid (RNA);

   C. On Stable anti-retroviral therapy for greater than three (3) months; **and**

   D. All other criteria within the policy are met.

RELATED POLICIES

Corporate Medical Policy

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

07.02.01 Pancreas Transplant: (Pancreas Transplant Alone, Pancreas Transplant after Kidney Transplant, Simultaneous Pancreas Kidney Transplant): Islet Cell Transplant

POLICY GUIDELINE(S)

I. Recipient Selection

A. Each individual considered for renal transplantation will have an evaluation completed by the transplant center for potential difficulties that would complicate and diminish the success of transplantation. Consideration will be given to the individual's risk of death without transplantation, along with the presence and severity of potential contraindications to transplantation. Candidates considered for transplant must be psychologically stable, demonstrate motivation and compliance, and have no ongoing problems with drug or alcohol abuse.

B. Nutritional issues are important predictors of surgical outcomes. For candidates with a body mass index (BMI) outside of the "normal range," documentation of dietary counseling will be required at the time of evaluation and while on the waiting list.

C. Diabetic complications often fall into the realm of relative contraindications (except for significant cardiovascular disease); however, renal transplantation is associated with improved survival in individuals with end-stage renal disease (ESRD) caused by type 1 diabetes mellitus. Individuals with diabetes may be candidates for combined kidney-pancreas transplantation.

II. Prior authorization requirements are contract dependent. Approval for all transplants, including arrangements with an approved transplant center, may be required.

III. Pre-transplant evaluation documentation must include the following clinical information (if testing is unable to be performed, the rationale for not performing the testing must be included in the documentation):

A. Clinical Evaluation:

1. Confirmation of diagnosis;
2. Identification of comorbidities;
3. Current assessment of co-morbidities;
4. Management of co-morbidities; and
5. Consult notes (if applicable).

B. Psycho-Social Evaluation:

1. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol, or smoking/substance abuse).

C. Performance Status:

1. Karnofsky performance score;

2. Palliative Performance Scale (PPS) score;
3. Eastern Cooperative Oncology Group (ECOG) performance status; or
4. Lansky Play-Performance Scale (for age 1 to 16 years).

D. Oral Health Evaluation;

E. Lab Tests:

1. Complete Blood Count (CBC), metabolic profile;
2. Serologies: Cytomegalovirus (CMV); Hepatitis B and C; and
3. Human Immunodeficiency Virus (HIV) Testing.

F. Cardiac Assessment:

1. 12 Lead Electrocardiogram (EKG);
2. Stress (exercise, nuclear, or dobutamine); and
3. Echocardiogram (Echo) or Multigated Acquisition (MUGA) Scan.

G. Pulmonary Assessment:

1. Chest x-ray;
2. Pulmonary function tests (PFTs) for high-risk respiratory failure (COPD, emphysema, alpha 1-antitrypsin deficiency, hepatopulmonary syndrome, or significant smoking history); and

H. Age-appropriate Screening Tests: Please refer to the U.S Preventive Services Task Force (USPSTF) [Internet] for list of age-appropriate screening guidelines (e.g., colorectal cancer screening, cervical cancer screening for guidance). [accessed 2026 Feb 25]. Available from: https://uspreventiveservicestaskforce.org/uspstf/

IV. Hepatitis C virus (HCV) infections are common among individuals with chronic renal failure and result in significant morbidity and mortality. Therefore, the assessment of hepatitis C virus infection in the potential recipient has a major clinical significance. HCV infections are associated with an increased risk of death, irrespective of whether the individual stays on dialysis or has a renal transplant. Transplantation has a beneficial, rather than adverse, effect on long-term survival in an anti-HCV-positive individual. An HCV-positive status is not a contradiction for renal transplantation.

V. A person who gives consent to be a live organ donor should be competent, willing to donate, free from coercion, medically and psychologically suitable, fully informed of the risks and benefits as a donor, and fully informed of the risks, benefits, and alternative treatment available to the recipient. The benefits to both donor and recipient must outweigh the risks associated with the donation and transplantation for the living donor organ.

VI. Candidates may be wait-listed at more than one transplant center. Since waiting time priority is first calculated among candidates at all hospitals within the local donation area, listing at

transplant centers in different local allocation areas is recommended. Requirements for multiple-listed candidates may vary among transplant centers. When possible, results of tests used in the evaluation for the transplant at one center should be used at subsequent centers where the individual is listed.

VII. Transplant re-authorization must be completed annually while actively waiting for a transplant. Re-authorization documentation must be within the past 11 months (unless specified) and include the following clinical information (if testing is unable to be performed, the rationale must be included in the documentation). If the individual's health condition has not changed from the previous year some testing would not be applicable.

A. Clinical Evaluation:

1. Updated list of diagnoses to include identification of comorbidities, current assessment, and treatment plan.
2. Specialty consultation notes (if applicable).

B. Current functional ability as evidenced by current Karnofsky performance score (KPS); Palliative Performance Scale (PPS) score; ECOG, or Lansky Play-Performance Scale.

C. Follow-up Oral Health Evaluation;

D. Lab Tests:

1. CBC, metabolic profile;
2. Serologies: CMV, Hepatitis B and C; and
3. HIV testing (If applicable).

E. Cardiac Assessment:

1. 12 Lead EKG (If applicable);
2. Stress (exercise, nuclear, or dobutamine) (If applicable); and
3. Echo or Muga scan (If applicable).

F. Pulmonary Assessment:

1. Chest x-ray (If applicable);
2. Pulmonary function tests (PFTs) for high-risk respiratory failure (COPD, emphysema, a-1-antitrypsin deficiency, hepatopulmonary syndrome, or significant smoking history); **and**

G. Age-appropriate Screening Tests: Please refer to the USPSTF [Internet] for a list of age-appropriate screening guidelines (e.g., colorectal cancer screening, cervical cancer screening for guidance). [accessed 2026 Feb 25]. Available from: https://uspreventiveservicestaskforce.org/uspstf/

DESCRIPTION

The kidneys are two bean-shaped organs located on each side of the spine just below the rib cage. Kidneys are about the size of a fist. Their main function is to filter blood toxins and transform the waste into urine to be eliminated. When kidneys lose filtering abilities, harmful levels of fluid and waste accumulate in the body, which can result in kidney (renal) failure. Estimated glomerular filtration rate (eGFR) is a calculation used to estimate how well the kidneys are filtering certain products produced by the body. In adults, the normal eGFR number is usually 90-100. Which means that the kidney function is 90-100%. eGFR declines with age, even in people without kidney disease.

The National Kidney Foundation (NKF) states that Stage 5 chronic kidney disease (end-stage renal disease) is eGFR less than 15 for 3 months or more, or the individual is on dialysis. GFR estimate is considered the best measure of kidney function (NKF 2023).

Individuals with kidney failure are treated with dialysis, or with transplant.

A kidney transplant is the removal of a healthy kidney from a living donor or deceased (cadaveric) donor and the placement of the kidney into a person whose kidneys are no longer functioning properly. Transplant recipients require life-long immunosuppression to prevent rejection. Individuals are prioritized for transplant by mortality risk and severity of illness criteria developed by the Organ Procurement and Transplantation Network (OPTN) and United Network of Organ Sharing (UNOS). Data collected in 2023 (Lentine et al) show over 28,000 kidney transplantations performed in the United States in that year, with a rise noted due to an increase in deceased donor transplants. Five-year graft survival rates were 90% for living donor transplants and 82.2% for deceased donor transplants (ages 18-34 years). There were more than 140,000 adult candidates on the waiting list in 2023.

SUPPORTIVE LITERATURE

Chaudhry et al (2022) published a systematic review that compared survival for waitlisted patients with kidney failure who received a transplant compared to those who remained on the transplant waiting list. A total of 48 observational studies were included in the systematic review, of which 18 studies were suitable for meta-analysis. Results demonstrated a 55% reduction in the risk of mortality in patients who received a transplant compared to those who remained on dialysis.

Kainz et al (2022), retrospectively compared the association of time on the waitlist with survival of those who received a second transplant to those who remained on the waitlist. A total of 2,346 individuals from the Austrian Dialysis and Transplant Registry and Eurotransplant were included in the study. Inclusion criteria were individuals with a failed first graft, who were over the age of 18 years, and waitlisted for a second kidney transplantation in Austria between the years of 1980 and 2019. Study results demonstrated that second kidney transplantation improved survival at 10 years of follow-up compared with those remaining on the waitlist. The survival difference diminished in the individuals with longer wait times after loss of the first allograft. Individuals with a waitlist for retransplantation of 1 year or less, gained 8.0 life months compared to those who remained on the waiting list for 8 years (0.1 life month gained).

<u>Kidney Retransplant</u>

Pediatric kidney transplant recipients will likely require a retransplant in their lifetime. Gupta et al (2015) retrospectively analyzed OPTN data, focusing on patients who had an initial kidney transplant as children. A total of 2,281 patients were identified. Included were those who had their first transplant before 18 years of age and a second kidney transplant at any age following. In multivariate analysis, the length of first graft survival and age at second graft were significantly associated with second graft survival. Specifically, the first graft survival time of more than 5 years was associated with better second graft survival. However, patients who were between 15 and 20 years old at second transplant were at increased risk of second kidney graft failure compared with individuals in other age groups. It is likely that most pediatric renal allograft recipients will require one or more retransplants during their lifetime. Unfortunately, the use of a second or subsequent graft in pediatric recipients has inferior long-term graft survival rates compared with initial grafts, with decreasing rates with each subsequent graft (Saeed et al 2024).

More recent research is aimed at strategies to prevent transplant rejection, while cell-based therapies are being investigated to minimize the impacts of immunosuppression.

PROFESSIONAL GUIDELINE(S)

The 2021 Chronic Kidney Disease Epidemiology Collaboration (2021 CKD-EPI) removed race as a variable from the GFR equation and recalibrated the other coefficients variables (e.g., age, sex, and serum creatinine). Subsequently, the National Kidney Foundation and American Society of Nephrology Task Force recommended that the 2021 CKD-EPI equation be implemented for eGFR reporting (Delgado et al 2022).

OPTN requires all transplant hospitals to use race-neutral calculations when estimating a candidate's GFR for any purpose covered by OPTN policy. Kidney transplant programs are required to assess their waiting lists and correct wait times for any African American kidney candidates disadvantaged by having their kidney function overestimated because of the use of a race-inclusive calculation (OPTN 2023).

Kidney Disease Improving Global Outcomes (KDIGO) 2024 Clinical Practice Guideline for the Evaluation and Management of CKD recommended considering "planning for preemptive kidney transplantation or dialysis access in adults when the GFR is < 15-20ml/min per 1.734 m^2 or risk of kidney replacement therapy (KRT) is greater than 40% over 2 years."

REGULATORY STATUS

Kidney transplants, as surgical procedures, do not require U.S. Food and Drug Administration (FDA) approval.

The Health Resources Services Administration (HRSA) oversees the transplantation of vascularized human organs through the Organ Procurement and Transplantation Network (OPTN), which was established through the National Organ Transplant Act (NOTA) approved by U.S. Congress in October 1984. It served as a model for development of other transplant networks worldwide, directing how organ allocation would be managed on a national basis. The model was developed through a unique public-private partnership with the United Network for Organ Sharing (UNOS). For more information

view the UNOS website, available from: https://unos.org/about/ [accessed 2026 Feb 26].

The HIV Organ Policy Equity (HOPE) Act was enacted in November 2013 and amended regulations of NOTA. The amendment removed clinical research and institutional review board (IRB) requirements for transplantation of kidneys and livers from donors with HIV to recipients with HIV.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
50300	Donor nephrectomy (including cold preservation); from cadaver donor, unilateral or bilateral
50320	Donor nephrectomy (including cold preservation); open, from living donor
50323	Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50325	Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary
50327	Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each
50340	Recipient nephrectomy (separate procedure)
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	Renal allotransplantation, implantation of graft; with recipient nephrectomy
50370	Removal of transplanted renal allograft
50380	Renal auto-transplantation, reimplantation of kidney

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
N18.1-N18.9	Chronic kidney disease (CKD) (code range)

REFERENCES

American Society of Transplant Surgeons (ASTS), The American Society of Transplantation (AST), The Association of Organ Procurement Organizations (AOPO) [Internet] Statement on transplantation of organs from HIV-infected deceased donors.[accessed 2026 Feb 25] Available from: https://asts.org/docs/default-source/position-statements/transplantation-of-organs-from-hiv-infected-deceased-donors-july-22-2011.pdf?sfvrsn=fbae5a20_4

Black CK, et al. Solid organ transplantation in the 21st century. Ann Transl Med. 2018 Oct;6(20):409.

Chaudhry D, et al. Survival for waitlisted kidney failure patients receiving transplantation versus remaining on waiting list: systematic review and meta-analysis. BMJ. 2022 Mar 01;376:e068769.

Choi A, et al. First porcine to human kidney transplantation performed in the United States. Artif Organs. 2022 Feb;46(2):178-179.

Delgado C, et al. A unifying approach for GFR estimation: Recommendations of the NKF-ASN task force on reassessing the inclusion of race in diagnosing kidney disease. Am J Kidney Dis. 2022 Feb;79(2):268-288.e1.

Gupta M, et al. Repeat kidney transplantation after failed first transplant in childhood: past performance informs future performance. Transplantation. 2015 Aug;99(8):1700-8.

Kainz A, et al. Waiting time for second kidney transplantation and mortality. Clin J Am Soc Nephrol. 2022 Jan;17(1):90-97.

Kute VB, et al, Outcomes of living donor kidney transplant after sars-cov-2 infection in both the donor and the recipient: a multicenter study. Exp Clin Transplant. 2022 Oct;20(10):908-916.

Lentine KL, et al. OPTN/SRTR 2023 annual data report: kidney. Am J Transplant. 2025 Feb;25(2):S22-S137.

Meshram KV, et al. Update on coronavirus 2019 vaccine guidelines for transplant recipients. Transplant Proc. 2022 Jul-Aug;54(6):1399-1404.

National Kidney Foundation. [Internet] Glomerular filtration rate (GFR). [updated 2026 Feb 05; accessed 2026 Feb 25]. Available from: https://www.kidney.org/atoz/content/gfr

Navaneethan SD, et al. KDOQI US commentary on the KDIGO 2024 clinical practice guideline for the evaluation and management of CKD. Am J Kidney Dis. 2025 Feb;85(2):135-176.

Organ Procurement and Transplant Network (OPTN). [Internet]. [accessed 2026 Feb 26]. Available from: https://www.hrsa.gov/optn?from=optn.transplant.hrsa.gov

Philipse DM, et al. Timing of the pre-transplant workup for renal transplantation: is there room for improvement? Clin Kidney J. 2022 Jan 17;15(6):1100-1108.

Porrett PM, et al. First clinical-grade porcine kidney xenotransplant using a human decedent model. Am J Transplant 2022 Jan 20.

Saeed B. Kidney retransplantation in children. Exp Clin Transplant. 2024 Jan;22 (Suppl 1):37-43.

Steinman TI, et al. The clinical practice committee of the American Society of Transplantation. Guidelines for the referral and management of patients eligible for solid organ transplantation. Transplant 2001;71(9):1189-204.

Trullas JC, et al. Renal transplantation in HIV-infected patients: 2010 update. Kidney Int. 2011 Apr;79(8):825-42.

United Network for Organ Sharing (UNOS) [Internet]. How we match organs. 2026 Jan 12. [accessed 2026 Feb 25]. Available from: https://unos.org/transplant/how-we-match-organs/

United Network for Organ Sharing (UNOS) [Internet]. [accessed 2026 Feb 26]. Available from: https://unos.org/about/

Wallisch SS, et al. Survival benefit of first single-organ deceased donor kidney transplantation compared with long-term dialysis across ages in transplant-eligible patients with kidney failure. JAMA Netw Open. 2022 Oct 3;5(10):e2234971.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Kidney Transplantation.

Please refer to the following Medicare Benefit Policy Manual Chapter 11-End Stage Renal Disease (ESRD). Revised 257, 03/01/19. Medicare Benefit Policy Manual [accessed 2026 Feb 26]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.

- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 2/26 **Revised:** **Reviewed:** 7/26	
Date	**Summary of Changes**
7/1/2026 * No change to effective date of policy	• Annual review. No content change for criteria.
7/1/2026	• New

MEDICAL POLICY

Medical Policy Title	**Knee Joint Procedures for Managed Medicaid (MMC), Health and Recovery Plan (HARP), Child Health Plus (CHP), and Essential Plan (EP) Members**
Policy Number	**7.01.123**
Current Effective Date	**January 1, 2027**
Next Review Date	**September 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

SECTION LINKS

Knee Arthroplasty

Knee Arthroscopy and Associated Procedures

Ligament Reconstruction & Repair

Meniscal Procedures

Patellofemoral Realignment Procedures

Motion Restoration Procedures

Restorative Cartilage Procedures

POLICY STATEMENT(S)

Knee Arthroplasty

Total Knee Arthroplasty

I. Total knee arthroplasty is **medically necessary** when **ALL** the following are met:
   A. BMI 40 kg/m² or less;
   B. Pain results in functional impairment that limits range of motion and interferes with activities of daily living;
   C. Conservative management meets **either** of the following:
      1. Conservative management is not required when **any** of the following is documented:
         a. Osteonecrosis/Avascular Necrosis (AVN);
         b. Malignancy involving the knee or adjacent structures;
         c. Distal femur or proximal tibia malunion/nonunion fracture;
         d. Failed partial knee arthroplasty;

e. Severe deformity, condylar collapse, or end-stage bone-on-bone disease; **or**

2. For all other indications, conservative management must include **both** the following:
   a. Physical Therapy (PT) meets **all** the following:
      i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
      ii. Participation for a minimum of 6 weeks during the previous 6 months; **and**
      iii. Failure to improve symptoms or functional impairments;
   b. Pain management includes **any** of the following:
      i. Non- pharmacologic pain management such as modification of activity/protective weight-bearing/use of an orthotic;
      ii. Intra-articular corticosteroid injection; **or**
      iii. Medication management (e.g., non-steroidal anti-inflammatory drugs [NSAIDS]); **and**

D. Condition includes **either** of the following:
   1. Disease is progressed into an uninvolved compartment; **or**
   2. **All** the following are met:
      a. Arthritic condition includes **any** of the following:
         i. Osteoarthritis;
         ii. Inflammatory arthropathy;
         iii. Post-traumatic arthritis; **and**
      b. Knee pain causing loss of function for 12 weeks or more that interferes with activities of daily living;
      c. Weight-bearing radiographs within the last 3 to 6 months demonstrate advanced degenerative joint disease including **one (1)** or more of the following:
         i. Bone-on-bone contact involving two or more knee compartments;
         ii. Marked narrowing of the joint space; **or**
         iii. Moderate-to-severe osteoarthritic changes (Kellgren-Lawrence grade III or IV.

<u>Total Knee Arthroplasty-Revision</u>

II. Revision total knee arthroplasty is **medically necessary** when **ALL** the following are met:
   A. BMI less than 40 kg/m²;
   B. Pain results in functional impairment that limits range of motion and interferes with activities of daily living;

C. Prosthetic failure or removal requirement due to infection;

D. Weight-bearing radiographs within the last 3 to 6 months or physical examination demonstrate **one (1)** or more of the following:

1. Aseptic loosening;
2. Component instability;
3. Component failure;
4. Prosthetic recall;
5. Osteolysis;
6. Periprosthetic infection;
7. Periprosthetic fracture;
8. Recurrent instability, dislocation, or subluxation.

III. Total knee arthroplasty is **not medically necessary** for **ANY** of the following contraindications:

A. Active local or systemic infection;

B. Uncontrolled diabetes mellitus (HbA1c greater than 8%);

C. Uncontrolled hypertension;

D. Nicotine or tobacco, including cigar, cigarette, e-cigarette, nicotine pouch, smokeless tobacco or vape pen use within 6 weeks of surgery;

E. Intra-articular corticosteroid injection within 12 weeks of surgery;

F. Clinically unstable or unmanaged comorbid condition(s);

G. Material allergy incompatible with implantation;

H. Untreated or unmanaged substance use disorder.

<u>Partial Knee Arthroplasty (PKA) or Unicompartmental Knee Arthroplasty (UKA)</u>

IV. A partial knee arthroplasty (PKA) or unicompartmental (UKA) knee arthroplasty is **medically necessary** when documentation supports **ALL** the following:

A. The remaining knee compartments do not demonstrate degenerative changes;

B. The anterior cruciate ligament is functional, either through native integrity or prior successful reconstruction/repair;

C. The individual has **one (1)** of the following:

1. Advanced unicompartmental osteoarthritis;
2. Isolated medial or lateral compartment osteoarthritis (Kellgren-Lawrence grade III or IV); **or**

3. Post-traumatic arthritis limited to a single compartment;

D. BMI is **either**:
   1. 40 kg/m² or less; or
   2. If BMI is 40 kg/m² or greater, documented weight reduction of at least 10% before surgery;

E. Conservative management must include **both** of the following:
   1. Physical Therapy (PT) meets **all** the following:
      a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
      b. Participation for a minimum of 6 weeks during the previous 6 months; **and**
      c. Failure to improve symptoms or functional impairments;
   2. Pain management includes **any** of the following:
      a. Non- pharmacologic pain management such as modification of activity/protective weight-bearing/use of an orthotic;
      b. Intra-articular corticosteroid injection; **or**
      c. Medication management (e.g., NSAIDS);

F. Pain in the last 12 weeks (or more) has resulted in functional impairment that limits range of motion and interferes with activities of daily living or painful weight-bearing;

G. Physical examination is consistent with advanced unicompartmental disease and include **one (1)** or more of the following:
   1. Contracture;
   2. Crepitus;
   3. Correctable angular deformity (valgus deformity of 20 degrees or less or varus deformity of 15 degrees or less);
   4. Joint swelling or effusion;
   5. Instability; **or**
   6. Restricted range of motion;

H. Recent knee radiographs demonstrate at least **one (1)** of the following:
   1. Severe narrowing of the affected compartment joint space;
   2. Bone-on bone contact confined to a single compartment; **or**
   3. Moderate-to-severe osteoarthritic degeneration (Kellgren-Lawrence grade III or IV) within the last 3 to 6 months.

V. PKA or UKA are **contraindicated** when **ANY** of the following are present:

A. Presence of osteoporosis or osteopenia;
B. Active local or systemic infection;
C. Uncontrolled diabetes mellitus (HbA1c greater than 8%);
D. Nicotine or tobacco, including cigar, cigarette, e-cigarette, nicotine pouch, smokeless tobacco or vape pen use in the 6 weeks prior to surgery;
E. Intra-articular corticosteroid injection in the operative joint within 12 weeks of surgery;
F. Meniscectomy, total, in remaining compartment;
G. Angular deformity or contracture (or contracture exceeding the specified range) with **any** of the following:
    1. Fixed valgus deformity greater than 20 degrees;
    2. Fixed varus deformity greater than 15 degrees;
    3. Flexion contracture of at least 15 degrees;
    4. Flexion of less than 110 degrees;
H. Clinically unstable or unmanaged comorbid condition(s);
I. Material allergy incompatible with implantation;
J. Untreated or unmanaged substance use disorder.

Patellofemoral Arthroplasty (PFA)

VI. A patellofemoral knee arthroplasty (PFA) is **medically necessary** when **ALL** the following are met:
    A. BMI is 40 kg/m² or less;
    B. The individual has **one (1)** of the following:
        1. Unsuccessful outcome following a patellofemoral extensor mechanism unloading procedure;
        2. Severe patellofemoral osteoarthritis (Kellgren- Lawrence grade III or IV) limited to a single knee compartment;
        3. Isolated anterior knee pain or patellar pain that has persisted for 3 months or longer and is further exacerbated by functional activities including stairs, inclines, transfers or prolonged sitting;
    C. Pain in the last 12 weeks (or more) has resulted in functional impairment that limits range of motion and interferes with activities of daily living or painful weight-bearing;
    D. Conservative management must include **both** of the following:
        1. Physical Therapy (PT) meets **all** the following:

a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
b. Participation for a minimum of 6 weeks during the previous 6 months; **and**
c. Failure to improve symptoms or functional impairments;

2. Pain management includes **any** of the following:
   a. Non- pharmacologic pain management such as modification of activity/protective weight-bearing/use of an orthotic;
   b. Intra-articular corticosteroid injection; **or**
   c. Medication management (e.g., NSAIDS); **and**

E. Physical examination includes **one (1)** or more of the following:
1. Contracture;
2. Crepitus;
3. Deformity;
4. Joint swelling or effusion;
5. Patellar instability; **or**
6. Restricted range of motion;

F. Weight-bearing radiographs confirm **both** the following:
1. No degenerative changes in the lateral or medial compartments; **and**
2. **either** of the following:
   a. Severe narrowing of the patellofemoral joint space; **or**
   b. Patellofemoral bone-on bone contact confined to a single compartment.

VII. A patellofemoral arthroplasty is **contraindicated** in **ANY** of the following:
A. Active local or systemic infection;
B. Abnormal patellofemoral alignment or tracking;
C. Uncontrolled diabetes mellitus (HbA1c greater than 8%);
D. Uncontrolled hypertension;
E. Inflammatory arthritis;
F. Knee instability related to ligament deficiency;
G. Nicotine or tobacco, including cigar, cigarette, e-cigarette, nicotine pouch, smokeless tobacco or vape pen use in the 6 weeks prior to surgery;
H. Intra-articular corticosteroid injection in the operative joint within 12 weeks of surgery;

I. Meniscectomy, total, in remaining compartment;

J. Clinically unstable or unmanaged comorbid condition(s);

K. Material allergy incompatible with implantation;

L. Untreated or unmanaged substance use disorder;

M. Fixed flexion contracture of 10 degrees or more.

Diagnostic Knee Arthroscopy

VIII. Diagnostic knee arthroscopy is **medically necessary** when documentation supports **ALL** the following:

A. Weight-bearing radiographs do not demonstrate moderate-to-severe osteoarthritic degeneration (Kellgren-Lawrence grade III or IV), including anteroposterior and Rosenberg views when available;

B. Pain in the last 12 weeks (or more) has resulted in functional impairment that limits range of motion and interferes with activities of daily living or painful weight-bearing;

C. Conservative management must include **both** of the following:

1. Physical Therapy (PT) meets **all** the following:

a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;

b. Participation for a minimum of 6 weeks during the previous 6 months; **and**

c. Failure to improve symptoms or functional impairments;

2. Pain management includes **any** of the following:

a. Non- pharmacologic pain management such as modification of activity/protective weight-bearing/use of an orthotic;

b. Intra-articular corticosteroid injection; **or**

c. Medication management (e.g., NSAIDS);

D. Conventional diagnostic studies have failed to establish a definitive diagnosis, including **both**:

1. Plain radiographs; **and**

2. MRI;

E. Physical examination is consistent with intra-articular knee pathology and includes **one (1)** or more of the following:

1. Joint swelling or effusion;

2. Restricted range of motion; **or**

3. A positive meniscal provocation examination consistent with joint-line tenderness.

Arthroscopic Chondroplasty

IX. Arthroscopic chondroplasty of the knee is **medically necessary** when **ALL** the following are met:
   A. Conservative management must include **both** of the following:
      1. Physical Therapy (PT) meets **all** the following:
         a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
         b. Participation for a minimum of 6 weeks during the previous 6 months; **and**
         c. Failure to improve symptoms or functional impairments;
      2. Pain management includes **any** of the following:
         a. Non- pharmacologic pain management such as modification of activity/protective weight-bearing/use of an orthotic;
         b. Intra-articular corticosteroid injection; **or**
         c. Medication management (e.g., NSAIDS);
   B. Weight-bearing radiographs conducted within the previous 3 to 6 months demonstrate minimal degenerative joint disease, consistent with Kellgren-Lawrence grade 0 or I;
   C. Knee pain that has resulted in functional impairment that interferes with activities of daily living, work-related activities, routine ambulation, participation in athletics, or other age-appropriate activities;
   D. The presence of mechanical symptoms consistent with intra-articular knee pathology, including **one (1)** or more of the following during weight bearing activity:
      1. Painful clicking or popping;
      2. Recurrent catching; **or**
      3. True mechanical locking or limitation of joint motion.

Debridement

X. Debridement, with or without chondroplasty, is **medically necessary** when documentation supports **ONE (1)** of the following clinical indications, when associated criteria are met:
   A. Arthrofibrosis, when **all** the following are met:
      1. Weight-bearing radiographs do not demonstrate moderate-to-severe osteoarthritic changes (Kellgren-Lawrence grade III or IV);
      2. Clinical findings are consistent with arthrofibrosis, including pain, stiffness, and restricted range of motion;
      3. A physical therapy program (including telehealth-based rehabilitation when appropriate) that is provided by a physical therapist or chiropractor for at least 6 weeks in the past 6

months;

B. Debridement of femoral condyle or tibial plateau articular cartilage when **all** the following are met:
   1. Absence of moderate-to-severe osteoarthritis on weight-bearing radiographs;
   2. Conservative management must include **all** of the following:
      a. Use of an orthotic/brace;
      b. Physical Therapy (PT) meets **all** the following:
         i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
         ii. Participation for a minimum of 6 weeks during the previous 6 months; **and**
         iii. Failure to improve symptoms or functional impairments;
      c. Pain management includes **any** of the following:
         iv. Intra-articular corticosteroid injection; **or**
         v. Medication management (e.g., NSAIDS);
   3. Recurrent joint effusions (**two [2]** or more episodes);
   4. MRI findings demonstrating an unstable chondral lesion within the previous 3 to 6 months;
   5. Knee pain that has resulted in functional impairment;

C. Patellofemoral chondrosis when **all** the following are met:
   1. No evidence of an alternative pain generator, including:
      a. Referred pain;
      b. Bursitis;
      c. Radicular pain; **or**
      d. Tendinopathy;
   2. Weight-bearing radiographs do not demonstrate moderate-to-severe osteoarthritis (Kellgren-Lawrence grade III or IV);
   3. Conservative management must include **all** of the following:
      a. Use of an orthotic/brace;
      b. Physical Therapy (PT) meets **all** the following:
         i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
         ii. Participation for a minimum of 6 weeks during the previous 6 months; **and**
         iii. Failure to improve symptoms or functional impairments;

c. Pain management includes **any** of the following:
   i. Intra-articular corticosteroid injection; **or**
   ii. Medication management (e.g., NSAIDS);

D. Anterior knee pain localized to the patellofemoral compartment;

E. Functional limitation attributable to the patellofemoral symptoms;

F. Osteochondritis Dissecans (Pediatric Population), when **all** the following are met:

1. At least **two (2)** of the following are present:
   a. Restricted range of motion;
   b. Limping;
   c. Locking or catching symptoms;
   d. Joint pain, particularly during or after activity;
   e. Joint swelling; **or**
   f. Localized tenderness;
2. Imaging conducted within the previous 3 to 6 months includes **both** radiographs and MRI;
3. Conservative management must include **all** of the following:
   a. Use of an orthotic/brace;
   b. Physical Therapy (PT) meets **all** the following:
      i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
      ii. Participation for a minimum of 6 weeks during the previous 6 months; **and**
      iii. Failure to improve symptoms or functional impairments;
4. Presence of at least **one (1)** of the following factors associated with failure of nonoperative management:
   a. Lesion size greater than 150 mm^2;
   b. Lesion extending into shoulders or talus;
   c. Limited remaining skeletal growth potential; **or**
   d. Unstable or detached osteochondral lesion.

<u>Removal of a Loose or Foreign Body</u>

XI. Arthroscopic or open removal of an intra-articular loose body or foreign body of the knee is **medically necessary** when **ALL** the following are met:

A. Symptoms are present and include:

1. Pain, with **one (1)** or more of the following:
    a. Buckling during weight-bearing activities;
    b. Instability or weakness; **or**
    c. Mechanical symptoms including clicking, popping, catching, or locking;

B. Imaging requirements are met:
1. Knee radiographs obtained within the previous 3 to 6 months; **or**
2. MRI obtained within the previous 3 to 6 months;

C. **any** of the following indications are present:
1. Intra-articular loose body;
2. Foreign body within the knee joint; **or**
3. Impinging osteophyte contributing to symptoms.

Synovectomy and/or Synovial Biopsy

XII. Synovectomy or synovial biopsy is **medically necessary** when documentation supports **ONE (1)** of the following clinical indications:

A. Hemarthrosis, when **both** of the following are met:
1. Associated with trauma, coagulation disorder, or bleeding disorder; **and**
2. Diagnosis confirmed by physical examination, joint aspiration, MRI, or a combination of these;

B. Symptomatic Synovial Plica, when **all** the following are met:
1. Examination and MRI findings support the diagnosis of plica;
2. Conservative management must include **both** of the following:
    a. Physical Therapy (PT) meets **all** the following:
        i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
        ii. Participation for a minimum of 6 weeks during the previous 6 months; **and**
        iii. Failure to improve symptoms or functional impairments;
    b. Pain management includes **any** of the following:
        i. Activity modification, protected weight-bearing, brace, or orthotic use;
        ii. Intra-articular corticosteroid injection; **or**
        iii. Pharmacologic treatment (e.g., NSAIDS or analgesics);
3. Joint aspiration or corticosteroid injection has been performed when clinically appropriate;

C. Proliferative Synovial Disease, when **all** the following are met:
   1. Condition includes **one (1)** or more of the following:
      a. Pigmented villonodular synovitis (PVNS);
      b. Synovial chondromatosis;
      c. Sarcoid synovitis;
      d. Traumatic hypertrophic synovitis; **or**
      e. Similar proliferative synovial disorder;
   2. Diagnosis is confirmed by biopsy, MRI, clinical history, or a combination of these;
   3. Conservative management must include **both** of the following:
      a. Physical Therapy (PT) meets **all** the following:
         i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
         ii. Participation for a minimum of 6 weeks during the previous 6 months; **and**
         iii. Failure to improve symptoms or functional impairments;
      b. Pain management includes **any** of the following:
         i. Activity modification, protected weight-bearing, brace, or orthotic use;
         ii. Intra-articular corticosteroid injection; **or**
         iii. Pharmacologic treatment (e.g., NSAIDS or analgesics);

D. Rheumatoid Synovitis, when **all** the following are met:
   1. Rheumatoid arthritis with symptomatic synovial involvement;
   2. Conservative management must include **both** of the following:
      a. Physical Therapy (PT) meets **all** the following:
         i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
         ii. Participation for a minimum of 6 weeks during the previous 6 months; **and**
         iii. Failure to improve symptoms or functional impairments;
      b. Pain management includes **any** of the following:
         i. Activity modification, protected weight-bearing, brace, or orthotic use;
         ii. Intra-articular corticosteroid injection; **or**
         iii. Pharmacologic management (e.g., NSAIDS or analgesics);
   3. Disease remains refractory following at least 6 months of disease-modifying antirheumatic drug (DMARD) therapy.

XIII. Arthroscopic Knee Procedures are **contraindicated** when an intra-articular corticosteroid injection has been administered within 4 weeks of the planned arthroscopic procedure.

Knee Ligament Reconstruction and/or Repair- Pediatric/Skeletally Immature

XIV. Anterior cruciate ligament (ACL) reconstruction is **medically necessary** in skeletally immature individuals when **ALL** the following are met:

A. At least **two (2)** of the following are present:
   1. Audible pop at the time of injury;
   2. Difficulty achieving full knee extension;
   3. Instability during cutting, pivoting, jumping, or athletic activities;
   4. Localized joint tenderness;
   5. Pain with weight-bearing activities;
   6. Quadriceps muscle atrophy;
   7. Reduced range of motion;
   8. Swelling occurring within 6 to 8 hours following injury;

B. Knee radiographs obtained within the previous 3 to 6 months;

C. MRI obtained within the previous 3 to 6 months;

D. **Either** of the following indications are present:
   1. Complete ACL tear associated with significant instability; **or**
   2. Partial ACL tear with ongoing instability despite a structured rehabilitation program

Knee Ligament Reconstruction and/or Repair- Adult

XV. Anterior cruciate ligament (ACL) reconstruction is **medically necessary** when **ALL** the following criteria are met:

A. Conservative management must include **all** of the following:
   1. Use of an orthotic/brace;
   2. Physical Therapy (PT) meets **all** the following:
      a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
      b. Participation for a minimum of 6 weeks during the previous 6 months;
      c. Includes attempts at full-joint extension; **and**
      d. Failure to improve symptoms or functional impairments;
   3. Pain management includes **any** of the following:
      a. Intra-articular corticosteroid injection; **or**

b. Medication management (e.g., NSAIDS);

B. **All** age-specific criteria must be met:

1. Individuals aged 18-25 years must meet **all** the following criteria:

a. Weight-bearing radiographs do not demonstrate advanced degenerative joint disease (Kellgren-Lawrence grade III or IV);

b. Symptomatic functional instability symptoms;

c. ACL rupture confirmed by **all** the following:

i. MRI performed within the previous 6 to 12 months;

ii. Physical examination demonstrates objective anterior instability, including **one (1)** or more of the following:

a) Positive anterior drawer test with increased anterior tibial translation compared with the uninvolved knee;

b) Positive Lachman examination with increased tibial translation and a diminished, soft, or absent endpoint; **or**

c) Positive pivot-shift examination;

iii. Physical Therapy* for range of motion requirements are met, including **either** of the following:

a) Physical therapy is NOT required for individuals with full range of motion defined as having **any** of the following:

1) Extension to 0 degrees;

2) Flexion ≥ 130 degrees;

3) Symmetry to the contralateral limb; **or**

b) Physical therapy* is required for individuals with restricted range of motion defined as having **any** of the following:

1) Loss of full extension;

2) Measurable side-to-side ROM asymmetry;

3) Pain-limited range of motion affecting functional activities;

4) Reduced flexion;

*A physical therapy program (including telehealth-based rehabilitation when appropriate) must be provided by a physical therapist or chiropractor for at least 6 weeks in the past 6 months and must attempt a full-joint extension.

OR

2. Individuals aged 26-40 years must meet **all** the following criteria:
    a. Weight-bearing radiographs do not demonstrate advanced degenerative joint disease (Kellgren-Lawrence grade III or IV);
    b. The individual reports symptomatic instability resulting in recurrent giving-way episodes, pivoting limitations, safety concerns, or impairment of daily activities, occupational demands, athletic participation, or other desired functional activities;
    c. ACL rupture confirmed by **all** the following:
        i. MRI performed within the previous 6 to 12 months;
        ii. Physical examination demonstrates objective anterior instability, including **one (1)** or more of the following:
            a) Positive anterior drawer test with increased anterior tibial translation compared with the uninvolved knee;
            b) Positive Lachman examination with increased tibial translation and a diminished, soft, or absent endpoint; **or**
            c) Positive pivot-shift examination;

OR

3. Individuals 40 years of age or greater must meet **all** the following criteria:
    a. Weight-bearing radiographs do not demonstrate advanced degenerative joint disease (Kellgren-Lawrence grade III or IV);
    b. The individual reports symptomatic instability resulting in recurrent giving-way episodes, pivoting limitations, safety concerns, or impairment of daily activities, occupational demands, athletic participation, or other desired functional activities;
    c. ACL rupture confirmed by MRI within the last 6 to 12 months.

<u>Multiple Ligament Reconstruction</u>

XVI. Reconstruction or repair of multiple knee ligaments is **medically necessary** when **BOTH** the following are met:
    A. The presence of at least **two (2)** of the following:
        1. Weight-bearing difficulty or the need for protective bracing due to pain or instability;
        2. Functional impairment affecting activities of daily living, occupational activities, **or** athletic participation;
        3. Instability, including recurrent giving-way, buckling, or rotational instability;
        4. Localized joint-line tenderness or pain consistent with ligamentous or meniscal injury;
        5. Symptoms such as catching, locking, or painful clicking; or

6. Joint swelling or effusion following the injury; **and**

B. Documentation confirms injury involving **two or more** major stabilizing ligaments of the knee, as demonstrated by **either** of the following:

1. MRI; **or**
2. Physical examination is consistent with multiligamentous* instability.

*Multiligament knee injuries do not require prior conservative management, as these injuries are characteristically unstable and are unlikely to be adequately managed with physical therapy, bracing, or other nonoperative treatments alone.

Posterior Cruciate Ligament (PCL) Reconstruction

XVII. Posterior cruciate ligament (PCL) reconstruction is **medically necessary** when **ALL** the following are met:

A. Weight-bearing radiographs do not demonstrate moderate-to-severe osteoarthritis (Kellgren-Lawrence grade III or IV);

B. MRI obtained within the previous 3 to 6 months demonstrates a near-complete or complete PCL tear;

C. Reported knee instability, weakness, or episodes of giving-way;

D. Objective physical examination is consistent with PCL insufficiency, including **any** of the following:

1. Positive posterior drawer examination;
2. Reverse pivot-shift test;
3. Positive quadriceps active test;
4. Posterior sag sign; **or**
5. Tibial drop-back sign;
6. Conservative management must include **all** of the following:
   a. Physical Therapy (PT) meets **all** the following:
      i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
      ii. Participation for a minimum of 6 weeks during the previous 6 months; **and**
      iii. Failure to improve symptoms or functional impairments;
   b. Pain management includes **any** of the following:
      i. Nonpharmacologic management including activity modification, protected weight-bearing, brace, or orthotic use; **or**
      ii. Medication management (e.g., NSAIDS or analgesics);

Lateral Collateral Ligament (LCL) or Medial Collateral Ligament (MCL) Repair/Reconstruction

Isolated repair or reconstruction of the lateral collateral ligament (LCL) or medial collateral ligament (MCL) is uncommon and is generally performed in conjunction with treatment of additional ligamentous injuries.

Requests for collateral ligament repair or reconstruction in the absence of an acute traumatic injury will be assessed individually based on the clinical circumstances.

Arthroscopic Meniscectomy or Meniscal Repair

XVIII. Arthroscopic meniscectomy is **medically necessary** when **ALL** the following are met:

A. Weight-bearing radiographs do not demonstrate advanced osteoarthritis (Kellgren-Lawrence grade IV);

B. **One (1)** of the following clinical scenarios is present:

1. Individual is younger than 18 years of age;
    a. MRI confirms a meniscal tear; and
    b. Physical examination is consistent with meniscal pathology;

C. Repairable tear pattern, when **all** the following are met:

1. MRI demonstrates **any** of the following:
    a. Meniscal root tear;
    b. Peripheral tear involving the vascular zone; **or**
    c. Other repairable meniscal tear;
2. Pain localizes to the involved compartment on physical examination;
3. Bucket-handle tear, when **all** the following are met:
    a. MRI confirms a bucket-handle meniscal tear;
    b. Acute traumatic injury with a locked knee; **and**
    c. Examination demonstrates meniscal findings or loss of terminal extension;
4. Symptomatic meniscal tear after unsuccessful conservative management:
    a. Physical examination is consistent with a meniscal tear;
    b. Clinical findings include **ONE (1)** or more:
        i. Joint-line pain with forced hyperextension;
        ii. Joint-line pain with maximal flexion; or
        iii. Catching or locking symptoms;

D. Conservative management must include **all** of the following:

a. Physical Therapy (PT) meets **all** the following:
   i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
   ii. Participation for a minimum of 6 weeks during the previous 6 months; **and**
   iii. Failure to improve symptoms or functional impairments;
b. Pain management includes **any** of the following:
   i. Nonpharmacologic management including activity modification, protected weight-bearing, brace, or orthotic use; **or**
   ii. Intra-articular corticosteroid injection;
   iii. Medication management (e.g., NSAIDS or analgesics); **and**

E. Imaging performed within the previous 3 to 6 months demonstrates **either:**
1. Mild, minimal, or no arthritic change on weight-bearing radiographs; **or**
2. MRI-confirmed meniscal tear with mild or absent degenerative findings and **all** the following:
   a. No full-thickness cartilage loss;
   b. No moderate or severe cartilage thinning;
   c. No meniscal extrusion;
   d. No greater than mild osteophyte formation; **and**
   e. No subchondral cystic change or bone edema.

XIX. Arthroscopic meniscal repair is **medically necessary** when **ALL** the following are met:

A. Weight-bearing radiographs do not demonstrate advanced osteoarthritis (Kellgren-Lawrence grade III or IV);
B. **All** age-based criteria are met:
1. Individual younger than eighteen (18) years:
   a. MRI demonstrates a meniscal tear with physical examination supporting meniscal pathology; including **any** of the following:
      i. Meniscal root tear;
      ii. Peripheral tear involving the vascular zone;
      iii. Other repairable meniscal tear and compartment-specific pain is present on examination; **or**
2. Individual is 19-40 years:
   a. Examination demonstrates **one (1)** or more:

i. Joint-line pain with hyperextension;
ii. Joint-line pain with maximal flexion;
iii. Catching or locking symptoms;

b. Imaging performed within the previous 3 to 6 months demonstrates **either:**
i. Mild, minimal, or no arthritic change on weight-bearing radiographs; **or**
ii. MRI-confirmed meniscal tear with mild or absent degenerative findings and **all** the following:
a) No full-thickness cartilage loss;
b) No moderate or severe cartilage thinning;
c) No meniscal extrusion;
d) No greater than mild osteophyte formation;
e) No subchondral cystic change or bone edema; **or**

3. Individual is 41 years of age or older:
a. Examination demonstrates **one (1)** or more:
i. Joint-line pain with hyperextension;
ii. Joint-line pain with maximal flexion; **or**
iii. Catching or locking symptoms;
b. Imaging requirements outlined above are satisfied;
c. Conservative management meets **either** of the following:
i. Conservative management is not required when **any** of the following is documented:
a) Acute traumatic unstable meniscal tear with mechanical symptoms;
b) Displaced bucket-handle tear;
c) Extension block or inability to fully extend the knee;
d) Obstructing meniscal fragment producing loss of motion;
e) True mechanical locking of the knee; **or**
ii. For all other indications, conservative management must include **all** of the following:
a) Physical Therapy (PT) meets **all** the following:
1) Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
2) Participation for a minimum of 6 weeks during the previous 6 months;

3) Failure to improve symptoms or functional impairments; **and**

b) Pain management includes **any** of the following:

1) Nonpharmacologic management including activity modification, protected weight-bearing, brace, or orthotic use; **or**

2) Intra-articular corticosteroid injection;

3) Medication management (e.g., NSAIDS or analgesics).

XX. Arthroscopic meniscectomy or meniscal repair is **contraindicated** when **ANY** of the following are present:

A. Intra-articular corticosteroid injection administered within four weeks prior to the planned procedure;

B. Advanced osteoarthritis including **either**:

1. Kellgren-Lawrence grade IV osteoarthritis when meniscectomy is requested; **or**

2. Kellgren-Lawrence grade III or IV osteoarthritis when meniscal repair is requested;

C. Degenerative, non-traumatic meniscal pathology when partial meniscectomy is proposed.

<u>Meniscal Allograft Transplantation</u>

XXI. Meniscal allograft transplantation is **medically necessary** when **ALL** the following are met:

A. BMI is less than 40kg/m²;

B. Individual is less than 40 years of age and is skeletally mature;

C. Weight-bearing radiographs do not demonstrate **either** of the following:

1. Moderate-to-severe articular degeneration corresponding to Modified Outerbridge grade III or IV; **or**

2. Moderate-to-severe osteoarthritis (Kellgren-Lawrence grade III or IV);

D. Lower extremity alignment demonstrates no significant varus or valgus deformity;

E. Conservative management must include **all** of the following:

1. Non-steroidal anti-inflammatory drugs (NSAIDS) or analgesics;

2. Physical Therapy (PT) meets **all** the following:

a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;

b. Participation for a minimum of 6 weeks during the previous 6 months; **and**

c. Failure to improve symptoms or functional impairments;

3. Pain management includes **at least one (1)** of the following:

a. Nonpharmacologic management including activity modification, protected weight-

bearing, brace, or orthotic use; **or**

b. Intra-articular corticosteroid injection;

F. Ligamentous stability has been established before transplantation or will be addressed concurrently;

G. MRI demonstrates a meniscal-deficient compartment or prior diagnostic evaluation confirms subtotal or total meniscectomy.

XXII. Meniscal Allograft Transplantation is **not medically necessary** for **ANY** of the following:

A. Intra-articular corticosteroid injection within 4 weeks of the proposed procedure; or

B. **Any** of the following conditions, which have not been corrected, either before or in conjunction with the planned procedure:

1. Full-thickness articular cartilage defects, including advanced focal chondral lesions (e.g., International Cartilage Repair Society Grade III or IV or Outerbridge Grade IV);
2. Ligamentous insufficiency resulting in joint instability;
3. Coronal plane malalignment greater than 5 degrees of varus or valgus; **or**
4. Severe osteoarthritis (Kellgren-Lawrence grade IV).

<u>Patellar Realignment</u>

XXIII. Patellar realignment is **medically necessary** when documentation supports **ONE (1)** of the following:

A. Symptomatic patellar maltracking or malalignment and **all** the following:

1. Imaging demonstrates abnormal patellofemoral alignment or patellar maltracking;
2. Imaging does not identify an associated fracture or intra-articular loose body;
3. Physical examination demonstrates **both**:
   a. Patellofemoral pain; **and**
   b. Patellar instability findings, including apprehension or a positive J-sign;

B. Conservative management must include **all** of the following:

1. Physical Therapy (PT) meets all the following:
   a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
   b. Participation for a minimum of 3 months during the previous 6 months; **and**
   c. Failure to improve symptoms or functional impairments;
2. Pain management includes **at least one (1)** of the following:
   a. Nonpharmacologic management including activity modification, protected weight-bearing, brace, or orthotic use;

b. Intra-articular corticosteroid injection; **or**

c. Medication management (e.g., NSAIDS or analgesics);

C. Recurrent patellar instability and **both** of the following:

1. **Two (2)** or more documented patellar dislocations or subluxation events; **and**
2. **Either** of the following are met:
   a. Imaging demonstrates medial patellofemoral ligament insufficiency; **or**
   b. Physical examination confirms patellar instability with a positive apprehension test;

D. Acute traumatic patellar dislocation with associated structural injury demonstrated on imaging, including **one (1)** or more of the following:

1. Intra-articular fracture;
2. Osteochondral fracture; **or**
3. Loose body.

XXIV. Lateral retinacular release is **medically necessary** for **EITHER** of the following:

A. Diagnostic imaging demonstrates confirms patellar tilt and physical examination identifies isolated patellofemoral pain that is reproduced with patellar tilt testing; **or**

B. Symptomatic lateral patellofemoral cartilage pathology and **all** the following are met:

1. Weight-bearing radiographs show no evidence of moderate-to-severe osteoarthritis (Kellgren-Lawrence grade III or IV);
2. Imaging findings or intraoperative assessment confirm a cartilage lesion involving the lateral trochlear surface of the femur or the lateral patellar facet;
3. Conservative management must include **all** of the following:
   a. Physical Therapy (PT) meets **all** the following:
      i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
      ii. Participation for a minimum of 6 weeks during the previous 6 months; **and**
      iii. Failure to improve symptoms or functional impairments; and
   b. Pain management includes **at least one (1)** of the following:
      i. Nonpharmacologic management including activity modification, protected weight-bearing, brace, or orthotic use;
      ii. Intra-articular corticosteroid injection; **or**
      iii. Medication management (e.g., NSAIDS or analgesics).

<u>Knee Lysis of Adhesions</u>

XXV. Knee arthroscopy with lysis of adhesions is **medically necessary** when **EITHER** of the following is met:

A. Post-surgical stiffness following ligament reconstruction or knee joint reconstruction, and **all** the following:
   1. At least 12 weeks have elapsed since the prior procedure;
   2. Physical examination demonstrates **either**:
      a. Knee flexion is less than 105 degrees; **or**
      b. Flexion contracture greater than 10 degrees;
   3. A physical therapy program (including telehealth-based rehabilitation when appropriate) provided by a physical therapist or chiropractor has been completed for at least 6 weeks within the 6 months without meaningful improvement in symptoms or function'

B. Arthrofibrosis associated with prior knee trauma or resolved knee infection, and **both** of the following:
   1. At least 12 weeks have passed since the traumatic event or resolution of infection; **and**
   2. Manipulation under anesthesia is planned in conjunction with the lysis of adhesions procedure.

<u>Manipulation Under Anesthesia (MUA)</u>

XXVI. Manipulation under anesthesia of the knee is **medically necessary** when **ALL** the following criteria are met:

A. Conservative management must include **all** of the following:
   1. Physical Therapy (PT) meets **all** the following:
      a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
      b. Participation for a minimum of 6 weeks during the previous 6 months;
      c. Failure to improve symptoms or functional impairments; **and**
   2. Pain management includes **at least ONE (1)** of the following:
      a. Nonpharmacologic management including activity modification, protected weight-bearing, brace, or orthotic use;
      b. Medication management (e.g.,NSAIDS) or analgesics; **and**

B. Diagnostic evaluation performed within the previous 3 to 6 months includes **both** the following:
   1. Computed tomography (CT) imaging;
   2. Knee radiographs confirming **both**:

a. Intact surgical hardware when present; **and**

b. Absence of a mechanical cause for restricted motion (e.g., component malposition or fracture); **and**

C. Clinical findings demonstrate **all** the following:

1. Flexion contracture greater than ten (10) degrees;
2. Knee flexion less than 90 degrees; **and**
3. Pain and stiffness has resulted in functional impairment and interferes with activities of daily living.

Restorative Cartilage Procedures of the Knee

Restorative cartilage procedures include osteochondral autograft transfer, osteochondral allograft transplantation, autologous chondrocyte implantation, mosaicplasty, microfracture, abrasion arthroplasty, subchondral drilling, or similar cartilage restoration techniques.

XXVII. Restorative cartilage procedures are **medically necessary** when documentation supports **EITHER** of the following:

A. Focal Chondral or Osteochondral Defect, when **all** the following are met:

1. Weight-bearing radiographs do not demonstrate moderate-to-severe osteoarthritis (Kellgren-Lawrence grade III or IV);
2. Individual is skeletally mature and younger than 50 years of age; requests for older individuals may be considered when activity demands and clinical circumstances support intervention;
3. Conservative management must include **all** of the following:
   a. Physical Therapy (PT) meets **all** the following:
      iv. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
      v. Participation for a minimum of 6 weeks during the previous 6 months;
      vi. Failure to improve symptoms or functional impairments; **and**
   b. Pain management includes **at least one (1)** of the following:
      vii. Nonpharmacologic management including activity modification, protected weight-bearing, brace, or orthotic use;
      viii. Intra-articular corticosteroid injection; **or**
      ix. Medication management (e.g., NSAIDS or analgesics); **and**
4. MRI confirms **one (1)** of the following:
   a. Full-thickness weight-bearing cartilage lesion measuring less than 2.5 cm^2;

b. Single full-thickness grade III or IV Outerbridge lesion measuring between 1.0 cm^2 and 2.0 cm^2 and involving only one articular surface; **or**

c. Full-thickness chondral or osteochondral lesion involving the femoral condyle or trochlea measuring less than 2.5 cm^2;

5. Localized knee pain has been present for at least 6 months and results in significant functional limitation;
6. Physical examination demonstrates restricted range of motion and/or mechanical symptoms including clicking, popping, catching, or locking;
7. Physical examination or imaging confirms **both**:
   a. ligamentous stability; **and**
   b. Intact meniscal integrity;

B. Patellofemoral Chondrosis, when **all** the following are met:
1. Examination demonstrates pain localized to the patellofemoral compartment;
2. Imaging demonstrates patellofemoral chondrosis classified as Outerbridge grade III or IV;
3. Weight-bearing radiographs do not demonstrate moderate-to-severe osteoarthritis (Kellgren-Lawrence grade III or IV);
4. Anterior knee pain results in functional impairment that interferes with activities of daily living;
5. Symptoms correlate with the documented patellofemoral chondral abnormality;
6. Conservative management must include **all** of the following:
   a. Physical Therapy (PT) meets **all** the following:
      i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
      ii. Participation for a minimum of 6 weeks during the previous 6 months;
      iii. Failure to improve symptoms or functional impairments; **and**
   b. Pain management includes **at least ONE (1)** of the following:
      i. Nonpharmacologic management including activity modification, protected weight-bearing, brace, or orthotic use;
      ii. Intra-articular corticosteroid injection; **or**
      iii. Medication management (e.g., NSAIDS or analgesics).

RELATED POLICIES

Not Applicable

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Several factors increase the risk of developing knee osteoarthritis, including advanced age, increased body weight, bone density abnormalities, meniscal derangement, sex, and prior trauma. Individuals with knee osteoarthritis commonly experience pain and functional limitations that may interfere with ambulation, activities of daily living, or the ability to work. Imaging may demonstrate the severity of disease through findings such as joint space narrowing, osteophyte formation, subchondral sclerosis, or exposed bone.

The Kellgren-Lawrence Grading System is a radiographic grading system that has been developed for describing osteoarthritic changes to the knee. When used, the radiographic findings are typically reported within one of the following categories:

- Grade 0 – No radiographic features of osteoarthritis are present;
- Grade I – Doubtful narrowing of joint space and possible osteophytic lipping;
- Grade II – Definite osteophytes and possible narrowing of joint space;
- Grade III – Moderate multiple osteophytes, definite narrowing of joint space, some sclerosis, and possible deformity of bone contour;
- Grade IV – Large osteophytes, marked narrowing of joint space, severe sclerosis, and definite deformity of bone contour.

Modified Outerbridge Classification is a system that has been developed for judging articular cartilage injury to the knee. This system allows delineation of varying areas of chondral pathology, based on the qualitative appearance of the cartilage surface as viewed on MRI, and can assist in identifying those injuries that are suitable for repair techniques. The characterization of cartilage in this system is as follows:

- Grade I – softening with swelling;
- Grade II – fragmentation and fissuring less than one square centimeter (1 cm2);
- Grade III – fragmentation and fissuring greater than one square centimeter (1 cm2);
- Grade IV – subchondral bone exposed.

Initial management typically consists of conservative treatment, which may include physical therapy, exercise, weight loss, nonsteroidal anti-inflammatory medications, and intra-articular injections. These treatments are generally attempted before surgical intervention is considered, except in circumstances such as significant trauma where conservative treatment would not be expected to provide meaningful benefit.

Knee arthroplasty, also known as knee replacement, is a commonly performed orthopedic procedure

in which damaged portions of the knee joint are resurfaced and replaced with prosthetic components made of materials such as metal, plastic, or ceramic. The procedure is most commonly performed for advanced osteoarthritis but may also be indicated for inflammatory arthritis or osteonecrosis with secondary arthritis when symptoms and functional impairment warrant surgical intervention. Potential complications of knee arthroplasty include infection, pulmonary embolism, deep vein thrombosis, nerve injury, and the need for subsequent revision surgery.

Arthroscopy and Associated Procedures

Damage to the articular cartilage or menisci of the knee may develop over time or result from an acute injury. Individuals with these conditions may experience pain, swelling, catching, or locking, which can limit the ability to fully extend the knee and interfere with activities of daily living.

When surgical treatment is indicated, knee arthroscopy is a minimally invasive procedure that may be performed to evaluate and treat the affected structures. During the procedure, the surgeon makes small incisions and inserts a fiber-optic camera through one incision and surgical instruments through another to repair or remove torn or frayed tissue or loose fragments.

Because arthroscopic surgery is not without risk, conservative treatment is generally recommended as first-line therapy and may include supervised physical therapy, activity modification, nonsteroidal anti-inflammatory drugs (NSAIDs) or other analgesics for pain management, and intra-articular injections. Recommended durations of conservative therapy vary among published sources, generally ranging from four to 12 weeks depending on the specific procedure and clinical indication. Arthroscopy most commonly involves debridement and meniscectomy, though chondroplasty, loose body removal, and ligament reconstruction are also performed.

Ligament Reconstruction and Repair

The knee has four main cruciate ligament complexes that respond to the loads and forces placed upon them by body weight, ground reaction, and external trauma. The anterior cruciate ligament (ACL), medial collateral ligament (MCL), posterior cruciate ligament (PCL) and posterolateral corner (PLC). The ACL and PCL help with anteroposterior stability, which resists the forward and backward displacement of the tibia. The MCL is the primary restraint against valgus rotation ("knock-kneed" alignment), and the PLC is a complex of ligaments that resists varus ("bow-legged" alignment). Injuries involving multiple ligaments do not require prior conservative management.

Meniscal procedures

The meniscus is a set (one medial, one lateral) of fibrocartilage pads that help to distribute and absorb the loads and forces placed upon the knee, while reducing contact stress on the articular cartilage, additionally stabilizing the joint. Conservative treatment is preferred over surgery in the setting of most meniscal tears. Partial meniscectomy is the removal of torn pieces of mensicus related to non-traumatic pathology. Partial arthroscopic meniscectomy has been associated with future osteoarthritis risk and high rates of knee replacement.

Patellofemoral Realignment Procedures

The patella (kneecap) normally rides up and down within a shallow groove at the end of the thigh

bone. Several things can disrupt this smooth tracking:

- The patella is pulled too far to one side.
- The patella sits too high in the groove.
- The groove itself is too flat or shallow.

When tracking is disrupted, the kneecap can rub, cause pain, or dislocate, and the cartilage behind the kneecap can wear down, adding to the pain.

Realignment procedures are designed to correct whichever problem is present, tightening or reconstructing the ligaments that hold the kneecap in place, reshaping a groove that is too flat, or relocating the bony bump (tubercle) just below the kneecap to change its pull. Malalignment is confirmed by imaging. A lateral retinacular release is a procedure to divide tissue on the lateral side of the patella to relieve excessive lateral tilt and pressure. These operations are considered for symptomatic individuals only after physical therapy, bracing, and other conservative treatments have failed.

After surgery, trauma, infection, or prolonged immobilization, the knee can develop adhesions-arthrofibrosis, that mechanically limits motion. When conservative management such as physical therapy and bracing fails to restore adequate function and near-full extension, surgery is considered.

Surgeons arthroscopically release and remove these adhesions using shavers, radiofrequency or ablation devices, and cutting tools. Manipulation of the joint under anesthesia commonly follows the release to further improve range of motion, particularly flexion.

Restorative Cartilage procedures

Osteochondral autografting and allografting are used for full-thickness cartilage defects of weight-bearing surfaces caused by trauma or by conditions such as osteochondritis dissecans. The goal is to restore the cartilage surface along with its supporting bone, improving joint function and reducing pain. The surgeon harvests one or more plugs of cartilage and bone from the patient's own non-/less-weight-bearing surfaces (autograft) or from a donor joint (fresh or cryopreserved allograft). The base of the defect is abraded or curetted down to subchondral bone, and the graft is press-fit into place.

Mosaicplasty (osteochondral autograft transfer, or OATS) harvests cylindrical bone-cartilage plugs from the patient's own knee and transplants them into a focal defect. After the lesion is excised and the base refreshed, grafts are taken from low-weight-bearing areas such as the intercondylar notch or trochlear margins, and a recipient tunnel is created and sized. The plug is seated by press-fit; when several are used, they are arranged side by side in a mosaic pattern to resurface the area. Autograft is best suited to smaller lesions (generally <2–4 cm^2) because of limited donor tissue.

Osteochondral allograft transplantation (OCA) is conceptually similar but uses donor (cadaver) tissue, often as a single larger plug that fills the entire defect. Because there is no donor-site limitation, OCA is favored for larger lesions (>2 cm^2). For optimal cartilage restoration, any associated instability (e.g., ligament deficiency), malalignment, or meniscal loss should be corrected at the same time.

Autologous chondrocyte implantation (ACI) treats deep, larger (typically >2–4 cm^2) full-thickness defects in two stages: cartilage cells (chondrocytes) are first harvested arthroscopically and expanded in culture, then implanted into the defect at a second operation, where they regenerate a cartilage-like surface. ACI is generally reserved for larger lesions in higher-demand patients.

These restoration techniques are reserved for symptomatic, skeletally mature patients with imaging-confirmed focal chondral or osteochondral defects and maintained (or concurrently restored) ligament stability, including those with patellofemoral chondrosis.

SUPPORTIVE LITERATURE

Knee Arthroplasty

Total knee arthroplasty (TKA) is an effective surgical treatment for appropriately selected patients with symptomatic moderate-to-severe knee osteoarthritis. Randomized controlled evidence has demonstrated greater improvements in pain and physical function following TKA combined with nonsurgical treatment compared with comprehensive nonsurgical treatment alone, with benefits evaluated through two years of follow-up (Skou et al., 2015, 2017).

Knee Arthroscopy and Associated Procedures

A 2019 Cochrane systematic review by Palmer et al. evaluated the benefits and harms of surgical interventions for symptomatic mild-to-moderate knee osteoarthritis. The review included individuals with knee pain and imaging evidence of Kellgren-Lawrence grade 1, 2, or 3 osteoarthritis. Outcomes assessed included pain, function, radiographic progression, quality of life (QOL), short-term serious adverse events, reoperation rates, and withdrawals due to adverse events.

Five randomized controlled trials involving 566 participants compared surgical with non-surgical interventions. One U.S. study involving 320 participants compared arthroscopic partial meniscectomy (APM) followed by physical therapy, consisting of home-based exercises, with physical therapy (PT) alone. This was the primary comparison reported in the review. A second U.S. study involving 32 participants compared arthroscopic surgery, including debridement with or without synovectomy or chondroplasty, with closed-needle joint lavage using saline. Two studies involving 152 participants, including 120 from Pakistan and 32 from the United Kingdom, compared arthroscopic surgery, consisting of washout with or without debridement, with hyaluronic acid injection. One study involving 62 participants from the Netherlands compared high tibial osteotomy with knee joint distraction surgery. Compared with non-surgical treatment, surgery was associated with a 0.2% reduction in pain, a 0.8% improvement in function, and a 1% increase in serious adverse events. Five participants in the surgical group subsequently underwent total knee replacement. Progression of osteoarthritis and quality of life were not measured. The quality of evidence was rated as low because of limitations in study design and small sample sizes. The authors concluded that there may be little difference between APM and a home exercise program for the treatment of mild-to-moderate knee osteoarthritis.

A second Cochrane systematic review, published by O'Connor et al. in 2022, evaluated the benefits and harms of arthroscopic surgery compared with placebo surgery or non-surgical treatment for

degenerative knee disease, including osteoarthritis and degenerative meniscal tears. Sixteen randomized or quasi-randomized controlled trials met the inclusion criteria. Four trials involving 380 participants compared arthroscopic surgery with placebo surgery. In the remaining trials, arthroscopic surgery was compared with exercise (eight trials; 1,371 participants), a single intra-articular glucocorticoid injection (one trial; 120 participants), non-arthroscopic lavage (one trial; 34 participants), nonsteroidal anti-inflammatory drugs (one trial; 80 participants), or weekly hyaluronic acid injections for five weeks (one trial; 120 participants).

Most trials without a placebo control were susceptible to bias, including selection bias (56%), performance bias (75%), detection bias (75%), attrition bias (44%), and selective reporting bias (75%). The placebo-controlled trials were less susceptible to bias, with none considered at risk for performance or detection bias. The primary findings focused on the comparison between arthroscopic and placebo surgery. At three months, participants who underwent arthroscopic surgery had improvements of 4.6 points in pain, 0.1 points in knee function, and 5.6 points in quality of life compared with placebo surgery, based on 0-to-100-point scales. At five years, 8% more participants who underwent arthroscopic surgery rated their treatment as successful compared with those who underwent placebo surgery. Serious adverse events were 2% more frequent among participants who underwent arthroscopic surgery. The authors concluded that knee arthroscopy does not provide clinically important benefits in pain or function for degenerative knee disease. However, the certainty of evidence for some outcomes was limited by heterogeneity among trials and the small number of events.

Ligament Reconstruction and Repair

Evidence supporting best practices for ACL injury is evolving and that which is available today is of low-quality. Clinical decision making is based on recommendations from international consensus groups (Diermeier et al 2020), and professional society guidelines.

Meniscal Procedures

Migliorini et al (2023) conducted a meta-analysis comparing outcomes of meniscal repair and meniscal resection in patients with symptomatic meniscal tears. The analysis included 20 comparative studies, consisting of 16 retrospective studies and four prospective clinical investigations, representing 31,783 patients. Studies evaluating all types of meniscal repairs and tears were eligible, regardless of surgical technique, tear etiology, or prior conservative treatment, provided that follow-up was at least 12 months. The mean patient age was 37.6 ± 14.0 years, mean BMI was 28.3 ± 3.2 kg/m², and the mean interval from injury to surgery was 12.1 ± 10.2 months. No randomized controlled trials were included, resulting in an overall moderate-to-high risk of bias. At a mean follow-up of 6 years, meniscal repair was associated with a lower rate of knee osteoarthritis compared with partial meniscectomy; however, no significant differences were observed in patient-reported outcome measures, medial joint space width, or treatment failure rates.

Patellofemoral Realignment Procedures

Straume-Naesheim and colleagues (2026) reported three-year outcomes from a previously conducted randomized controlled trial (Erickson et al 2019) that compared recurrent instability in patients with

recurrent lateral patellar dislocation without significant underlying anatomic risk factors who underwent medial patellofemoral ligament reconstruction (MPFL-R) (n=30) with those who received active rehabilitation alone (n=31). Individuals aged 12 to 30 years were eligible if they did not have severe trochlear dysplasia and had a tibial tuberosity-trochlear groove distance of ≤20 mm on computed tomography (CT). Participants were randomized to undergo knee arthroscopy with isolated MPFL-R followed by active rehabilitation (MPFL group) or knee arthroscopy without reconstruction followed by active rehabilitation (control group). At three years, outcomes included subjective persistent patellar instability and patient-reported outcome measures (PROMs), including the Knee injury and Osteoarthritis Outcome Score (KOOS), Kujala Knee Score, Cincinnati Knee Rating System, and Noyes Sports Activity Rating Scale. Persistent subjective patellar instability was reported by 5 patients in the MPFL group (16.7%) compared with 15 patients in the control group (53.6%), corresponding to an odds ratio of 5.8 (95% CI, 1.7-19.4; P=.003). Both groups demonstrated improvement during the first year of follow-up and significant improvements from baseline to three years across all PROMs. However, no statistically significant differences in PROM scores were observed between the groups at any follow-up time point.

The authors identified several study limitations, including the study methodology, small sample size, lack of questions specifically addressing persistent instability within the PROM instruments, and the single-center design using a single MPFL reconstruction technique.

Motion Restoration Procedures

Reddy and colleagues (2024) conducted a systematic review to characterize the treatment strategies and reported outcomes for arthrofibrosis following knee arthroscopy or anterior cruciate ligament reconstruction (ACLR), including differences between pediatric and adult populations. Of 1,208 articles identified, 42 studies met the eligibility criteria, including 29 (69.0%) involving adults and 13 (31.0%) involving pediatric patients. Manipulation under anesthesia (MUA), lysis of adhesions (LOA), or a combination of these procedures was evaluated in 39 studies (92.8%), while two studies (4.8%) evaluated pharmacologic treatment. Interpretation of the findings was limited by substantial variability in the definitions and diagnostic criteria used for knee arthrofibrosis. In addition, the review did not address arthrofibrosis resulting from other etiologies, including trauma or multiligamentous knee injury. Overall, MUA and/or LOA were the most frequently reported treatment strategies for arthrofibrosis following knee arthroscopy or ACLR.

Cartilage Restoration Techniques

Evidence is sufficient to consider osteochondral allografting medically appropriate as a technique to repair large (e.g., 10 cm2), full-thickness chondral defects of the knee caused by acute or repetitive trauma.

Several systematic reviews of randomized controlled trials (RCTs) have evaluated autologous osteochondral transplantation for cartilage repair of the knee in the short- and mid-term. When compared with abrasion techniques (e.g., microfracture, drilling), there is evidence that autologous osteochondral transplantation decreases failure rates and improves outcomes in patients with medium-size lesions (e.g., 2-6 cm^2) when measured at longer follow-up. This is believed to be due to

the improved durability of the natural hyaline cartilage compared with the fibrocartilage that is obtained with abrasion techniques. Factors shown to affect success in observational studies are male sex, younger age, and lesions smaller than 3 cm^2. Thus, there is a relatively narrow range of lesion size for which autologous osteochondral transplantation is most effective. In addition, the best results have been observed with lesions on the femoral condyles, although treatment of trochlea and patella lesions also improves outcomes. Correction of malalignment is important for the success of the procedure.

Zamborsky and colleagues (2020) completed a systematic review and network meta-analysis that evaluated the most appropriate surgical interventions for patients with knee articular cartilage defects. A total of 21 articles (from 12 RCTs) were analyzed with a total population of 891 patients. Follow-up varied widely among the included studies, ranging from 12 months to 15 years. Of the surgical interventions evaluated, microfracture was associated with significantly higher failure rates compared to autologous chondrocyte implantation at 10 years of follow-up. No significant differences in failure rates were seen between microfracture and osteochondral autograft transplantation, matrix-induced autologous chondrocyte implantation, or characterized chondrocyte implantation at 2, 5, and 10 years of follow-up. Osteochondral autograft transplantation was associated with significantly more excellent or good results at >3 years of follow-up as compared to microfracture, whereas microfracture was associated with significantly poorer results as compared to autologous chondrocyte implantation and matrix-induced autologous chondrocyte implantation. No significant differences between the interventions were noted regarding reintervention, biopsy types, or adverse events. Based on efficacy and safety, autologous chondrocyte implantation was ranked as the best intervention for failure outcome at 10 years of follow-up, followed by osteochondral autograft transplantation, then microfracture. Microfracture was consistently ranked worse than cartilage repair techniques for other outcomes including quality of tissue repair and return-to-activity rates.

There is sufficient data published in the peer-reviewed literature to conclude that autologous chondrocyte transplantation results in relief of symptoms and improved function in patients who had failed conservative management and arthroscopic or other surgical treatments. Several studies include reports of histological examinations of the graft site showing stable hyaline cartilage after surgery.

Migliorini and colleagues conducted a systematic review of the literature in 2022 to evaluate the safety and efficacy of ACI for chondral defects of the knee in skeletally immature patients. A total of 9 studies (three prospective and six retrospective studies) representing 251 procedures were analyzed for patient reported outcome measures and complications. The mean age of the patients was 16.4 ±0.7 years, and the mean length of follow up was 44.2±29.4 months. Studies with follow up less than 12 months were not included in the review. Authors analyzed the KOOS score, Visual Analog Scale (VAS), Tegner Activity Scale, Lysholm Knee Score, and the International Knee Document Committee (IKDC) Score. Increases were identified in the KOOS (+41.9/100 [P=0.003]), IKCD (+33.2/100 [P=<0.0001]), and Lysholm (+20.6/100 [P=0.02]). The VAS score was reduced by 3.6/10 (P=0.004) points. There was no statistically significant improvement noted in the Tegner scale. Authors expressed concern with the rate of complications. More than 12% of patients demonstrated graft hypertrophy and 5.6% of procedures were considered failures. It is believed that

these numbers were underestimated given an unclear reporting of complications in several of the studies. Several other limitations of the studies were noted, including the lack of control groups creating a moderate risk of bias. There was also a limited sample size, and lack of quantitative data to conduct analyses. Further, there was a difference in the method of membrane application (suture versus fibrin glue) between studies which may have negatively impacted the results. Authors concluded that ACI of chondral defects in the knees of skeletally immature patients is effective in improving patient reported outcome measures, however the review was granted a level of evidence of III, noting that the safety profile of ACI in skeletally immature patients is controversial and requires further investigation.

PROFESSIONAL GUIDELINE(S)

The American Academy of Orthopaedic Surgeons (AAOS) has five knee-related clinical practice guidelines listed under its lower extremity quality programs:

Management of Acute Isolated Meniscal Pathology, 2024 [accessed 10/05/26]

Diagnosis and Treatment of Osteochondritis Dissecans, 2023 [accessed 10/05/26]

Management of Anterior Cruciate Ligament Injuries, 2022 [accessed 10/05/26]

Surgical Management of Osteoarthritis of the Knee, 2022 [accessed 10/05/26]

Management of Osteoarthritis of the Knee (Non-Arthroplasty), 2021[accessed 10/05/26]

In 2022, AAOS published evidence-based clinical practice guidelines on surgical management of osteoarthritis of the knee after a review of the clinical evidence available. Recommendations were defined as being "strong" if there was evidence from two or more high-quality studies, two or more moderate quality studies, or statements resulting in a strong or moderate strength following Evidence to Decision framework upgrading and/or downgrading.

The guidelines include the following as quality of evidence "high" and a "strong" strength of recommendation:

- There is no difference in postoperative functional scores between patients with a BMI <30 and obese patients (BMI 30-39.9); however, there may be increased risk of complications in morbidly obese patients (≥40), in particular, surgical site infections.
- Optimization of perioperative glucose control (<126mg/dl) after total knee arthroplasty should be attempted in diabetic and non-diabetic patients with HgbA1C <6.5, as hyperglycemia can lead to less favorable postoperative
- outcomes and higher complication rates.
- Evidence reports that there is no difference between patellar surfacing or non-patellar resurfacing in total knee arthroplasty
- Cruciate retaining (CR) and posterior stabilized (PS) total knee arthroplasty (TKA) designs have similarly efficacious/favorable postoperative outcomes.

- The practitioner should not use patient specific technology (e.g., guides, cutting blocks) because there is no significant difference in patient outcomes, function, or pain as compared to conventional total knee arthroplasty (TKA). Additionally, it does not reduce operating time, blood loss, length of stay, and/or complications.
- There is no difference in composite/functional outcomes or complications between kinematic or mechanical alignment principles in total knee arthroplasty.

The guidelines state the following as quality of evidence "high" and a "moderate" strength of recommendation:

- The practitioner can use unicompartmental arthroplasty vs total knee arthroplasty for patients with predominantly medial compartment osteoarthritis, as evidence reports improved patient reported and functional outcomes in the short term; however, long-term rates of revision in unicompartmental knee arthroplasty may be higher than total knee arthroplasty.
- There is no difference in outcomes, function, or pain between navigation and conventional techniques

The guidelines also provide "options" when there is little or no evidence on a particular topic. They state the following in regard to smoking cessation:

"Smoking cessation should be attempted before total knee arthroplasty, as a history of smoking may result in higher complications, lower functional scores, higher pain scores, and SSIs." (Quality of evidence: low, strength of option "consensus").

Cartilage Restoration Techniques

In 2017, The National Institute for Health and Care Excellence (NICE) published guidance on autologous chondrocyte implantation for treating symptomatic articular cartilage defects of the knee, recommending it be used as an option only if:

- The person has not had previous surgery to repair articular cartilage defects;
- There is minimal osteoarthritic damage to the knee (as assessed by clinicians experienced in investigating knee cartilage damage using a validated measure for knee osteoarthritis;
- The defect is over 2cm2;
- The procedure is done at a tertiary referral center.

In 2018, the National Institute for Health and Care Excellence (NICE) issued new guidance on mosaicplasty for symptomatic articular cartilage defects of the knee (IPG607). The guidance states that the evidence for the safety and efficacy of mosaicplasty for knee cartilage defects is adequate to support the use of the procedure.

In 2022, the American Society of Pain and Neuroscience (ASPN) published the Consensus Guidelines on Interventional Therapies for Knee Pain (STEP Guidelines) (Hunter 2022). These guidelines were developed by a multidisciplinary panel of experts, including specialists in pain management, anesthesiology, orthopedic surgery, and rehabilitation medicine. The guideline makes the following

recommendation statements:

- "Mosaicplasty is an effective long-term treatment option for patients 18–50 years old with hyaline cartilage lesions 2–5 cm2 (Level I, Grade A, Consensus Moderate)."
- OAT is an effective knee joint preservation technique (Level II, Grade C, Consensus Weak).

For larger lesions, autograft osteochondral harvesting carries a great of risk of morbidity and as such osteochondral allograft transplantation (OAT) has traditionally been used. Laboratory studies demonstrate superior chondrocyte viability with fresh allografts; however, good results and chondrocyte viability have still been demonstrated with frozen grafts implanted within 28 days from harvest."

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA), through the Center for Devices and Radiological Health (CDRH), regulates medical devices used in orthopedic procedures, including certain implants, prostheses, fixation devices, surgical instruments, and other devices that may be used in knee surgery. Refer to the FDA regulations for orthopedic devices, 21 CFR Part 888. Available from: https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-888 [accessed 2026 Oct 6].

The FDA maintains information regarding medical device recalls and early alerts. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls-and-early-alerts [accessed 2026 Oct 6]

The FDA also regulates vaccines, blood and blood products, and biologics via the Center for Biologics Evaluation and Research (CBER) which ensures the safety, efficacy, and quality of these products. Refer to the FDA vaccines/blood/biologics website. Available from: https://www.fda.gov/vaccines-blood-biologics [accessed 2026 Oct 6]

Additionally, the FDA maintains information for consumers and health professionals on vaccine, blood and biologics warnings and other safety information. Available from: Recalls (Biologics) | FDA [accessed 2026 Oct 6]

Carticel received FDA approval in 1997 through a biologics license application for the culturing of chondrocytes. The approval restricted Carticel to use for the repair of symptomatic cartilaginous defects of the femoral condyle (medial, lateral, or trochlear), caused by acute or repetitive trauma in patients who have had an inadequate response to a prior arthroscopic or other surgical repair procedure. The product was phased out with the development of MACI.

In December 2016, the FDA approved MACI (autologous cultured chondrocytes on porcine collagen membrane) for the repair of symptomatic single or multiple full-thickness cartilage defects of the knee, with or without bone involvement, in adults. MACI is the first FDA-approved, cellularized, scaffold product that applies tissue engineering processes to grow cells on scaffolds using healthy cartilage tissue from the patient's own knee. The package insert includes the following contraindications: known history of hypersensitivity to gentamicin, other aminoglycosides, or products of porcine or bovine origin, severe osteoarthritis of the knee, inflammatory arthritis, inflammatory

joint disease, or uncorrected congenital blood coagulation disorders, prior knee surgery (within 6 months), excluding surgery to procure a biopsy or a concomitant procedure to prepare the knee for a MACI implant, inability to cooperate with a physician-prescribed post-surgical rehabilitation program.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
27310	Arthrotomy, knee, with exploration, drainage, or removal of foreign body (e.g., infection)
27332	Arthrotomy, with excision of semilunar cartilage (meniscectomy) knee; medial OR lateral
27333	Arthrotomy, with excision of semilunar cartilage (meniscectomy) knee; medial AND lateral
27334	Arthrotomy, with synovectomy, knee; anterior OR posterior
27340	Excision, prepatellar bursa
27365	Radical resection of tumor, femur or knee
27403	Arthrotomy with meniscus repair, knee
27405	Repair, primary, torn ligament and/or capsule, knee; collateral
27407	Repair, primary, torn ligament and/or capsule, knee; cruciate
27409	Repair, primary, torn ligament and/or capsule, knee; collateral and cruciate ligaments
27455	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); before epiphyseal closure
27466	Osteoplasty, femur; lengthening
27516	Closed treatment of distal femoral epiphyseal separation; without manipulation
27517	Closed treatment of distal femoral epiphyseal separation; with manipulation, with or without skin or skeletal traction

Code	Description
27519	Open treatment of distal femoral epiphyseal separation, includes internal fixation, when performed
27412	Autologous chondrocyte implantation, knee
27415	Osteochondral allograft, knee, open
27416	Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s])
27418	Anterior tibial tubercleplasty (e.g., Maquet type procedure)
27420	Reconstruction of dislocating patella; (e.g., Hauser type procedure)
27422	Reconstruction of dislocating patella; with extensor realignment and/or muscle advancement or release (e.g., Campbell, Goldwaite type procedure)
27424	Reconstruction of dislocating patella; with patellectomy
27425	Lateral retinacular release, open
27427	Ligamentous reconstruction (augmentation), knee; extra-articular
27428	Ligamentous reconstruction (augmentation), knee; intra-articular (open)
27429	Ligamentous reconstruction (augmentation), knee; intra-articular (open) and extra-articular
27472	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)
27570	Manipulation of knee joint under general anesthesia (includes application of traction or other fixation devices)
29850	Arthroscopically aided treatment of intercondylar spine(s) and/or tuberosity fracture(s) of the knee, with or without manipulation; without internal or external fixation (includes arthroscopy)
29851	Arthroscopically aided treatment of intercondylar spine(s) and/or tuberosity fracture(s) of the knee, with or without manipulation; with internal or external fixation (includes arthroscopy)
29855	Arthroscopically aided treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed (includes arthroscopy)
29856	Arthroscopically aided treatment of tibial fracture, proximal (plateau); bicondylar, includes internal fixation, when performed (includes arthroscopy)
29866	Arthroscopy, knee, surgical; osteochondral autograft(s) (e.g., mosaicplasty) (includes harvesting of the auto-graft[s])

Code	Description
29867	Arthroscopy, knee, surgical; osteochondral allograft (e.g., mosaicplasty)
29868	29868 Arthroscopy, knee, surgical; meniscal transplantation (includes arthrotomy for meniscal insertion), medial or lateral
29870	29870 Arthroscopy, knee, diagnostic, with or without synovial biopsy (separate procedure)
29873	Arthroscopy, knee, surgical; with lateral release
29874	Arthroscopy, knee, surgical; for removal of loose body or foreign body (eg, osteochondritis dissecans fragmentation, chondral fragmentation)
29875	Arthroscopy, knee, surgical; synovectomy, limited (eg, plica or shelf resection) (separate procedure)
29876	Arthroscopy, knee, surgical; synovectomy, major, 2 or more compartments (eg, medial or lateral)
29877	Arthroscopy, knee, surgical; debridement/shaving of articular cartilage (chondroplasty)
29879	Arthroscopy, knee, surgical; abrasion arthroplasty (includes chondroplasty where necessary) or multiple drilling or microfracture
29880	Arthroscopy, knee, surgical; with meniscectomy (medial AND lateral, including any meniscal shaving) including debridement/shaving of articular cartilage (chondroplasty), same or separate compartment(s), when performed
29881	Arthroscopy, knee, surgical; with meniscectomy (medial OR lateral, including any meniscal shaving) including
29882	Arthroscopy, knee, surgical; with meniscus repair (medial OR lateral)
29883	Arthroscopy, knee, surgical; with meniscus repair (medial AND lateral)
29884	Arthroscopy, knee, surgical; with lysis of adhesions, with or without manipulation (separate procedure)
29885	Arthroscopy, knee, surgical; drilling for osteochondritis dissecans with bone grafting, with or without internal fixation (including debridement of base of lesion)
29887	Arthroscopy, knee, surgical; drilling for intact osteochondritis dissecans lesion with internal fixation
29888	Arthroscopically aided anterior cruciate ligament repair/augmentation or reconstruction

Code	Description
29889	Arthroscopically aided posterior cruciate ligament repair/augmentation or reconstruction

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HCPCS Codes

Code	Description
J7330	Autologous cultured chondrocytes, implant
S2112	Arthroscopy, knee, surgical for harvesting of cartilage (chondrocyte cells)

ICD10 Codes

Code	Description
M12.561-M12.569	Traumatic arthropathy, knee (code range)
M17.0-M17.9	Osteoarthritis of knee (code range)
M22.40-M22.42	Chondromalacia patella, knee (code range)
M23.8x1-M23.92	Other and unspecified internal derangement of knee (code range)
M25.861-M25.869	Other specified joint disorders, knee (code range)
M85.9	Disorder of bone density and structure, unspecified
M89.8X6	Other specified disorders of bone, lower leg
M89.9	Disorder of bone, unspecified
M93.261-M93.269	Osteochondritis dessicans knee (code range)
M94.261-M94.269	Chondromalacia of knee (code range)

REFERENCES

American Academy of Orthopaedic Surgeons (AAOS) [Internet]. Acute isolated meniscal pathology. 2024 Jun 10 [accessed 2026 Oct 06]. Available from: https://www.aaos.org/globalassets/quality-and-

practice-resources/acute-meniscal-pathology/amp-cpg.pdf

American Academy of Orthopaedic Surgeons (AAOS) [Internet]. The diagnosis and treatment of osteochondritis dissecans-evidence based clinical practice guideline. 2023 Dec 01 [accessed 2026 Oct 06]. Available from: https://www.aaos.org/globalassets/quality-and-practice-resources/osteochondritis-dissecans/osteochondritis-dissecans-rapid-update-2023.pdf

American Academy of Orthopaedic Surgeons (AAOS) [Internet]. Management of anterior cruciate ligament injuries. 2022 Aug 22 [accessed 2026 Oct 06]. Available from: https://www.aaos.org/globalassets/quality-and-practice-resources/anterior-cruciate-ligament-injuries/aclcpg.pdf

American Academy of Orthopaedic Surgeons (AAOS) [Internet]. Management of osteoarthritis of the knee (non-arthroplasty). 2021 Aug 31 [accessed 2026 Oct 06]. Available from: https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-knee/oak3cpg.pdf

American Academy of Orthopaedic Surgeons (AAOS) [Internet]. Surgical management of osteoarthritis of the knee. 2022 Dec 02 [accessed 2026 Oct 06]. Available from: https://www.aaos.org/globalassets/quality-and-practice-resources/surgical-management-knee/smoak2cpg.pdf

Akhtar M, et al. Outcomes of early versus delayed manipulation under anesthesia for stiffness following total knee arthroplasty: a systematic review and meta-analysis. J Arthroplasty. 2024 Nov;39(11):2872-2879.

American Academy of Orthopaedic Surgeons (AAOS) [Internet]. Management of osteoarthritis of the knee (non-arthroplasty). 2021 Aug 31 [accessed 2026 Oct 06] Available from: https://www.aaos.org/oak3cpg

Bateni CP, et al. ACR appropriateness criteria chronic knee pain: update 2026. American College of Radiology. 2026;23:1799-1809.

Bradley, KE et al. Younger patients are more likely to undergo arthroscopic meniscal repair and revision meniscal surgery in a large cross-sectional cohort. Arthroscopy. 2022 Oct;38(10):2875-83.

Crawford, DA, et al. Unicompartmental knee arthroplasty. Orthop Clin North Am. 2020 Apr;51(2),147-159.

Carlson VR, et al. Compliance with the AAOS guidelines for treatment of osteoarthritis of the knee: a survey of the American Association of Hip and Knee Surgeons. J Am Acad Orthop Surg. 2018 Feb 1; 26(3):103-107

Cotter, EJ, et al. Clinical considerations and joint preservation principles in the management of patients with symptomatic chondral lesions. Clin Sports Med. 2025 Jul 44(3):499-512.

Diermeier TA, et al. Treatment after ACL injury: panther symposium ACL treatment consensus group. Br J Sports Med. 2020 Jul 13;55:14-22.

Ericson BJ, et al. Isolated medial patellofemoral ligament reconstruction for patellar instability

regardless of tibial tubercle-trochlear groove distance and patellar height: outcomes at 1 and 2 years. Am J Sports Med. 2019 May;47(6):1331-1337.

Forsythe B, et al. Corticosteroid injections 1 month before arthroscopic meniscectomy increase the risk of surgical-site infection. Arthroscopy. 2021 Sep;37(9): 2285-2890.

Hannon, CP, et al. 2023 American College of Rheumatology and American Association of Hip and Knee Surgeons clinical practice guideline for the optimal timing of elective hip or knee arthroplasty for patients with symptomatic moderate-to-severe osteoarthritis or advanced symptomatic osteonecrosis with secondary arthritis for whom nonoperative therapy is ineffective. Arthritis Care & Research. 2023;75(11):2227-2238.

Jolissaint JE, et al. An update on the management and optimization of the patient with morbid obesity undergoing hip or knee arthroplasty. Ortho Clin N Am. 2023;54:251-257.

Migliorini F, et al. Autologous chondrocyte implantation in the knee is effective in skeletally immature patients: a systematic review. Knee Surg Sports Traumatol Arthrosc. 2023;31:2518-2525.

Migliorini F, et al. Meniscectomy is associated with a higher rate of osteoarthritis compared to meniscal repair following acute tears: a meta-analysis. Knee Surgery, Sports Traumatology, Arthroscopy. 2023;31:5485-5495.

Migliorni N, et al. Surgical management of focal chondral defects of the knee: a Bayesian network meta-analysis. Journal of Orthopaedic Surgery and Research. 2021(16):543-556.

National Institute for Health and Care Excellence (NICE) [Internet]. Osteoarthritis in over 16s: diagnosis and management. 2022 Oct 19 [accessed 2026 Oct 06]. Available from: https://www.nice.org.uk/guidance/ng226

Nowak, LL and Schemitsch EH. Trends in outpatient total knee arthroplasty from 2012 to 2020. The Journal of Arthroplasty. 2023;38:S21-S25.

O'Connor, D, et al. Arthroscopic surgery for degenerative knee disease (osteoarthritis including degenerative meniscal tears). Cochrane Database of Systematic Reviews. 2022. Issue 3. Art. No.: CD014328.

Palmer JS, et al. Surgical interventions for symptomatic mild to moderate knee osteoarthritis. Cochrane Database of Systematic Reviews. 2019, Issue 7. Art. No.:CD012128.

Rahardja R, et al. Early manipulation under anaesthesia for stiffness following total knee arthroplasty is associated with a greater gain in knee flexion. Knee Surg Sports Traumatol Arthrosc. 2023 Mar;31(3):979-985.

Reddy R, et al. Manipulation under anesthesia and lysis of adhesions are the most commonly reported treatments for arthrofibrosis of the knee after arthroscopy or anterior cruciate ligament reconstruction in both pediatric and adult patients. Arthroscopy, Sports Medicine and Rehabilitation. 2024 April;6(2):1-12.

Roaten J, et al. Osteochondritis dissecans lesions of the pediatric and adolescent knee. Orthop Clin North America. 2022 Oct;53(4):445-459.

Skou ST, et al. A randomized, controlled trial of total knee replacement. NEJM. 22 Oct 2015;373(17):1597-1606.

Skou ST, et al. Two-year outcome from two parallel randomized trails on total knee replacement and non-surgical treatment of knee osteoarthritis. Osteoarthritis and Cartilage; 2017:S42.

Straum-Naesheim TM, et al. Medial patellofemoral ligament reconstruction vs. nonoperative treatment for recurrent lateral patellar dislocation: three-year results from a randomized controlled trial. The American Journal of Sports Medicine. 2026;54(4):773-779.

Tischer T, et al. Management of anterior cruciate ligament revision in adults: the 2022 ESSKA consensus part III—indications for different clinical scenarios using the RAND/UCLA appropriateness method. Knee Surg Sports Traumatol Arthrosc. 2023 May 3; 31(11):4662-46.

Thompson A, et al. AHA/ACC/ACS/ASNC/HRS/SCA/SCCT/SCMR/SVM Guideline for perioperative cardiovascular management for noncardiac surgery, a report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines. Circulation. 2024 Sep;150(19): e351-e442.

Xu Z, et al. How to evaluate and treat skeletally mature patients with patellar dislocation. Arthroscopy Techniques; 2021 Mar;10(3), e721-e726.

Zamborsky R and Danisovic L. Surgical techniques for knee cartilage repair: an updated large-scale systematic review and network meta-analysis of randomized controlled trials. Arthroscopy. 2020 Mar;36(3):845-858.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Total Joint Arthroplasty (LCD L36039) [accessed 2026 Sept 12]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date.

Policy/Procedure Name: Kresladi (marnetegragene autotemcel) **Control Number: 1350/20.000526**

Disclaimer Notice

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Background

Leukocyte adhesion deficiency (LAD) syndromes are a group of rare disorders affecting the immune system and are characterized by defects affecting how leukocytes respond and migrate to wound or infection sites. There are three subtypes of this primary immunodeficiency disease: LAD I is caused by mutations of the *ITGB2* gene, LAD II is caused by mutations of the *SLC35C1* gene, and LAD III is a mutation in the gene for Kindlin 3. Severity and symptoms vary person to person however all affected individuals develop an increased susceptibility to developing recurrent bacterial and fungal infections. In infants, umbilical cord complications (delayed separation and omphalitis), impaired wound healing, and persistent Leukocytosis is common in LAD-I. Patients with severe cases of LAD-I express 2% of normal levels of CD18-expressing neutrophils.

Specifically addressing LAD-I, the estimated prevalence is one case per one million people and those afflicted with a severe form carry a significant mortality risk (> 60%) in those under two who do not receive a stem cell transplant. Hematopoietic Stem Cell Transplant is the only curative treatment for this condition and requires one to match with a donor.

Kresladi (marnetegragene autotemcel) is a gene therapy containing autologous hematopoietic stem cells that have been genetically modified with a lentiviral vector to deliver a functional copy of the ITGB2 gene (targeting those with LAD-I). Mechanistically, this therapy functions to deliver the gene encodes the beta-2 integrin component CD18, a key protein that facilitates leukocyte adhesion and enables extravasation from blood vessels to fight infection. In addition to stem cell collection, treatment with Kresladi requires myeloablative conditioning prior to infusion, as well as inpatient monitoring post infusion.

In its October 3, 2023 press release, Rocket Pharmaceuticals reported that in a Phase 1/2 Kresladi demonstrated 100% overall survival at 12 months post infusion (and for the entire duration of follow-up) for all nine patients with LAD-I with 12 to 24 months of available follow-up. These nine subjects were between five months and nine years of age. Results from the trial also showed large decreases compared with pre-treatment history in the incidences of significant infections, combined with evidence of resolution of disease-related skin lesions and restoration of wound repair capabilities. In a relative comparator, results from a 2021 multicenter, retrospective study of data collected from 84 patients with LAD-I and -III who received allogeneic HSCT between 2007 and 2017 demonstrated a three-year overall survival of 83%.

On March 26, 2026, the FDA granted accelerated approval to Kresladi. The safety and effectiveness of Kresladi were established in an open-label study in nine pediatric patients with molecularly confirmed *ITGB2*-associated, severe LAD-I. All of the patients received Kresladi as a single IV infusion at a median dose of 4.3×10^6 CD34+ cells/kg (range: 2.8 to 10×10^6 CD34+ cells/kg). Kresladi increased key biomarker (CD18 and CD11a) expression 12 months post-infusion, with sustained effects through 24 months post-infusion. All nine patients enrolled in the pivotal Kresladi study remained alive through 24 months of follow-up and continue to be followed post-approval.

Summary

Effective Date of Policy:	9/23/2026
Indications	Treatment of pediatric patients with severe leukocyte adhesion deficiency-I (LAD-I) due to biallelic variants in ITGB2 without an available human leukocyte antigen (HLA)-matched sibling donor for allogeneic hematopoietic stem cell transplant
ICD10 Diagnosis Codes	Subcode(s) of D72
HCPCS Code	J3590; No permanent code assigned yet
Availability	*See FDA Prescribing Information*
Duration	6 months to allow one-time administration

Required Criteria for Approval

1. Must be at least 3 months of age
2. Prescribed by or in consultation with an immunologist, hematologist, or prescriber that specializes in the treatment of leukocyte adhesion deficiency (LAD)
3. Enrollee has confirmed diagnosis of Severe LAD-I as demonstrated by:
    a. Molecular genetic testing revealing a characteristic mutation in the ITGB2 gene
    b. Flow cytometry indicating:
        i. CD18 expression on < 2% neutrophils (polymorphonuclear neutrophils (PMNs)) OR
        ii. CD18+ PMNs are > 2% with < 2% CD11a or CD11b expressing PMNs with documented ITGB2 mutation and clinical history consistent with LAD-I
4. Enrollee has clinical history supporting Severe LAD-I including:
    a. Recurrent, often severe, bacterial and/or fungal infections. These infections are most often involving skin and mucous membranes
    b. Absence of pus formation at the site of infection
    c. For neonates, delayed detachment of umbilical cord along with infection of umbilical cord stump
    d. Other indicative conditions include periodontitis and gingivitis
5. Must have documentation that the patient does not have a human leukocyte antigen (HLA)-identical related donor available for hematopoietic stem cell transplant
6. The patient must be eligible to undergo hematopoietic stem cell transplant (HSCT)
7. Patients with any of the following will not be eligible for coverage (documentation, including laboratory results [taken within the past 3 months] is required):
    a. Hepatic dysfunction defined as bilirubin > 1.5x upper limit of normal (ULN) or alanine aminotransferase (ALT) or asparate aminotransferase (AST) > 2.5x ULN
    b. Renal dysfunction as defined by either Grade 3 or higher abnormalities in serum sodium, potassium, calcium, magnesium or phosphate as defined by NCI Common Terminology Criteria for Adverse Events (CTCAE) v5.0, or the requirement for either peritoneal dialysis or hemodialysis
    c. Pulmonary dysfunction as defined by either:
        i. need for supplemental oxygen during the prior 2 weeks (in absence of acute infection)
        ii. Oxygen saturation (by pulse oximetry) < 90%
    d. Significant medical conditions, including documented human immunodeficiency virus (HIV) infection, poorly controlled diabetes, poorly controlled hypertension, poorly controlled cardiac arrhythmia or congestive heart failure; or arterial thromboembolic events (including stroke or myocardial infarction) within the 6 prior months
8. Kresladi is indicated for one-time single-dose intravenous use only and therefore will not be authorized for retreatment. Retreatment will be considered experimental and investigational when any FDA approved gene therapy, or any other gene therapy under investigation, has been previously administered.
9. Use of Kresladi is considered experimental and investigational when the above criteria are not met.
10. Use of Kresladi to treat other indications will be considered experimental and investigational.
11. Approval will be for 6 months to allow one-time administration

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.

References

		Updated	Accessed
1	National Organization for Rare Disorders – Leukocyte Adhesion Deficiency Syndromes. Updated March 14, 2018. Available at: https://rarediseases.org/rare-diseases/leukocyte-adhesion-deficiency-syndromes/#causes	2018	6/2024
2	A Clinical Trial to Evaluate the Safety and Efficacy of RP-L201 in Subjects With Leukocyte Adhesion Deficiency-I. ClinicalTrials.gov. Available at: https://clinicaltrials.gov/study/NCT03812263?intr=RP-L201&rank=1	11/2023	6/2024
3	Rocket Pharmaceuticals Announces Update on FDA Review Timeline of KRESLADI™ (marnetegragene autotemcel) for the Treatment of Severe Leukocyte Adhesion Deficiency-I (LAD-I). Published February 13, 2024. Available at: https://www.biospace.com/article/releases/rocket-pharmaceuticals-announces-update-	2/2024	6/2024

	on-fda-review-timeline-of-kresladi-marnetegragene-autotemcel-for-the-treatment-of-severe-leukocyte-adhesion-deficiency-i-lad-i-/		
4	Kresladi [prescribing information]. Rocket Pharmaceuticals, Inc. Cranbury, NJ	3/2026	4/2026

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE CHOICES: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 9/23/2026

New: 6/2024

Revised	Reviewed
5/2026, 9/2026	6/2025

Revision Date	Changes Made
5/2026	Reformatted policy
9/2026	Removed serious or active infection from criteria

Policy/Procedure Name: Lamzede (velmanase afla) **Control Number: 1350/20.000476**

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Background

Alpha-mannosidosis is a lysosomal storage disorder characterized by the deficiency of the enzyme alpha-D mannosidase. The disease is caused by mutations in the MAN2B1 gene and occurs at a rate of roughly 1-2 per million live births. Alpha-mannosidosis presents in a highly heterogenous fashion but can be generally classified into three types based on severity and speed of progression. Type 1 is a mild form that is normally recognized after 10 years of age. Patients present with myopathy, but not with skeletal abnormalities, and progression is slow. Type 2 is a moderate form that is normally recognized before age 10. Patients present with myopathy and skeletal abnormalities, but progression is normally still slow. Across both type 1 and type 2, other symptoms can include mild to moderate intellectual disability, impaired hearing, ataxia, and immunodeficiency. Type 3 is the most severe form, with clinical presentation within the first year of life characterized by rapid progression of intellectual disability, hydrocephalus, ataxia, hepatosplenomegaly, skeletal abnormalities, and coarse facial features. In Type 3, death occurs either prenatally or early in life due to progressive central nervous system involvement or infection.

Velmanase alfa is a recombinant human alpha-mannosidase enzyme replacement therapy approved by the FDA for the treatment of non-central nervous system manifestations of alpha-mannosidosis. Once internalized by the cell, velmanase-alfa is transported into lysosomes where it catalyzes the degradation of accumulated mannose-containing oligosaccharides. Velmanase-alfa does not cross the blood brain barrier, and therefore does not treat the neurological aspects of alpha-mannosidosis.

In a phase III, randomized, double-blind, placebo-controlled trial, velmanase alfa was compared with placebo in 25 patients with alpha-mannosidosis. Primary endpoints were changes in serum oligosaccharide levels and three minutes stair climb test at week 52. Secondary endpoints included changes in six-minute walk test and forced vital capacity percentage. At week 52, there was a statistically significant reduction in oligosaccharide levels, with a mean relative change of -77.6% (95% CI -81.6 to -72.8%) in the velmanase alfa group compared with – 24.1% (95% CI -40.3 to -3.6) in the placebo group. Motor and pulmonary endpoints were not statistically significant, but results were noted to trend towards improvement in the active treatment group relative to placebo.

In a phase 2 pediatric study, five patients with alpha-mannosidosis who were under six years of age (3.7-5.9 years, mean - 4.5 years) were treated with 1 mg/kg of velmanase alfa once weekly. At 24 months, it was found that the mean percentage change from baseline in serum oligosaccharides was -65.8%.

Summary

Effective Date of Policy:	2/12/2026
Indications	Treatment of non-central nervous system manifestations of alpha-mannosidosis
ICD10 Diagnosis Codes	E77.1
HCPCS	J0217
Availability	Single dose vials containing 10 mg of velmanase alfa as a lyophilized powder
Duration	Initial approval: 12 months Subsequent approval: 12 months

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy:

Indication	Inclusion Criteria	Recommended Dosing
Alpha-mannosidosis (FDA approval) ICD10: E77.1	• The request is submitted by a provider with expertise in the treatment of alpha-mannosidosis • The member has a confirmed diagnosis of alpha-mannosidosis as defined by alpha-mannosidase activity in leukocytes or fibroblasts < 10% of normal activity • Member has Type 1 (mild) or Type 2 (moderate) alpha-mannosidosis without central nervous system manifestations • Member is able to ambulate independently	• 1 mg/kg of actual body weight once weekly as an IV infusion

Exclusion Criteria
• History of hematopoietic stem cell transplant bone marrow transplant • Member cannot walk without support • Member has Type 3 alpha mannosidosis (severe alpha-mannosidosis)

Continuation Criteria
• Requests will be reviewed per criteria every twelve months • Documentation of positive clinical response to therapy, attested by the provider (i.e., improvement or stabilization in motor function, FVC, reduction in frequency of infections, etc.)

Considerations
• Prior authorization is obtained through the CDPHP pharmacy department

References

		Updated	Accessed
1	Malm D, Nilssen Ø. Alpha-Mannosidosis. 2001 Oct 11 [updated 2019 Jul 18]. In: Adam MP, Mirzaa GM, Pagon RA, Wallace SE, Bean LJH, Gripp KW, Amemiya A, editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993–2023. PMID: 20301570.	7/19	3/23
2	Borgwardt, L., Guffon, N., Amraoui, Y. *et al.* Efficacy and safety of Velmanase alfa in the treatment of patients with alpha-mannosidosis: results from the core and extension phase analysis of a phase III multicentre, double-blind, randomised, placebo-controlled trial. *J Inherit Metab Dis* **41**, 1215–1223 (2018).	5/18	3/23
3	NORD. (2018) *Alpha Mannasidosis.* https://rarediseases.org/rare-diseases/alpha-mannosidosis/	11/23	1/25
4	Prescribing information: Lamzede. Chiesi Farmaceutici S.p.A. Parma, Italy	2/23	1/25

GOVERNMENT PROGRAMS

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MEDICARE CHOICES:	Subject to all terms and conditions noted in above application if administered under the medical benefit
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application if administered under the medical benefit

CDPHP Pharmacy Services 2/12/2026

New: 4/2023

Revised	Reviewed
4/2025, 2/2026	

Revision Date	Changes Made
4/2025	Added inclusion criteria member is able to ambulate independently Added exclusion criteria member cannot walk without support and member Type 3 alpha mannosidosis (severe alpha-mannosidosis) Changed continuation duration from 6 months to 12 months
2/2026	Removed known chromosomal abnormality and syndromes affecting psychomotor development other than alpha mannosidosis from exclusion criteria Removed option of bi-allelic mutation in the MAN2B1 gene via genetic testing

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MEDICAL POLICY

Medical Policy Title	**Left Atrial Appendage Closure Devices**
Policy Number	**7.01.92**
Current Effective Date	**January 1, 2026**
Next Review Date	**September 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Percutaneous left atrial appendage (LAA) occlusion (e.g., the WATCHMAN, Amplazter Amulet) devices are considered **medically appropriate** when **ALL** of the following criteria are met:

   A. U.S. Food and Drug Administration (FDA) approved device;

   B. Nonvalvular atrial fibrillation (AF);

   C. Increased risk of stroke and systemic embolism, based on CHA_2DS_2-VASc score greater than or equal to two (2);

   D. Systemic anticoagulation therapy is recommended;

   E. Long-term risks of systemic anticoagulation outweigh the risks of the device implantation. (See Policy Guideline section)

II. Surgical exclusion/excision of the LAA during cardiac surgery is **medically appropriate** when **ALL** of the following criteria are met:

   A. Individual is planning to continue long-term anticoagulation post-surgery;

   B. When goal is to reduce the risk of stroke;

   C. Individual is diagnosed with atrial fibrillation;

   D. Individual has a CHA_2DS_2-VASc score greater than or equal to two (2) or equivalent stroke risk.

III. Percutaneous left atrial appendage closure devices are considered **investigational** when the above criteria are not met.

IV. Surgical LAA exclusion devices, including the AtriClip device, in individuals with AF for stroke prevention is considered **investigational** for **EITHER** of the following indications:

   A. As a stand-alone procedure; **or**

   B. undergoing a thoracoscopic cardiac procedure.

RELATED POLICIES

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. The balance of risks and benefits associated with implantation of a percutaneous LAA occlusion device for stroke prevention, as an alternative to systemic oral anticoagulation, should be determined on an individual basis, through administration of an evidence-based decision tool, taking into account a patient's demonstrated bleeding episodes.

II. The patient's suitability for short-term oral anticoagulation but inability to take long-term oral anticoagulation, must be documented in the medical record and decided by a shared decision-making interaction between the patient and non-implanting physician(s) involved in the patient's care (primary care physician and/or primary cardiologist).

DESCRIPTION

Stroke is the most serious complication of atrial fibrillation (AF). The estimated incidence of stroke in untreated patients with AF is 5% per year. Stroke associated with AF is primarily embolic in nature, tends to be more severe than the typical ischemic stroke, and causes higher rates of mortality and disability. As a result, stroke prevention is one of the main goals of AF treatment. Stroke in AF occurs primarily as a result of thromboembolism from the left atrium. The lack of atrial contractions in AF leads to blood stasis in the left atrium, and this low-flow state increases the risk for thrombosis. The area of the left atrium with the lowest blood flow in AF, and, therefore, the highest risk of thrombosis, is the left atrial appendage (LAA). It has been estimated that 90% of left-atrial thrombi occur in the LAA.

$CHADS_2$ or the CHA_2DS_2-VASc stratification scores

The $CHADS_2$ or the CHA_2DS_2-VASc are frisk stratification scores used to calculate the risk of stroke in patients with AF. The $CHADS_2$ score assigns points for each of the following findings: congestive heart failure, hypertension, age greater than 75, diabetes, stroke/transient ischemia attack/thromboembolism. The CHA_2DS_2-VASc assigns points for some of the same findings (congestive heart failure, hypertension, diabetes, stroke/transient ischemia attack/thromboembolism), but with some different or additional criteria: age greater than or equal to 65, vascular disease, gender category.

Anti-Coagulation Treatment

The main treatment for stroke prevention in AF is anticoagulation, which has proven efficacy. Warfarin is the predominant agent in clinical use. A number of newer anticoagulant medications, including dabigatran, rivaroxaban, and apixaban, have received FDA approval for stroke prevention in nonvalvular AF and have demonstrated non-inferiority to warfarin in clinical trials. While anticoagulation is effective for stroke prevention, there is an increased risk of bleeding. Also, warfarin requires frequent monitoring and adjustments, as well as lifestyle changes. Dabigatran does not require monitoring. However, unlike warfarin, the antithrombotic effects of dabigatran are not

reversible with any currently available hemostatic drugs.

A number of risk scores have been developed to estimate the risk of significant bleeding in patients treated with systemic anticoagulation. An example is the HAS-BLED score, which assesses the annual risk of significant bleeding in AF patients treated with warfarin. The score ranges from 0 to 9, based on a number of clinical characteristics: hypertension, abnormal renal and/or liver function, stroke, bleeding, labile international normalized ratios, advanced age (older than 65), drug and/or alcohol use. Scores of 3 or greater are considered to be associated with high risk of bleeding.

Surgical Removal or Exclusion

Surgical removal, or exclusion, of the LAA is often performed in patients with AF who are undergoing open heart surgery for other reasons. Percutaneous LAA closure devices have been developed as a non-pharmacologic alternative to anticoagulation for stroke prevention in AF patients. The devices may prevent stroke by occluding the LAA, thus preventing thrombus formation. Several versions of LAA occlusion devices have been developed.

The WATCHMAN and WATCHMAN FLX left atrial appendage systems (Boston Scientific, Maple Grove, MN) are self-expanding, nickel titanium devices. The devices have a polyester covering and fixation barbs for attachment to the endocardium. Implantation is performed percutaneously through a catheter delivery system, utilizing venous access and transseptal puncture to enter the left atrium. Following implantation, patients are anticoagulated with warfarin or alternate agents for approximately one to two months. After this period, patients are maintained on antiplatelet agents (e.g., aspirin and/or clopidogrel) indefinitely.

The Lariat Loop Applicator is a suture delivery device that is placed around the outside of the LAA and tightened to seal the LAA off from the rest of the heart. This procedure can be done by going through the groin and chest wall. Rather than opening up the chest (open-heart surgery), a long needle is passed under the rib cage to gain access.

The Amplatzer Amulet Left Atrial Appendage Occluder (LAAO) is a second-generation permanent implanted device. It was developed to provide protection against thromboembolic events in high-risk, AF patients by Left Atrial Appendage Closure (LAAC). The device is made of a Nitinol (nickel-titanium) mesh with polyester fabric cover. The Amplatzer Amulet is placed in the patient's left atrial appendage (LAA), the device is intended to prevent blood clots formed in the LAA from entering the bloodstream and potentially causing a stroke.

The AtriClip Left Atrial Appendage Exclusion System has approval from the U.S. Food and Drug Administration for surgical LAA occlusion for stroke prevention in patients with AF. The AtriClip is made of two parallel titanium tubes with elastic nitinol springs covered by knit braided polyester. The delivery allows for application on a beating heart, as well as allows redeployment in case of initial suboptimal placement.

SUPPORTIVE LITERATURE

WATCHMAN Devices

Doshi et al (2023) reported the 2-year results of The PINNACLE FLX trial. The trial evaluated the

safety and efficacy of the next-generation WATCHMAN FLX device for left atrial appendage closure in patients with non-valvular atrial fibrillation who were at increased risk of stroke. Conducted across 29 U.S. centers, the study enrolled 395 patients with a mean age of 74 and an average CHA_2DS_2-VASc score of 4.2. At the 2-year mark, the device demonstrated a low rate of ischemic stroke or systemic embolism at 3.4%, which was significantly better than the 8.7% performance goal. Other notable outcomes included a 9.3% rate of all-cause mortality, 5.5% cardiovascular death, 3.4% stroke, and 10.1% major bleeding. There were no additional device-related complications such as embolization or symptomatic thrombi reported after the first year. These final results confirm that the WATCHMAN FLX device offers favorable long-term safety and efficacy for stroke prevention in this high-risk population.

The PREVAIL trial, conducted by Holmes et al (2014), was a randomized controlled study designed to address limitations identified in the earlier PROTECT-AF trial following the FDA's 2009 decision not to approve the WATCHMAN device. This study enrolled 407 patients with nonvalvular atrial fibrillation at moderate-to-high stroke risk (primarily $CHADS_2 \geq 2$) and randomized them in a 2:1 ratio to receive either the WATCHMAN left atrial appendage closure device or standard warfarin therapy. Patients in the device group received short-term warfarin and aspirin post-implantation, transitioning to dual antiplatelet therapy and then long-term aspirin alone if adequate closure was confirmed. The trial evaluated three non-inferiority primary endpoints at 18 months using Bayesian methods that incorporated prior PROTECT-AF data. Results showed that the WATCHMAN device did not meet non-inferiority criteria for the first primary endpoint (composite of stroke, cardiovascular death, or systemic embolism) because the upper confidence limit exceeded the predefined margin. Similarly, non-inferiority was not met for the second endpoint (late ischemic stroke or systemic embolism) based on relative risk, although it was achieved when assessed using rate differences. Importantly, the third endpoint—focused on early safety outcomes including procedural complications—did meet non-inferiority criteria. Overall, while PREVAIL demonstrated improved procedural safety compared to earlier studies, its efficacy results were mixed and did not fully confirm non-inferiority of the WATCHMAN device versus warfarin for preventing thromboembolic events.

Reddy et al (2011) reported Longer-term follow-up from the PROTECT AF. At a mean follow-up of 2.3 years, the results were similar to the initial report. The relative risk for the composite primary outcome in the WATCHMAN group, compared with the warfarin group, was 0.71, and this met non-inferiority criteria with a confidence of greater than 99%. Complications were more common in the WATCHMAN group, with an estimated rate of 5.6% per year, compared with 3.6% per year in the warfarin group.

Holmes et al (2009) conducted a randomized, unblinded trial that evaluated the non-inferiority of an LAA closure device, compared with warfarin, for stroke prevention in AF. The single RCT published is the PROTECT-AF study, the trial randomized 707 patients from 59 centers in the U.S. and Europe to the WATCHMAN device or warfarin treatment in a 2:1 ratio. Mean follow-up was 18±10 months. The primary efficacy outcome was a composite end point of stroke (ischemic or hemorrhagic), cardiovascular or unexplained death, or systemic embolism. There was also a primary safety outcome, which was a composite end point of excessive bleeding (intracranial or gastrointestinal bleeding) and procedure-related complications (pericardial effusion, device embolization, procedure-

related stroke). The primary efficacy outcome occurred at a rate of 3.0 per 100 patient years in the LAA closure group, compared with 4.9 per 100 patient years in the warfarin group (rate ratio (RR), 0.62; 95% credible interval (CrI), 0.35 to 1.25). Based on these outcomes, the probability of noninferiority was greater than 99.9%. For the individual components of the primary outcome, cardiovascular/ unexplained death and hemorrhagic stroke were higher in the warfarin group. In contrast, ischemic stroke was higher in the LAA closure group at 2.2 per 100 patient years, compared with 1.6 per 100 patient years in the warfarin group (RR=1.34; 95% Crl, 0.60 to 4.29). The primary safety outcome occurred more commonly in the LAA closure group, at a rate of 7.4 per 100 patient years, compared with 4.4 per 100 patient years in the warfarin group (RR=1.69; 95% CrI, 1.01 to 3.19). The higher adverse event rates for the LAA closure group were primarily the result of early adverse events associated with placement of the device. The most frequent type of complication related to LAA closure device placement was pericardial effusion requiring intervention, which occurred in 4.8% of patients (22/463).

Amplatzer Amulet Occluder

Lakkireddy et al (2021) conducted a randomized control trial was conducted to evaluate the safety and effectiveness of the dual-seal mechanism of the Amulet LAA Occluder compared to the Watchman device (Amplatzer Left Atrial Appendage Occluder IDE Trial). Patients with nonvalvular atrial fibrillations at increased risk of stroke were randomly assigned (1:1) to undergo percutaneous implantation of a LAA occlude (Amulet or Watchman device). The primary endpoints included safety, effectiveness, and the rate of LAA occlusion at 45 days. Prespecified secondary endpoints included a composite of all strokes, systemic embolism, or cardiovascular/unexplained death at 18 months, major bleeding at 18 months and superiority test of the three primary end points. A total of 1878 patients were enrolled; the Amulet occlude was noninferior to the Watchman device for primary safety end point 14.5% versus 14.7%. Procedure-related complications were higher for the Amulet Occluder 4.5% versus 2.5%, largely related to more frequent pericardial effusion and device embolization. The Amulet Occluder was noninferior to the Watchman device for the primary effectiveness end point 2.8% versus 2.8%, and the composite of stroke, systemic embolism, or cardiovascular/unexplained death 5.6% versus 7.7%. The rate of major bleeding was similar between groups 11.6% versus 12.3%. LAA occlusion was higher for the Amulet Occluder than for the Watchman device 98.9% versus 96.8%. The Amulet was noninferior for safety and effectiveness of stroke prevention for nonvalvular atrial fibrillation compared with the Watchman device and superior for LAA occlusion. Procedure related complications were higher with the Amulet Occluder and decreased with operator experience.

Whitlock et al (2021) reported the results of the Left Atrial Appendage Occlusion Study (LAAOS) III that randomized 4,811 individuals with preexisting AF to LAA occlusion, or no occlusion scheduled to undergo cardiac surgery. Following post-randomization exclusions prior to surgery, 2,379 individuals were included in the occlusion group and 2,411 were included in the no occlusion group. The treating surgeon selected occlusion method. Among those with data regarding the occlusion method, 15% underwent LAA occlusion with an epicardial closure device (e.g., AtriClip). The primary outcome was the incidence of ischemic stroke or systemic arterial embolism. At a mean 3.8 years follow-up, occlusion was associated with a significant reduction in risk of the primary outcome when compared

with no occlusion, without an increased risk of post-procedural bleeding or mortality. Occlusion appeared to result in greater risk reduction among those using either oral anticoagulation DOAC or vitamin K antagonist therapy at baseline than in those not on anticoagulant therapy. Anticoagulant use was 83% in the occlusion group and 81% in the no occlusion group at the time of hospital discharge, and the majority of study participants in both groups continued to use anticoagulants at 1- (80% and 79%), 2- (77% and 78%), and 3-year follow-up (75% and 78%). In conclusion among the individuals with AF who had cardiac surgery completed, most continued antithrombotic therapy. The risk of ischemic stroke or systemic embolism was lower with concomitant LAAO performed during cardiac surgery than without it.

Nietlispach et al (2013) reported a 10-year single center study on the experience with Amplatzer devices for LAA occlusion. The study included 152 patients from a single institution in Europe. Short-term complications occurred in 9.8% (15/152) of patients. Longer-term adverse outcomes occurred in 7% of patients, including two strokes, one peripheral embolization, and four episodes of major bleeding. Device embolization occurred in 4.6% (7/152) of patients. Other, smaller series of patients treated with the Amplatzer device include a series from several European studies and one from China with small sample sizes. All of these series reported high procedural success, but also reported various complications such as vascular complications, air embolism, esophageal injury, cardiac tamponade, and device embolization.

Wiebe et al (2013) reported results of a retrospective cohort of 60 patients with NVAF who had a CHA_2DS_2-VASc score of at least 1 and contraindications to warfarin anticoagulation, and who underwent percutaneous LAA closure with the Amplatzer device. Contraindications to warfarin were defined as the contraindications identified on the warfarin product label, a history of severe bleeding while receiving anticoagulant therapy, and a history of bleeding tendencies in the absence of anticoagulation or blood dyscrasia, along with the inability to maintain a stable INR, a known hypersensitivity to warfarin, or a high-risk of falling. Patients received heparin during the closure procedure; they were maintained on clopidogrel for three months post-procedure, and daily aspirin indefinitely. Device implantation was successful in 95% of patients. Over a median follow-up of 1.8 years, no patients experienced a stroke. The rate of major bleeding complications was 1.9% during the year of follow-up.

AtriClip

Wang et al (2024) conducted a prospective study aimed to evaluate the clinical outcomes of thoracoscopic left atrial appendage occlusion (LAAO) using the AtriClip PRO2 device. The study included 144 procedures; 56 standalone and 88 performed alongside other minimally invasive surgeries, all by a single surgeon. The results showed no mortality or major complications, with a 100% success rate in complete LAA closure and 87% follow-up imaging completion. Patients who underwent standalone procedures and discontinued anticoagulation experienced no thromboembolic events over 180 patient-years of follow-up. The findings support the safety and efficacy of thoracoscopic AtriClip placement, suggesting it as a reliable alternative to percutaneous methods, with future randomized trials recommended for comparative evaluation.

Ahmed et al (2023) reported the results of this retrospective study evaluating outcomes of surgical

left atrial appendage (LAA) occlusion using the AtriClip in 78 patients with long-standing persistent atrial fibrillation undergoing hybrid convergent ablation. At 3–6 months post-procedure, contrast-enhanced cardiac CT revealed that nearly half of patients (46.2%) had a residual LAA stump, with an average depth of about 4 mm; notably, 19% had a stump ≥10 mm, and one patient required additional endocardial closure. Over one year of follow-up, three patients experienced stroke, one had a device leak of 6 mm, and no thrombus formation near the clip was observed. Overall, the findings highlight a relatively high incidence of incomplete LAA closure with AtriClip and underscore the need for larger, long-term studies to better understand the clinical and thromboembolic implications of residual LAA stumps.

Lariat Device

Bartus et al (2012) conducted the largest case series on the efficacy of the lariat device for LAA closure. This study enrolled 89 patients with AF and either a contraindication to warfarin or previous warfarin failure. A total of 85/89 (96%) had successful left atrial ligation, and 81/89 (91%) had complete closure immediately. There were three access-related complications, two cases of severe pericarditis post-operatively, one late pericardial effusion, and two cases of unexplained sudden death. There were two late strokes, which the authors did not attribute to an embolic source. At one-year follow-up, complete closure was documented by echocardiography in 98% of available patients (n=65). In a smaller, earlier series from the same research group, 13 patients were treated with the Lariat device, 11 of whom were treated as part of percutaneous radiofrequency ablation for AF. One of the 11 procedures was terminated due to unsuccessful placement, and the other 10 procedures were successful, with complete closure verified on echocardiography. There was one procedural complication in which the snare was unable to be removed and needed to be retrieved by thoracoscopy.

PROFESSIONAL GUIDELINE(S)

The American College of Cardiology/American Heart Association (ACC/AHA) 2023 Guideline for the Diagnosis and Management of Atrial Fibrillation, Joglar et al (2023) lists the following recommendations:

Concomitant Surgical LAA Exclusion/Excision in Individuals with AF:

- In patients with AF undergoing cardiac surgery with a CHA_2DS_2-VASc score ≥2 or equivalent stroke risk, surgical LAA exclusion, in addition to continued anticoagulation, is indicated to reduce the risk of stroke and systemic embolism. (Class of Recommendations (COR):1; Level of Evidence (LOE): A)
- In patients with AF undergoing cardiac surgery and LAA exclusion, a surgical technique resulting in absence of flow across the suture line and a stump of <1 cm as determined by intraoperative transesophageal echocardiography should be used. (COR:1; LOE: A)
- In patients with AF undergoing cardiac surgery with CHA_2DS_2-VASc score ≥2 or equivalent stroke risk, the benefit of surgical LAA exclusion in the absence of continued anticoagulation to reduce the risk of stroke and systemic embolism is uncertain. (COR:2b; LOE: A)

Percutaneous Approaches to Occlude the LAA:

- In patients with AF, a moderate to high risk of stroke (CHA_2DS_2 score ≥2), and a contraindication to long-term oral anticoagulation due to a nonreversible cause, percutaneous LAAO (pLAAO) is reasonable. (COR:2a; LOE: B-NR)
- In patients with AF and a moderate to high risk of stroke and a high risk of major bleeding on oral anticoagulation, pLAAO may be a reasonable alternative to oral anticoagulation based on patient preference, with careful consideration of procedural risk and with the understanding that the evidence for oral anticoagulation is more extensive. (COR:2b; LOE: B-R)

The Society of Thoracic Surgeons released the 2023 clinical practice guidelines for the surgical treatment of atrial fibrillation; recommendations include the following:

- "For concomitant LAA management- LAA obliteration for AF is recommended for all first-time nonemergent cardiac surgery procedures, with or without concomitant surgical ablation, to reduce morbidity from thromboembolic complications." (COR: I, LOE: A)
- For stand-alone LAA management- Isolated surgical LAA obliteration may be considered in patients with longstanding persistent AF, a high stroke risk, and contraindications for or failure of long-term oral anticoagulation." (COR: IIb, LOE: B-NR)

In 2021, the National Institute on Health and Care Excellence (NICE) recommended consideration of LAA occlusion if anticoagulation is contraindicated or not tolerated.

The updated 2016 European Society of Cardiology (ESC) Guidelines, developed in collaboration with the European Association for Cardio-Thoracic Surgery, EACTS, recommend consideration of percutaneous LAAC for patients at high stroke risk with contraindications to long-term oral anticoagulation.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates LAAO devices as medical devices. All LAAO devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Jun 16]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2026 Jun 16]

Percutaneous devices that are currently approved by the FDA include:

- Watchman device LAA closure device, (Watchman and Watchman FLX) (Boston Scientific Corporation, Marlborough, MA), received FDA approval in March 2015.
- The WATCHMAN FLX device received FDA approval in July 2020
- The Amplatzer Amulet LAA occlude (Abbott, Minneapolis, MN), received FDA approval in August

2021.

The Amplatzer cardiac plug (St. Jude Medical, Minneapolis, MN), is FDA-approved for closure of atrial septal defects but has not received FDA approval for LAA closure.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I) =Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
33267 (E/I)	Exclusion of left atrial appendage, open, any method (e.g., excision, isolation via stapling, oversewing, ligation, plication clip)
33268	Exclusion of left atrial appendage, open, performed at the time of other sternotomy or thoracotomy procedure(s), any methods (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip) (List separately in addition to code for primary procedure)
33269 (E/I)	Exclusion of left atrial appendage, thoracoscopic, any method (e.g., excision, isolation via stapling, oversewing, ligation, plication, clip)
33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
I48.0-I48.21	Atrial fibrillation (code range)
I48.91	Unspecified atrial fibrillation

REFERENCES

Ahmed A, et al. Long-term imaging and clinical outcomes of surgical left atrial appendage occlusion with atriclip. Am J Cardiol. 2023 Aug 15;201:193-199.

Ailawadi G, et al. Exclusion of the left atrial appendage with a novel device: early results of a multicenter trial. J Thorac Cardiovasc Surg. 2011 Nov;142(5):1002-9, 1009.e1.

Bartus K, et al. Percutaneous left atrial appendage suture ligation using the LARIAT device in patients with atrial fibrillation: initial clinical experience. J Am Coll Cardiol. 2013 Jul 9;62(2):108-18.

Bergmann MW, et al. Real-world safety and efficacy of WATCHMAN LAA closure at one year in patients on dual antiplatelet therapy: results of the DAPT subgroup from the EWOLUTION all-comers study. EuroIntervention. 2018 Apr 20;13(17):2003-2011.

Cartledge R, et al. Standalone epicardial left atrial appendage exclusion for thromboembolism prevention in atrial fibrillation. Interact Cardiovasc Thorac Surg. 2022 Mar 31;34(4):548-555.

Connolly SJ, et al. Oral anticoagulation use and left atrial appendage occlusion in LAAOS III. Circulation. 2023 Oct 24;148(17):1298-1304.

D'Abramo M, et al. Different techniques of surgical left atrial appendage closure and their efficacy: a systematic review. Rev Cardiovasc Med. 2023 Jun 27;24(6):184.

Darden D, et al. Sex differences in procedural outcomes among patients undergoing left atrial appendage occlusion: Insights from the NCDR LAAO Registry. JAMA Cardiol. 2021 Aug 11:e213021.

Doshi SK, et al. Two-year outcomes with a next-generation left atrial appendage device: final results of the PINNACLE FLX trial. J Am Heart Assoc. 2023 Feb 21;12(4):e026295.

Hanif H, et al. Left atrial appendage occlusion for stroke prevention in patients with atrial fibrillation: a systematic review and network meta-analysis of randomized controlled trials. J Cardiovasc Surg. 2018 Feb;59(1):128-139.

Holmes DR Jr, et al. Percutaneous closure of the left atrial appendage versus warfarin therapy for prevention of stroke in patients with atrial fibrillation: a randomized non-inferiority trial. Lancet. 2009 Aug 15;374(9689):534-42.

Jackson LR et al. Left atrial appendage occlusion: A review of current devices, clinical evidence, patient selection, and post procedural antithrombotic management. Prog in cardiovascular disease. 2021;66: 92-100.

Joglar JA, et al. 2023 ACC/AHA/ACCP/HRS Guideline for the diagnosis and management of atrial fibrillation: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice guidelines. Circulation. 2024 Jan 2;149(1):e1-e156.

Lakkireddy D, et al. 5-Year Results from the AMPLATZER amulet left atrial appendage occluder randomized controlled trial. J Am Coll Cardiol. 2025 Mar 25;85(11):1141-1153.

Lakkireddy D, et al. Amplatzer amulet left atrial appendage occlude versus watchman device for stroke prophylaxis (Amulet IDE): a randomized, controlled trial. Circulation. 2021; 144(19):1543–

1552.

Majule DN, et al. The efficacy and safety of the WATCHMAN device in LAA occlusion in patients with non-valvular atrial fibrillation contraindicated to oral anticoagulation: a focused review. Ann Thorac Cardiovasc Surg. 2018 Jun;24(6): 271–278.

Mohanty S, et al. Risk of thromboembolic events after percutaneous left atrial appendage ligation in patients with atrial fibrillation: Long-term results of a multicenter study. Heart Rhythm. 2020 Feb;17(2):175-181.

National Institute for Health and Clinical Excellence (NICE) [Internet]. Atrial fibrillation: diagnosis and management. NG196. Updated 2021 Jun. [updated 2021 Jun 30; accessed 2026 Jun 16]. Available from: https://www.nice.org.uk/guidance/ng196

Nietlispach F, et al. Amplatzer left atrial appendage occlusion: single center 10-year experience. Catheter Cardiovasc Interv. 2013 Aug 1;82(2):283-9.

Osmancik P, et al; PRAGUE-17 Trial Investigators. Left atrial appendage closure versus direct oral anticoagulants in high-risk patients with atrial fibrillation. J Am Coll Cardiol. 2020 Jun 30;75(25):3122-3135.

Parikh V, et al. Long-term clinical outcomes from real-world experience of left atrial appendage exclusion with LARIAT device. J Cardiovasc Electrophysiol. 2019 Dec;30(12):2849-2857.

Reddy VY, et al. Safety of percutaneous left atrial appendage closure: results from the WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients with AF (PROTECT AF) clinical trial and the Continued Access registry. Circulation. 2011 Feb 1;123(4):417-24.

Reddy VY, et al. 5-year outcomes after left atrial appendage closure: from the PREVAIL and PROTECT AF trials. J Am Coll Cardiol. 2017 Dec 19;70(24):2964-2975.

Sahay S, et al. Efficacy and safety of left atrial appendage closure versus medical treatment in atrial fibrillation: a network meta-analysis from randomized trials. Heart. 2017 Jan 15;103(2):139-147.

Sahore A, et al. Clinical implications, and management strategies for left atrial appendage leaks. Card Electrophysiol Clin. 2020;12:89-96.

Saw J, et al. SCAI/HRS expert consensus statement on transcatheter left atrial appendage closure. Heart Rhythm. 2023 May;20(5):e1-e16.

Schnupp S, et al. Late clinical outcomes of lambre versus amplatzer occluders for left atrial appendage closure. J Cardiovasc Electrophysiol. 2020;31:934–942.

Tichelbäcker T, et al. Midterm outcomes of LAA occlusion with the Amplatzer cardiac plug and AMPLATZER amulet devices in a high-risk cohort. Sci Rep. 2020 Oct 1;10(1):16323.

Wang E, et al. Thoracoscopic left atrial appendage occlusion with the Atriclip pro2: an experience of 144 patients. Heart Lung Circ. 2024 Aug;33(8):1215-1220.

Whitlock RP, Belley-Cote EP, et al. Left atrial appendage occlusion during cardiac surgery to prevent stroke. N Engl J Med. 2021 Jun 3;384(22):2081-2091.

Wiebe J, et al. Safety of percutaneous left atrial appendage closure with the Amplatzer cardiac plug in patients with atrial fibrillation and contraindications to anticoagulation. Catheter Cardiovasc Interv. 2014 Apr 1;83(5):796-802.

Wyler von Ballmoos MC, et al. The Society of Thoracic Surgeons 2023 clinical practice guidelines for the surgical treatment of atrial fibrillation. Ann Thorac Surg. 2024 Aug;118(2):291-310.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Percutaneous Left Atrial Appendage Closure (LAAC) (NCD 20.34) [accessed 2026 Aug 19]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 5/24

Revised: 11/25

Reviewed: 5/25, 11/26

Date	Summary of Changes
1/1/2026	• Transitioned Procedures for Occlusion of the Left Atrial Appendage, 1370/20.000515 to Lifetime Healthcare Companies policy template.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

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If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Metachromatic leukodystrophy (MLD) is a rare autosomal recessive genetic disorder that results in progressive loss of motor and cognitive function. MLD has a prevalence of 1:40,000-160,000 worldwide as an autosomal recessive hereditary neurodegenerative disease. The disease is caused by one of over 250 mutations in the *ARSA* gene that codes for the enzyme arylsulfatase-A (ARSA), or rarely the *PSAP* gene that codes for saposin B, which activates ARSA. Both ARSA and saposin B are required to break down sulfatide fats in the myelin forming cells (oligodendrocytes and Schwann cells) of the central and peripheral nervous system, respectively. In MLD, as sulfatide fats accumulate, they cause breakdown of the myelin sheath (i.e., demyelination), permanently damaging nerves and triggering a secondary neurodegenerative process. This process leads to deterioration of motor and cognitive function. In addition, sulfatide fats can also accumulate outside the nervous system: including the gallbladder causing gallbladder thickening, biliary sludge, polyp formation and subsequent acute biliary complications, and/or an increased risk of gallbladder cancer.

The severity of the condition depends on the residual activity of ARSA and is categorized by age of onset, classified into three types being late infantile, juvenile, and adult.

The **late infantile MLD (LI-MLD)** form, which is the most common (50-60% of all cases) is also the most severe as clinical manifestation begins before 30 months of age. This type has minimal ARSA activity, thus rapid neurodegeneration which can start with gait abnormalities and progress to neuropathy and developmental regression. The terminal stage of this type is characterized by severe psychomotor retardation (loss of walking, if ever obtained) with breathing/swallowing difficulties and unfortunately leads to the death of patients with late infantile form in childhood (typically within eight years of diagnosis).

The juvenile MLD form has a slower progression of disease and patients may survive until early adulthood. There are two further subtypes: **early juvenile (EJ-MLD)** and late juvenile. EJ-MLD has a symptom onset of 30 months – six years of age whereas seven to 16 years of age is seen in late juvenile. Symptoms include cognitive impairment (learning disabilities) and behavioral issues. This disease can also progress rapidly in this population, especially after a loss of independent ambulation with significant disability seen within three years of symptom onset, and a total of 10-20 years of survival after symptoms begin.

The least severe and least common form of the disease is the adult form of MLD. This usually begins manifestation after 16 years of age and presents as psychoses, cognitive/behavioral impairment, ataxia, polyneuropathy, and epileptic seizures. It is commonly misdiagnosed as early-onset dementia or schizophrenia due to its slow progression. This could be attributable to symptoms that can include hallucinations and illusions with depressive disorder and sudden mood swings. The finals stages of adult form of MLD are similar to the former types and the life expectancy of this type is 20-30 years after diagnosis.

The diagnosis of this condition relies upon clinical manifestations, genetic analysis for the ARSA and PSAP genes, magnetic resonance imaging of the brain and biochemical tests of the ARSA enzymatic activity. Detection of mutations by sequencing is the most accurate method for diagnosing hereditary genetic diseases. However, diagnosis can be made using other methods (e.g., determination of ARSA activity or sulfatide levels as well as MRI) since not all the mutations associated with the disease have been currently identified. The disease course can be monitored by following ARSA enzyme activity, with specific substates that allow for this: methylumbelliferyl sulfate (4-MUS) and ρ.NCS (preferred substrate) are synthetic substrates for ARSA and arylsulfatase B (ARSB) and a natural substrates: d3-C18: 0-sulfatide.

The treatment options for MLD has been limited due to the difficulty of treating this disease of the nervous system via the poor permeability of the blood-brain barrier. This condition would require distribution of medication to the central and peripheral nervous system to prevent progression of the disease. Pre-symptomatic treatment via a bone marrow transplants (BMT) or hematopoietic stem cell transplantation (HSCT) is considered to have some therapeutic potential but is also considered controversial. In those with juvenile forms of MLD who receive BMT AFTER the onset of symptoms, demyelination occurs in 31% of cases, with a theory being that the BMT is administered too late. HSCT is noted as a therapeutic option, including a 40 subject cohort report, concluding that this is a viable treatment for MLD with significant limitations. Seventeen LI-MLD, J-MLD and adult subtype (A-MLD) survivors were evaluable for long-term adaptive functioning, activities of daily living, and/or cognition. Relative cognitive sparing was observed despite overall global decline. Later onset phenotypes may benefit most from early, pre-symptomatic HSCT. Unfortunately, with both BMT and HSCT it is described that it is possible that the amount of ARSA secreted by normal cells after the transplantation may not be enough to cross-correct a deficiency in the cells of the

patients' nervous system.

Institute for Clinical and Economic Review[3] states,

> Allogeneic hematopoietic stem cell transplant (HSCT) is sometimes offered as a treatment to attempt to slow down progression of disease, but it is uncertain what benefit it provides to late infantile or early juvenile MLD. However, since newborn screening for MLD has not been widely implemented, many patients are diagnosed too late to be considered for treatments other than supportive care.

The only other therapies are supportive to manage some of the clinical manifestations that occur with this disease such as antiepileptic drugs, muscle relaxants or anti-inflammatory therapies.

Lenmeldy (Atidarsagene autotemcel, arsa cel, OTL-200) is a one-time gene therapy for MLD caused by mutations in the ARSA gene. The therapy involves an autologous stem-cell transplant process. First, hematopoietic stem and progenitor cells are harvested from the patient. The cells are then sent to the manufacturer and CD34+ cells are then transduced with a lentiviral vector carrying a functional ARSA gene; cryopreserved cells are then shipped back to the treatment center. After a myeloablative conditioning regimen with busulfan, the cells are then delivered via intravenous infusion. Once the cells have engrafted, the CD34+ cells repopulate the bone marrow, giving rise to peripheral blood mononuclear cells (PBMCs) that can produce the normal to supranormal levels of ARSA enzyme.

Arsa-cel was studied in two key trials, phase I/II and a phase II study. Additionally, there were a small number of children studied through the expanded access frameworks (EAFs) and Compassionate Use Programs (CUPs). The two main trials were single-arm, open-label studies involving children with a diagnosis of MLD confirmed through biochemical and molecular confirmation. Between all studies, 35 children were treated and analyzed. The subtypes of MLD were: pre-symptomatic late infantile (n-18), presymptomatic early juvenile (n-8), early symptomatic early juvenile MLD (n-9). These subjects were compared to 43 natural history patients from a previously conducted study. Because of the length of the enrollment period (over ten years), not all arsa-cel patients reached specific follow-up points. Additionally, all arsa-cel treated MLD patients were reported to have deviated from the protocol with a missed or out of window assessment. Thus, not every patient contributed to each outcome at every timepoint. There were no deaths in up to 11 years of follow-up (up to 12 years of chronological age) in the presymptomatic LI-MLD group treated with arsa-cel. In the natural history cohort, the probability for survival at 12 chronological years was 0.23. In contrast to the LI-MLD subtype, there was not as large a difference in survival probabilities across treated EJ-MLD patients and those in the natural history cohort. In the pre-symptomatic EJ-MLD group (n=8), there was one death 415 days after arsa-cel infusion that was deemed unrelated to gene therapy or MLD; the survival probability was 0.88 up to 11 years of chronological age. In the early symptomatic EJ-MLD groups treated with arsa-cel (n=9), there were no deaths up to 19 years of chronological age, based on data provided by the manufacturer. Two deaths occurred in early symptomatic EJ-MLD patients due to disease progression; however, these two patients were excluded from analyses based on exclusion criteria being met.

In terms of GMFM-88 functional scores, at 24 months all arsa-cel treated patients had much higher GMFM-88 total scores compared to the natural history cohort subjects, as well as GMFC-MLD levels and ARSA enzyme activity levels.

In terms of safety, the most common side effects are fever, low WBCs, stomatitis, respiratory tract infections, rash, device related infections, other viral infections, pyrexia, gastroenteritis, and hepatomegaly. From a laboratory perspective, elevated D-dimer, neutropenia, and elevated liver enzymes were appreciated. Importantly, a warning exists for thrombosis and thromboembolic events, where a provider must consider the prophylactic use of anti-thrombotic agents prior to treatment with Lenmeldy. This is a result of one patient death in the pre-symptomatic EJ-MLD group, from ischemic cerebral infarction.

ICER reviewed this therapy and determined that for those that are considered presymptomatic late infantile and early juvenile MLD, the evidence rating is A, and a rating of B+ for those with early symptomatic early juvenile disease.
ICER further explains their ratings.[3]

> Given that the early onset forms of MLD are rapidly progressive and fatal, and the majority of presymptomatic LI and EJ-MLD patients who underwent arsa-cel therapy remained either asymptomatic or with mild symptoms, we conclude that in children with presymptomatic LI-MLD and presymptomatic EJ-MLD, we have high certainty of a substantial net health benefit ("A").
> The magnitude of benefit and certainty in that benefit are both smaller for treatment of children with early symptomatic EJ-MLD. These children will not return to normal health, treatment with busulfan carries a risk of death, and long-term outcomes are less certain. Additionally, clinical experts, based on experience in patients treated with hematopoietic stem cell therapy, were concerned that, in some patients, treatment with arsa-cel may carry the risk of hastening progression of physical and cognitive decline before stabilization occurs. Given these uncertainties, in children with early symptomatic EJ-MLD, we have moderate certainty of a small or substantial net health benefit with high certainty of at least a small net health benefit ("B+"). However, families for whom the possible risk of initial faster progression after treatment with arsa-cel is determinative may reasonably conclude that current evidence is insufficient.

ICER - Atidarsagene Autotemcel for Metachromatic Leukodystrophy, Final Evidence Report[3]

Table 3.3. GMFM-88 Scores[17]

Arms	Late Infantile		PS Early Juvenile		ES Early Juvenile	
	Arsa-cel	Natural History	Arsa-cel	Natural History	Arsa-cel	Natural History
Year 2						
N Evaluated	16	11	7	8	9	13
GMFM Total Score, Median	81.55	4.80	92.71	46.96	88.47	39.58
Treatment Difference	76.75		45.75		48.89	
Year 5						
N Evaluated	7	9	2	8	3	7
GMFM Total Score, Median	87.92	1.51	100	8.09	48.36	2.29
Treatment Difference	86.41		91.91		46.07	

95% CI: 95 percent confidence interval, Arsa-cel: atidarsagene autotemcel, ES: early symptomatic, GMFM: Gross Motor Function Measure, N: total number, NR: not reported, PS: pre-symptomatic, %: percent

Table 3.5. Time from Predicted/Actual Disease Onset to GMFC-MLD Level

Trial	Phase I/II, Phase II, Expanded Access Programs[17]									
GMFC-MLD Level	Presymptomatic Late Infantile (N=18)		Late Infantile Natural History (N=26)		Presymptomatic Early Juvenile (N=8)		Early Symptomatic Early Juvenile (N=9)		Early Juvenile Natural History (N=17)	
	n	Median months*	n	Median months	n	Median months	n	Median months	n	Median months
Level 0	18	NC	0	-	8	NC	9	NC	0	0
Level 1	11	9.7	11	0.4	0	-	8	32.6	16	0.98
Level 2	4	2.3	19	6.2	0	-	6	44	13	13.5
Level 3	1	32.8	12	12.2	0	-	4	76.6	2	17.8
Level 4	1	44.8	11	13	0	-	3	75.4	5	28.6
Level 5	1	66.4	13	16.7	0	-	2	115.6	9	33.9
Level 6	1	98.8	26	19.3	0	-	0	-	11	40.2

GMFC-MLD: Gross Motor Function Classification for MLD, n: number, N: total number, NC: not calculable
*Data for single patients are not medians.

Table 3.4. ARSA Activity in PBMCs in Arsa-cel Treated Patients

Trial	Phase I/II, Phase II, Expanded Access Programs[17]					
Timepoint	Pre-symptomatic Late Infantile (N=18)		Pre-symptomatic Early Juvenile (N=8)		Early Symptomatic Early Juvenile (N=9)	
	n	Median+ (nmol/mg/h)	n	Median+ (nmol/mg/h)	n	Median (nmol/mg/h)
Baseline	16	25.8*	8	25.8*	9	25.8*
Year 1	18	2028.5	8	771.6	9	169.4
Year 2	16	934.6	7	1242.3	8	88.4
Year 3	15	1557.1	4	1156.1	7	279.8
Year 4	1	1352.5	3	2217.9	4	703.9
Year 5	8	714.3	1	3234.1	3	362.9
Year 6	5	663.3	2	1311.5	2	1264.8
Year 7	6	963.4	1	1836.0	NR	NR
Year 8	4	114.4	1	779.8	NR	NR
Year 9	1	599.2	NR	NR	NR	NR
Year 10	1	328.0	NR	NR	NR	NR
Year 11	2	1357.5	NR	NR	NR	NR

*Values were imputed because the actual values were below the lower limits of quantification or not detected or not quantifiable.
+Data for single patients are not medians.

Summary	
Effective Date of Policy:	7/14/26
Indications	Specific subtypes of MLD
ICD10 Diagnosis Codes:	E75.25
HCPCS Code	J3391
Availability	Per FDA Prescribing Information
Duration	Authorization will be provided for 6 months to allow sufficient time for administration

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy:

Specific Indication	Inclusion Criteria	Recommended Dosing Regimen

Indication
Treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD) (FDA approval)
 	
ICD10: E75.25
	• Therapy is being requested by a provider who is knowledgeable in the management of MLD
	• Must have a diagnosis of MLD confirmed by ALL of the following:
	  ○ Biochemical Testing:
	  ▪ Deficient Arylsulfatase-A (ARSA) enzyme activity in leukocytes (ARSA activity below the normal range in peripheral blood mononuclear cells or fibroblasts) AND
	  ▪ 24-hour urine collection showing elevated sulfatide levels; AND
	  ○ Molecular Testing:
	  ▪ Identification of two pathogenic or novel ARSA alleles; AND
	• Must have a diagnosis of one of the following forms of MLD:
		• **For autologous use only**
		• **One-time single-dose intravenous use only**
		
		• Enrollees are required to undergo hematopoietic stem cell (HSC) mobilization followed by apheresis to obtain CD34+ cells for manufacturing
		• The minimum recommended dose is based on the MLD disease subtype

	○ Pre-symptomatic late infantile (PSLI) MLD defined by: ▪ Expected disease onset ≤ 30 months of age AND ▪ Pre- symptomatic status defined as the absence of neurological signs and symptoms of MLD or physical exam findings limited to abnormal reflexes and/or clonus (excluding abnormal reflexes or abnormalities on brain magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (ex: no tremor, no peripheral ataxia)) ○ Pre-symptomatic early juvenile (PSEJ) MLD defined by: ▪ Expected disease onset > 30 months and less than 7 years of age AND ▪ Pre- symptomatic status defined as the absence of neurological signs and symptoms of MLD or physical exam findings limited to abnormal reflexes and/or clonus (excluding abnormal reflexes or abnormalities on brain magnetic resonance imaging and/or nerve conduction tests not associated with functional impairment (ex: no tremor, no peripheral ataxia)) ○ Early symptomatic early juvenile (ESEJ) MLD defined by: ▪ Disease onset > 30 months and less than 7 years of age AND ▪ Early symptomatic status defined as GMFC-MLD Level 0 with ataxia or GMFC-MLD Level 1 and IQ ≥ 85 • The patient must be eligible for an autologous hematopoietic stem cell transplant (HSCT) **If approved, physician will evaluate risk factors for thrombosis prior to and after Lenmeldy infusion and consider prophylaxis with anti-thrombotic agents prior to treatment.	(see FDA Prescribing Information) • Myeloablative conditioning must be administered before infusion of Lenmeldy

Exclusion Criteria

Therapy will not be approved if any of the above Inclusion Criteria are not met OR any of the below Exclusion Criteria are met:

- Enrollee has any of the following:
  - Human immunodeficiency virus, hepatitis C virus, and/or hepatitis B virus positive
  - Neoplastic disease
  - Cytogenetic alteration typical of myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML)
  - End-organ dysfunction or other severe disease
  - Allogeneic hematopoietic stem cell transplant (HSCT) in past 6 months or evidence of residual cells of donor origin
- Lenmeldy (atidarsagene autotemcel) is considered not medically necessary when the above criteria are not met
- Lenmeldy (atidarsagene autotemcel) is considered not medically necessary for all other indications, including late juvenile and adult forms of MLD.

Continuation Criteria

Continuation criteria is not applicable, Lenmeldy is only authorized for one lifetime treatment and therefore repeat administration will not be covered. Retreatment will be considered not medically necessary when any FDA approved gene therapy, or any other gene therapy under investigation, has been previously administered

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.
- Qualified treatment centers: https://lenmeldy.com/#qtc
- Physician acknowledges that CDPHP will request documentation, not more frequently than biannually, of follow-up patient assessments including serial neurologic and functional measurements and other clinical assessments while the patient is under the

care of the physician.

Gross Motor Function Measure (GMFM): An assessment tool measuring changes in gross motor function over time with intervention across five dimensions: 1) lying and rolling, 2) sitting, 3) crawling and kneeling, 4) standing, and 5) walking, running, and jumping. Scores range from 0 to 100 with a higher score indicating better performance. In trials, an improvement of 10% between treated and natural history patients' GMFM scores was considered a clinically relevant change in response to treatment.
**It is important to note that the normal range of GMFM-88 differs according to chronological age of the child.

Gross Motor Function Classification in MLD (GMFC-MLD): A classification of children's movements like sitting and walking ranging from level 0 where children can walk without support to level 6 where children lose all locomotion and head and trunk control.
See below for more detail:

GMFC-MLD Level[42]	
Level 0	Walking without support with quality of performance normal for age
Level 1	Walking without support but with reduced quality of performance, i.e. instability when standing or walking
Level 2	Walking with support. Walking without support not possible (fewer than five steps)
Level 3	Sitting without support and locomotion such as crawling or rolling. Walking with or without support not possible
Level 4	Sitting without support but no locomotion OR sitting without support not possible, but locomotion such as crawling or rolling
Level 5	No locomotion nor sitting without support, but head control is possible
Level 6	Loss of any locomotion as well as loss of any head and trunk control

GMFC: gross motor function classification

References

		Updated	Accessed
1	Shaimardanova AA, Chulpanova DS, Solovyeva VV, Mullagulova AI, Kitaeva KV, Allegrucci C, Rizvanov AA. Metachromatic Leukodystrophy: Diagnosis, Modeling, and Treatment Approaches. Front Med (Lausanne). 2020 Oct 20;7:576221. doi: 10.3389/fmed.2020.576221. PMID: 33195324; PMCID: PMC7606900.		11/23
2	Lamichhane A, Rocha Cabrero F. Metachromatic Leukodystrophy. [Updated 2023 Jul 17]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK560744/		11/23
3	Lin G, Suh K, Fahim SM, Carlson JJ, Richardson M, Herce-Hagiwara B, Raymond F, Dickerson R, Pearson SD, Rind DM. Atidarsagene Autotemcel for Metachromatic Leukodystrophy. Institute for Clinical and Economic Review, October 30, 2023. https://icer.org/assessment/metachromatic-leukodystrophy-2023/#timeline		11/23
4	Fumagalli F, Calbi V, Natali Sora MG, et al. Lentiviral haematopoietic stem-cell gene therapy for early-onset metachromatic leukodystrophy: long-term results from a non-randomised, open-label, phase 1/2 trial and expanded access. Lancet. 2022 Jan 22;399(10322):372-383. doi: 10.1016/S0140-6736(21)02017-1. PMID: 35065785; PMCID: PMC8795071.		11/23
5	Boucher AA, Miller W, Shanley R, Ziegler R, Lund T, Raymond G, et al. Long-term outcomes after allogeneic hematopoietic stem cell transplantation for metachromatic leukodystrophy: the largest single-institution cohort report. Orphanet J Rare Dis. (2015) 10:94. doi: 10.1186/s13023-015-0313-y	2015	3/2024
6	ICER CTAF Public Meeting on Metachromatic Leukodystrophy: Policy Roundtable (video discussion). October 2, 2023. Available at: https://www.youtube.com/watch?v=Cf5iF1Tz-U4	2023	3/2024
7	Lenmeldy Prescribing Information, Orchard Therapeutics North America, Boston, MA 02210, Rev 3/2024	3/2024	1/2025

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE CHOICES: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 7/14/2026

New: 4/2024

Revised	Reviewed
4/2025, 12/2025, 5/2026, 7/2026	

Revision Date	Changes Made
4/2025	Added additional exclusion criteria: Enrollee has any of the following: • Human immunodeficiency virus, hepatitis C virus, and/or hepatitis B virus positive • Neoplastic disease • Cytogenetic alteration typical of myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML) • End-organ dysfunction or other severe disease
12/2025	Updated authorization duration to 6 months to allow adequate time for administration
5/2026	Removed qualified treatment center Reworded forms of MLD
7/2026	Removed age and weight requirement

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MEDICAL POLICY

Medical Policy Title	**Light and Laser Therapies for Dermatologic Conditions**
Policy Number	**8.01.21**
Current Effective Date	**9/1/2026**
Next Review Date	**October 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. The following treatments are considered **medically appropriate**:

A. Ultraviolet B (UVB) light, alone or in combination with other treatment modalities (e.g., topical coal tar [Goeckerman treatment]), when **ALL** the following criteria are met:

1. In the absence of **ALL** contraindications including the following:
   a. Xeroderma pigmentosum;
   b. Disorders with significant light sensitivity (e.g., albinism); **and**
   c. Lupus erythematosus;
2. Treatment is for **ANY** of the following indications:
   a. Moderate to severe psoriasis that is not responsive to topical or systemic (e.g., methotrexate) drug therapies alone;
   b. Eczema/atopic dermatitis that is not responsive to topical or systemic drug therapies alone or that interferes with an individual's normal functional capacity;
   c. Cutaneous T-cell lymphoma (e.g., mycosis fungoides);
   d. Vitiligo of sun-exposed regions (such as the face, neck, and dorsum of the hands) because the depigmented skin is sun-sensitive, is subject to severe sunburn, and may pose a risk for skin cancer; **or**
   e. Lichen planus;

B. Psoralen Ultraviolet A (PUVA) when **ALL** the following criteria are met:

1. In the absence of **ALL** the following contraindications:
   a. Xeroderma pigmentosum;
   b. Disorders with significant light sensitivity (e.g., albinism);
   c. Lupus erythematosus;
   d. Pregnancy;
   e. Breast-feeding; **and**

f. Uremia and hepatic failure;

2. Treatment is for **ANY** of the following indications:

a. Severe, disabling psoriasis that is not responsive to conservative therapy or UVB therapy;

b. Severe, disabling eczema/atopic dermatitis that is not responsive to conservative therapy or UVA/UVB therapy;

c. Cutaneous T-cell lymphoma (e.g., mycosis fungoides [MF]);

d. Vitiligo of sun-exposed regions (such as the face, neck, and dorsum of the hands) because the depigmented skin is sun-sensitive, is subject to severe sunburn, and may pose a risk for skin cancer; **or**

e. Severe lichen planus;

C. Ultraviolet A (UVA) light, alone or in combination with other treatment modalities, when **ALL** the following criteria are met:

1. In the absence of **ALL** contraindications including the following:

a. Xeroderma pigmentosum;

b. Disorders with significant light sensitivity (e.g., albinism); **and**

c. Lupus erythematosus;

2. Treatment is for **ANY** of the following indications:

a. Eczema/atopic dermatitis that is not responsive to topical or systemic drug therapies alone or that interferes with an individual's normal functional capacity; **or**

b. Lichen planus;

D. Targeted phototherapy using an excimer lamp or laser device that has received Section 510(k) approval from the U.S. Food and Drug Administration (FDA) (e.g., Fencer 308 Excimer Laser, XTRAC XL excimer laser and VTRAC excimer lamp system, BClear lamp, and European-manufactured Excilite and Excilite µ XeCL lamps) when **ALL** the following criteria are met:

1. In the absence of **ALL** contraindications including the following:

a. Xeroderma pigmentosum;

b. Disorders with significant light sensitivity (e.g., albinism); **and**

c. Lupus erythematosus;

2. Treatment is for **ANY** of the following indications:

a. Moderate-to-severe localized psoriasis comprising less than 20% of the body area for which narrowband UVB or PUVA is indicated; **or**

b. Mild-to-moderate psoriasis that is unresponsive to conservative treatment;

E. Home phototherapy utilizing UVB radiation for the treatment of moderate-to-severe psoriasis, comprising at least 3% of the body area, **OR** eczema/atopic dermatitis, that is not responsive to conservative therapies, when **ALL** the following criteria are met:

1. In the absence of **ALL** contraindications including the following:
   a. Xeroderma pigmentosum;
   b. Disorders with significant light sensitivity (e.g., albinism); **and**
   c. Lupus erythematosus;
2. The patient's dermatologist has submitted a letter of medical necessity stating the reason that the home-based, rather than office-based, therapy is needed;
3. The patient has had ineffective courses of treatment using topical or systemic drug therapy; **and**
4. The patient is motivated and reliable, ensuring that treatment is pursued correctly and consistently and that exposures are accurately recorded;

F. Photodynamic Therapy (PDT) with 5-aminolevulinic acid (5-ALA) topical preparations, when **ALL** the following criteria are met:

1. In the absence of **ALL** contraindications including the following:
   a. Xeroderma pigmentosum;
   b. Disorders with significant light sensitivity (e.g., albinism); **and**
   c. Lupus erythematosus;
2. Treatment is for **ANY** of the following:
   a. Actinic keratoses
   b. Superficial basal cell skin cancer, only when surgery and/or radiation is contraindicated; **or**
   c. Bowen's disease (squamous cell carcinoma in situ), only when surgery and/or radiation is contraindicated;

G. Pulsed Dye Laser for the treatment of port wine birthmarks.

II. **ALL** of the following treatments are considered **investigational**:

A. Targeted phototherapy (e.g., the XTRAC XL and VTRAC lamp, the BClear lamp, and the European-manufactured Excilite and Excilite μ XeCL lamps) for **ANY** of the following indications:

1. First-line treatment of mild psoriasis;
2. Treatment of generalized psoriasis or psoriatic arthritis; **or**

3. Vitiligo;

B. PDT with topical preparations for the treatment of other dermatologic conditions, including, but not limited to, acne vulgaris, regional squamous cell carcinoma, and non-superficial basal cell carcinoma;

C. Treatment of acne with light or laser therapy, (e.g., pulsed dye laser, smooth beam laser, photopneumatic therapy [TheraClear Acne System]).

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. The number of treatments required for clearance and remission for both UVB and PUVA therapy is based upon the severity of the disease and the individual response to treatment. The number of psoriatic flare-ups that a person experiences in a lifetime also varies by severity of the disease.

II. UVB therapy usually begins with three (3) to five (5) sessions per week until clearing is achieved, followed by maintenance therapy with a gradual reduction in sessions until sessions are no longer required. PUVA therapy begins with two (2) to three (3) sessions per week for initial clearing, then one (1) to two (2) times a month for maintenance. If no improvement in the psoriatic lesions is seen after four (4) weeks of either UVB or PUVA therapy, treatment should be discontinued.

III. Medical necessity documentation, such as a treatment plan and/or photographs, is generally not required until after a threshold of 30 visits.

IV. The number of treatments required for clearance and remission for atopic dermatitis/eczema and for re-pigmentation in vitiligo for both UVB a PUVA therapy is based upon the severity of the disease and the individual response to treatment.;

V. In general, a phototherapy home unit should be purchased only when there is anticipation of long-term use.

VI. PUVA is rarely indicated for children or young adults because of its potential long-term side effects.

VII. Light and laser treatment should be used with caution in the following circumstances:

A. History or family history of melanoma;

B. History of non-melanoma skin cancer, extensive solar damage, and previous treatment with ionizing arsenic;

C. Pemphigus or pemphigoid;

D. Immunosuppression;

E. Cataracts and aphakia;

F. Photosensitivity; and

G. Uremia and hepatic failure.

VIII. The National Psoriasis Foundation defines the classifications of psoriasis as: Mild < 3%; Moderate 3-10%, and Severe > 10%. However, the severity of psoriasis is also measured by how psoriasis affects a person's quality of life. For example, psoriasis can have a serious impact on one's daily activities even if it involves a small area such as the palms of the hands or soles of the feet.

DESCRIPTION

Ultraviolet light therapy is exposure to the skin with non-ionizing radiation for therapeutic benefit. It may involve exposure to UVB, UVA, or various combinations of UVB and UVA radiation.

Goeckerman therapy is a psoriasis treatment that was developed in 1921 and involves the use of coal tar in combination with UVB phototherapy. It is a safe and effective option for patients with severe or recalcitrant psoriasis. Coal tar and UVB are thought to work in concert to inhibit angiogenesis and keratinocyte proliferation, as well as to decrease T-lymphocyte numbers in the skin and alter inflammatory cytokine expression.

Photochemotherapy is the therapeutic use of radiation in combination with a photosensitizing chemical, currently PUVA. Psoralens make the skin more sensitive and responsive to this wavelength of light. It can be taken orally, applied topically, or added to a bath via a solution for soaking into the skin.

Excimer laser, a xenon chloride (XeCl) laser (e.g., XTRAC, Ex-308 laser), emits a narrow beam of UVB light from a handheld unit which results in a much higher concentration of UVB exposure than in the standard phototherapy unit. The use of excimer laser may shorten the number of exposures necessary, and only specific areas of the body are treated with the laser, limiting the number of exposures and the area being treated, potentially reducing the harmful effects of UV radiation.

PDT using 5-ALA has been investigated as a treatment of actinic keratoses (AK), skin cancers, and superficial dermatologic lesions such as Bowen’s disease. Levulan Kerastick is one example of a topical preparation of 5-ALA. The Levulan Photodynamic system is a two-step treatment, involving application of Levulan Kerastick, then exposure of the area to blue light via the BLU-U Blue Light Photodynamic Therapy Illuminator.

Topical application of methyl aminolevulinate (Metvix, MAL), followed by exposure with the CureLight Broadband (Model CureLight 01), a proprietary red-light source, or the PhotoCure Aktilite CL128 lamp, an LED-based narrow band (630 nm) red light technology device, is another variant of photodynamic therapy for skin lesions. Although MAL is an approved photosensitizer for PDT, it is no longer produced in the United States (NCCN, 2025).

Pulsed Dye Lasers (PDL) which use yellow light wavelengths (585-600 nm) that selectively target both oxyhemoglobin and deoxyhemoglobin. PDLs penetrate up to 2 mm in the skin. Newborns and young children, who have thinner skin, tend to respond well to this type of laser; the response in thicker and darker lesions may be lower.

Photopneumatic devices are a combination of light therapy and vacuum suction devices that mechanically clear obstructed pores and aim to visibly reduce acne lesions. An example of this type of device is the TheraClear X Acne System (Strata Skin Sciences, Horsham, Pennsylvania).

SUPPORTIVE LITERATURE

Psoriasis

The published data has demonstrated that psoriasis has an excellent response rate when treated with either UVB or PUVA. The overall risk of complications from phototherapy and photochemotherapy are low, when compared to the thousands of patients treated with these therapies. Phototherapy and photochemotherapy have been standard treatment alternatives used by dermatologists for severe psoriasis and for vitiligo.

Peer-reviewed literature is limited; however, the published evidence supports the use of targeted phototherapy for the treatment of moderate-to-severe psoriasis comprising less than 20% of the body area for which NB-UVB or PUVA is indicated, and for the treatment of mild-to-moderate psoriasis that is unresponsive to conservative treatment. There is insufficient evidence to support the use of targeted phototherapy for the first-line treatment of mild psoriasis or for the treatment of generalized psoriasis or psoriatic arthritis.

Eczema/Atopic Dermatitis

Published data have demonstrated that phototherapy in the form of UVA, UVB, and PUVA have been proven to be safe and effective treatments, with a low overall risk of complications, for eczema/atopic dermatitis.

Mycosis Fungoides

The peer-reviewed literature consists of small case series that indicate good outcomes when phototherapy in the form of PUVA and UVB is used for the treatment of mycosis fungoides, a very rare lymphoma of the skin.

Vitiligo

A 2016 systematic review identified three studies that compared targeted phototherapy with a 308 nm excimer lamp to NB-UVB and three studies that compared the excimer lamp to the excimer laser. No differences between the excimer lamp and NB-UVB were identified for the outcome of 50% or greater re-pigmentation (RR=1.14; 95% CI, 0.88 to 1.48) (Lopes). For re-pigmentation of 75% or greater, only two small studies were identified, and the relative risk was 1.81 (95% CI, 0.11 to 29.52), showing a lack of precision in the estimate. For the three studies that compared the excimer lamp to the excimer laser, there were no significant differences between treatments for either 50% or greater re-pigmentation (RR=0.97; 95% CI, 0.84 to 1.11) or 75% or greater re-pigmentation

(RR=0.96; 95% CI, 0.71 to 1.30). All treatments were most effective in lesions located on the face, with the worst response being lesions on the extremities. There was some evidence of an increase in adverse events such as blistering with targeted phototherapy.

Baeet al (2017) performed a systematic review and meta-analysis of patient response to narrowband UV-B (NBUVB) phototherapy and psoralen-UV-A (PUVA) phototherapy in the treatment of vitiligo. Inclusion criteria consisted of: (1) prospective studies; (2) participants with a diagnosis of generalized or symmetrical vitiligo; (3) at least one phototherapy group; (4) at least 10 participants in each treatment arm; (5) treatment duration of at least 12 weeks or 24 treatment sessions; (6) outcomes measured based on all vitiligo lesions on the participants whole or half body; and (7) degree of re-pigmentation based on a quartile scale. In the final analysis, 35 studies were included, with 29 studies of 1201 patients undergoing NBUVB phototherapy and nine studies of 227 patients undergoing PUVA phototherapy. A mild response (≥ 25%) to NBUVB phototherapy occurred in 62.1% of 130 patients in three studies at three months, 74.2% of 232 patients in 11 studies at six months, and 75.0% of 512 patients in eight studies at 12 months. A marked response, defined as ≥ 75%, was achieved in 13.0% of 106 patients in two studies at three months, 19.2% of 266 patients in 13 studies at six months, and 35.7% of 540 patients in nine studies at 12 months. For PUVA phototherapy, at least a mild response occurred in 51.4% of 103 patients in four studies at six months and 61.6% of 72 patients in three studies at 12 months. After at least six months of NBUVB phototherapy, at least a mild response occurred on the face and neck in 82.0% of 153 patients, and a marked response in 44.2%, while hands and feet received a mild response in 11.0% of 172 patients, and no marked responses of the same group. The authors could not determine the appropriate treatment duration of phototherapy but did verify treatment duration of at least one year to achieve maximal response and suggested at least six months of treatment to determine responsiveness to NBUVB phototherapy. Overall, treatment response to NBUVB phototherapy was better than PUVA therapy. The most responsive body sites were the face and neck, with hands and feet being the least responsive.

A 2015 systematic review (Sun 2015) was conducted of randomized, controlled trials (RCTs) that focused on treatment of vitiligo with the 308 nm excimer laser. Authors identified seven RCTs with a total of 390 patients. None of the studies was conducted in the United States. Three of the trials compared the excimer laser with an excimer lamp. Four studies compared the excimer laser with narrowband (NB)-UVB; however, two of these were not published in English, and one had a sample size of only 14 patients. The fourth study, published in 2010, did not report efficacy outcomes such as clinical response rate or re-pigmentation rate; but reported on the proportion of patients with various types of re-pigmentation: perifollicular, marginal, diffuse, or combined. Re-pigmentation rates did not differ significantly between groups treated with the excimer laser versus NB-UVB. The authors conducted a meta-analysis of the two studies that were not published in English, so results cannot be verified, but they reported that the likelihood of a minimum 50% re-pigmentation rate was significantly higher with the excimer laser, compared with NB-UVB (risk ratio, 1.39, 95% confidence interval [CI], 1.05 to 1.85) and that, in qualitative analysis, neither of these studies showed significant benefit of the excimer laser for achieving a minimum 75% re-pigmentation rate.

Studies addressing targeted phototherapy for treating vitiligo tended to have small sample sizes, few

were designed to isolate the effect of laser therapy, and were heterogeneous (e.g., different interventions or combinations of interventions, and different comparison interventions), making it difficult to pool study findings or to draw conclusions about the efficacy of targeted phototherapy for vitiligo.

Actinic Keratosis

Studies demonstrate that photodynamic therapy with 5-ALA is an effective nonsurgical technique for treating non-hyperkeratotic AKs of the face and scalp, with an acceptable rate of recurrence of 19% over 12 months. In two placebo-controlled RCTs, significantly more patients had complete clearance of AKs of the upper extremities with ALA and blue light, compared to placebo at 12 weeks (Schmieder 2012; Jiang 2019).

Basal Cell Skin Cancer

Lichen Planus

Dawood et al (2022) conducted a retrospective, single-center, cohort study which showed more than half of the 192 studied patients were disease-free for at least 4.8 years after a single course of Narrowband UVB (NB UVB). Younger aged and male patients achieved better outcomes while female patients and patients with lighter skin phototypes appeared to have higher major response rates.

Weber et al (2022) compared NB UVB with psoralen plus UVA photochemotherapy in a retrospective analysis. They reported the therapeutic outcome and the number of treatments required for achieving a complete or good response were comparable for NB-UVB and PUVA. Both were very effective and demonstrated their beneficial use in patients with generalized cutaneous LP. Based on the lower rate of side effects and its greater ease of use, the authors recommended NB-UVB be considered as the first-line phototherapeutic modality for this indication. In non-responding patients or in case of unavailability of NB-UVB, oral or bath PUVA may serve as a valid alternative therapeutic measure.

Port Wine Birthmarks

Sturge-Weber syndrome (SWS) is a neurocutaneous disorder that classically presents with a triad of vascular anomalies affecting the skin, eyes, and brain. Previously, the trigeminal nerve distribution of a PWB of the face was used to identify risk of SWS. However, recent evidence has demonstrated that PWBs are vascular, not neurologic, in embryologic origin, and facial PWBs at highest risk for the brain involvement of SWS involve the forehead location. Furthermore, a PWB involving the upper or lower eyelid carries a risk of glaucoma, which requires lifelong monitoring. The gold standard of treatment for PWB is the pulsed dye laser, which has many advantages when started as early as possible in infancy. Poliner et al (2022) states based on strong evidence, PDL is safe to use in children and is the gold standard of treatment for PWBs. PDL is most effective at fading the PWB when initiated early in infancy, preferably within the first year of life. Initiating treatment at this age also optimizes psychosocial development, minimizes school absenteeism, and minimizes the need for general anesthesia during early treatments.

Sabeti et al (2021) published a consensus statement of guidelines for treating SWS and PWB with

input from 12 nationally peer-recognized experts in dermatology with experience treating patients with SWS. The committee stated Treatment of PWBs is indicated to minimize the psychosocial impact and diminish nodularity and potentially tissue hypertrophy. Better outcomes may be attained if treatments are started at an earlier age. In the US, pulsed dye laser is the standard for all PWBs regardless of the lesion size, location, or color. When performed by experienced physicians, laser treatment can be safe for patients of all ages. The choice of using general anesthesia in young patients is a complex decision that must be considered on a case-by-case basis. These recommendations are intended to help guide clinical practice and decision-making for patients with SWS and those with isolated PWBs and may improve patient outcomes.

Acne

Overall, the literature investigating the use of photodynamic therapy or photopneumatic therapy in the treatment of acne consists of very small studies in which the patient is also the control. These studies lack long-term data on effectiveness and safety. Due to the small sample sizes of the published trials, lack of long-term follow-up, small number of studies on any particular type of laser, and paucity of studies comparing light therapy to standard acne treatments, the evidence is insufficient to draw conclusions about the impact of laser treatments on health outcomes in patients with active acne.

PROFESSIONAL GUIDELINE(S)

The National Institute for Health and Care Excellence (NICE) updated its Clinical Guideline for Psoriasis: Assessment and Management in 2017. The guidelines suggest offering narrowband ultraviolet B (UVB) phototherapy to people with plague or guttate-pattern psoriasis that cannot be controlled with topical treatments alone, to consider psoralen (oral or topical) with local ultraviolet A (PUVA) irradiation to treat palmoplantar pustulosis, and, when considering PUVA for psoriasis (plaque type or localized palmoplantar pustulosis), to discuss other treatment options and associated risk of increased skin cancer.

NICE procedural guidance for photodynamic therapy for non-melanoma skin tumors (including premalignant and primary non-metastatic skin lesions) were released in 2006. They state evidence of efficacy of this procedure for the treatment of basal cell carcinoma, Bowen's disease and actinic (solar) keratosis is adequate to support its use for these conditions. Evidence is limited on the efficacy of this procedure for the treatment of invasive squamous cell carcinoma. Recurrence rates are high and there is a risk of metastasis.

The American Academy of Dermatology and National Psoriasis Foundation guidelines (2019) for the management and treatment of psoriasis with phototherapy state the Goeckerman regimen is an old treatment, there are no RCTs or systematic reviews evaluating its effectiveness and long-term risks. Photo carcinogenesis is a theoretical risk but has not been demonstrated despite long-term follow-up. The most common reported adverse effects have been local burning as a result of tar sensitivity ("tar smarts"). The necessary time investment on the part of the patient is a disadvantage of Goeckerman therapy, and outpatient treatment requires close proximity to a capable medical facility. The relatively rapid and robust clinical response seen with the Goeckerman regimen, the long duration of remission,

and the low adverse effect profile render Goeckerman therapy an attractive option for the treatment of psoriasis, particularly for those with resistant disease. Because of the messy and cumbersome nature of tar application and the wide availability of highly effective NB-UVB, the Goeckerman regimen is no longer commonly used. Despite this, there is ample evidence to recommend this treatment for psoriasis.

The American Academy of Dermatology published guidelines for the management of Atopic Dermatitis recommend phototherapy as a second-line treatment, after failure of first-line treatment (emollients, topical steroids, and topical calcineurin inhibitors) (Davis 2024). Phototherapy can be used as maintenance therapy in patients with chronic disease. The light modality chosen should be guided by factors such as availability, cost, patient skin type, skin cancer history, and patient use of photosensitizing medications. Home phototherapy under the direction of a physician may be considered for patients who are unable to receive phototherapy in an office setting. Most current literature reports on the efficacy and safety of narrow band UVB. Wherever possible, use a light source that minimizes the potential for harm under the supervision of a qualified clinician.

In 2007, the International Society for Photodynamic Therapy in Dermatology published consensus-based guidelines on the use of PDT for nonmelanoma skin cancer. Based on efficacy and cosmetic outcome, the authors recommended PDT as a first-line therapy for actinic keratosis (Braathen 2007). The guideline recommended photodynamic therapy for superficial basal cell carcinoma as "a viable alternative when surgery would be inappropriate, or the patient or physician wishes to maintain normal skin appearance" and concludes that photodynamic therapy is at least as effective as cryotherapy or 5-FU for Bowen's disease. The authors found insufficient evidence to support the routine use of topical photodynamic therapy for squamous cell carcinoma.

In a 2021 Executive Summary, the American Academy of Dermatology published guidelines for the care and management of actinic keratosis [AK], which included conditional recommendations for the use of ALA red-light PDT or ALA blue-light PDT treatment for AKs and considered the associated risks of skin irritation, pain and cosmesis to represent a minimal potential for harm (Eisen). They highlighted the conditional recommendation is based on limited quality of evidence, however, noted that there is evidence suggesting complete clearance of AK with repeated treatment of ALA-PDT.

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for basal cell skin cancer (NCCN 2025) indicate, that while cure rates are approximately 10% lower than for surgical treatment modalities, topical therapies including topical imiquimod, topical 5-fluroruracil (5-FU), photodynamic therapy (e.g., aminolevulinic acid [ALA], porifimer sodium) or cryotherapy may be considered as well as recommended when surgery is contraindicated or impractical. The guidelines report that most studies have focused on the superficial and nodular histologic subtypes, and several have found higher cure rates for superficial versus nodular subtypes in both low- and high-risk locations. Compared to other superficial therapies, PDT has similar efficacy as cryotherapy but with much better cosmetic outcomes. The literature has demonstrated varied results in comparison of PDT and imiquimod.

The NCCN Clinical Practice Guidelines for Squamous Cell Skin Cancer (NCCN 2025) state in patients with cutaneous squamous cell cancer (CSCC) in situ (Bowen disease), therapies such as

photodynamic therapy (e.g., ALA, Porfimer sodium) may be considered. PDT wit photosensitizing agents including methyl aminolevulinate (MAL) and 5-aminolevulinic acid (ALA) or porfimer sodium is another option for superficial SCC. MAL is no longer produced in the United States.

The NCCN Clinical Practice Guidelines for Primary Cutaneous Lymphoma (NCCN 2025) state UVB, including narrowband-UVB and PUVA/UVA are effective treatment options for patients with early-stage MF. Narrowband-UVB is the most common phototherapy approach and less skin damaging than PUVA/UVA. While some retrospective studies have reported that PUVA results in better responses and improved disease-free survival, others have reported that UVB is as effective as PUVA for the treatment of early-stage MF. It may be beneficial to start with narrowband-UVB than PUVA in patients with early patch stage or thin plaque disease since narrowband-UVB has less skin toxicity than broadband UVB and PUVA.

The European Academy of Dermatology and Venereology released guidelines on the management of lichen planus which state squamous cell carcinoma may arise from mucosal lesions (mouth, vulva, penile) and hypertrophic LP lesions (distal extremities) (Ioannides 2020). Case reports of SCC emerging from hypertrophic cutaneous LP lesions or chronic anogenital or esophageal lesions have been described. Persistent ulcers/lesions should undergo biopsy, particularly when resistant to therapy. Infections, osteoporosis, adrenal insufficiency, bone marrow suppression, renal damage and hyperlipidemia may occur due to medication. Lichen planus is a chronic disease, and the primary focus of treatment is to control symptoms and minimize damage. The treatment should be associated with the severity of the disease and the less possible side-effects and should improve the patients' quality of life. First line treatment for cutaneous LP includes topical medications. When LP persists second-line treatments recommended are broadband or narrowband UVB, and combination of UV and acitretin. Third line treatment includes photodynamic therapy and Nd-YAG laser, low-dose 308 nm excimer laser.

The American Academy of Pediatrics clinical practice guidelines for the management of infantile hemangiomas (IH) state there is a window of opportunity to treat problematic IHs (Krowchuck 2019). Consult early (by 1 month of age) for lesions that are potentially high risk because of potential for disfigurement, life-threatening complications, functional impairment, ulceration and underlying abnormalities. Surgery and/or laser treatment are most useful for the treatment of residual skin changes after involution. They may be used earlier to treat selected His. PDL has been used for several decades to treat IHs. There is wide recognition that PDL is effective and safe in removing residual macular erythema and superficial telangiectasias in involuting or involuted IHs, but it often requires several treatments to achieve optimal results.

American Academy of Dermatology 2024 guidelines for care of Acne Vulgaris state the available evidence is insufficient to develop a recommendation on the use of acne lesion/comedo extraction, laser and light-based devices, or photodynamic therapy with aminolevulinic acid for the treatment of acne (Reynolds). This includes 585-595 nm pulsed dye laser, neodymium-doped yttrium aluminum garnet laser, 1450 diode laser, potassium titanyl phosphate laser, infrared light-emitting diode, 635-670 nm red light, combined 420 nm blue light and 660 nm red light, 589 nm/1319 nm laser, or intense pulsed light. The ADD also conditionally recommends against adding pneumatic broadband light to adapalene 0.3% gel based on low certainty evidence from one (1) study. Adding pneumatic

broadband light to adapalene did not reduce acne lesion counts and was associated with risks of hyperpigmentation and purpura (Tangjaturonrusamee 2016).

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates lasers and phototherapy as medical devices. All lasers and phototherapy including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Sep 16]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
10040 (*E/I)	Acne surgery (e.g., marsupialization, opening or removal of multiple milia, comedones, cysts, pustules) *E/I when utilized for TheraClear Acne System
17106	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); less than 10 sq cm
17107	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); 10.0 to 50.0 sq cm
17108	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); over 50.0 sq cm
96567	Photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitive drug(s), per day
96573	Photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s) provided by a physician or other qualified health care professional, per day
96574	Debridement of premalignant hyperkeratotic lesion(s) (i.e., targeted curettage, abrasion) followed with photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s) provided by a physician or other

Code	Description
	qualified health care professional, per day
96900	Actinotherapy (ultraviolet light)
96910	Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B
96912	Photochemotherapy; psoralens and ultraviolet A (PUVA)
96913	Photochemotherapy (Goeckerman and/or PUVA) for severe photoresponsive dermatoses requiring at least 4-8 hours of care under direct supervision of the physician (includes application of medication and dressings)
96920	Excimer laser treatment for psoriasis; total area less than 250 sq cm
96921	Excimer laser treatment for psoriasis; 250 sq cm to 500 sq cm
96922	Excimer laser treatment for psoriasis; over 500 sq cm

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HCPCS Codes

Code	Description
E0691	Ultraviolet light therapy system, includes bulbs/lamps, timer, and eye protection; treatment area 2 sq ft or less
E0692	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 4 ft panel
E0693	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 6 ft panel
E0694	Ultraviolet multidirectional light therapy system in 6 ft cabinet, includes bulbs/lamps, timer, and eye protection

ICD10 Codes

Code	Description
C44.00-C44.99	Other and unspecified malignant neoplasm of skin (code range)
C80.0-C80.2	Malignant neoplasm without specification of site (code range)
C84.00-C84.09	Mycosis fungoides; code range
C84.10-C84.19	Sézary disease; code range
D04.0-D04.9	Carcinoma in situ of skin (code range)
L40.0-L40.9	Psoriasis (code range)
L43.0 -L43.9	Lichen planus (code range)

Code	Description
L57.0	Actinic keratosis
L70.0-L70.9 (E/I)	Acne (code range)
L73.0 (E/I)	Acne keloid
L80	Vitiligo
Q82.5	Congenital non-neoplastic nevus

REFERENCES

Allam NM and Elshorbagy RT. Monopolar radiofrequency versus pulsed dye laser for treatment of acne scars: a randomized clinical trial. Physiotherapy Quarterly. 2022; 30(1): 73-77.

Alsenaid A, Alamri A, Prinz JC, Ruzicka T, Wolf R. Lichen planus of the lower limbs: successful treatment with psoralen cream plus ultraviolet A photochemotherapy. Dermatol Ther. 2016 Mar-Apr;29(2):109-13.

Ashraf AZ, et al. The effectiveness of home-based phototherapy for vitiligo: A systematic review of randomized controlled trials. Photodermatol Photoimmunol Photomed. 2022; 11:1-9.

Bae JM, et al. Phototherapy for vitiligo: a systematic review and meta-analysis. JAMA Dermatol. 2017 July1;153(7):666-674.

Barbaric J, Abbott R, Posadzki P, et al. Light therapies for acne. Cochrane Database Syst Rev. 2016 Sep 27;9:CD007917.

Batchelor JM, et al. Home-based narrowband UVB, topical corticosteroid or combination for children and adults with vitiligo: HI-Light Vitiligo three-arm RCT. Health Technology Assessment. 2020 Nov; 24 (64):1-5.

Braathen LR, et al. Guidelines on the use of photodynamic therapy for nonmelanoma skin cancer: an international consensus. International Society for Photodynamic Therapy in Dermatology. J Am Acad Dermatol 2007 Jan;56(1):125-43.

Davis DMR, et al. Guidelines of care for the management of atopic dermatitis in adults with phototherapy and systemic therapies. Jour Amer Aca Derm 2024 Feb;90(2):e43-e56.

Dawood M, et al. Narrowband ultraviolet B radiation for lichen planus: long-term follow-up of 192 patients. J Clin Aesthet Dermatol 2022 Apr;15(4):31-35.

Eisen DB, et al. Guidelines of care for the management of actinic keratosis: Executive summary. J Am Acad Dermatol 2021 Oct;85(4):945-955.

Elmets CA, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy. J Am Acad Dermatol. 2019

Sep;81(3):775-804.

Fernández-Guarino M, et al. Generalized lichen planus treated with narrowband UV-B phototherapy: Results from 10 patients and a review of the literature. Actas Dermosifiliogr. 2019 Jul-Aug;110(6):490-493.

Freeman M, et al. A comparison of photodynamic therapy using topical methyl aminolevulinate (Metvix) with single cycle cryotherapy in patients with actinic keratosis: a prospective, randomized study. J Dermatol Treat. 2003 Jun;14(2):99-106.

Gerber W, et al. Ultraviolet B 308-nm excimer laser treatment of psoriasis: a new phototherapeutic approach. Br J Dermatol. 2003 Dec;149(6):1250-8.

Ioannides D, et al. European S1 guidelines on the management of lichen planus: a cooperation of the European Dermatology Forum with the European Academy of Dermatology and Venereology. J Eur Acad Dermatol Venereol. 2020 Jul; 34(7):1403-1414.

Iraji F, et al. Comparison of the narrow band UVB versus systemic corticosteroids in the treatment of lichen planus: A randomized clinical trial. J Res Med Sci. 2011 Dec;16(12):1578-82.

Jiang SIB, et al. A randomized, vehicle-controlled phase 3 study of aminolevulinic acid photodynamic therapy for the treatment of actinic keratoses on the upper extremities. Dermatol Surg. 2019 Jul;45(7):890-897.

Krowchuk DP, Frieden IJ, Mancini AJ, et al. Subcommittee on the Management of Infantile Hemangiomas. Clinical practice guideline for the management of infantile hemangiomas. Pediatrics. 2019 Jan;143(1):e20183475.

Khandpur S, et al. Narrow-band ultraviolet B comb as an effective home-based phototherapy device for limited or localized non-segmental vitiligo: A pilot, open-label, single-arm clinical study. Indian Journal of Dermatology, Venereology, and Leprology. 2020 May-Jun;86 (3): 298-301.

Lopes, C, et al. Efficacy and safety of 308-nm monochromatic excimer lamp versus other phototherapy devices for vitiligo: a systematic review with meta-analysis. Am J Clin Dermatol. 2016 Feb;17:23–32.

Markham T, et al. Narrowband UV-B (TL-01) phototherapy vs. oral 8-methoxypsoralen psoralen-UV-A for the treatment of chronic plaque psoriasis. Arch Derm. 2003;139(3):325-8.

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical Practice Guidelines in Oncology. Basal cell skin cancers. V1.2026. 2025 Sep 2 [accessed 2025 Sep 16]. Available from:http://www.nccn.org/professionals/physician_gls/PDF/nmsc.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical Practice Guidelines in Oncology. Primary Cutaneous Lymphomas. V3.2025. 2025 Jun 10 [accessed 2025 Sep 16]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/primary_cutaneous.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical Practice Guidelines in Oncology. Squamous cell skin cancers. V1.2026. 2025 Sep 2 [accessed 2025 Sep 16]. Available from: http://www.nccn.org/professionals/physician_gls/pdf/squamous.pdf

National Institute for Health and Clinical Excellence (NICE) [Internet]. Psoriasis: assessment and management. CG153. 2012 Oct 25, updated 2017 Sep 1 [accessed 2025 Sep 16]. Available from: http://guidance.nice.org.uk/CG153

National Institute for Health and Clinical Excellence (NICE) [Internet]. Photodynamic therapy for non-melanoma skin tumours (including premalignant and primary non-metastatic skin lesions). IPG155. 2006 Feb 22 [accessed 2025 Sep 16]. Available from: https://www.nice.org.uk/Guidance/IPG155

National Psoriasis Foundation [Internet]. About Psoriasis. 2025 Jun 24 [accessed 2025 Sep 16]. Available from: https://www.psoriasis.org/about-psoriasis

Noe MH, et al. Patient-reported outcomes of adalimumab, phototherapy, and placebo in the Vascular Inflammation in Psoriasis Trial: A randomized controlled study. J Am Acad Dermatol. 2019 Oct;81(4):923-930.

Novak Z, et al. Xenon chloride ultraviolet B laser is more effective in treating psoriasis and in inducing T cell apoptosis than narrow-band ultraviolet B. J Photochem Photobiol B. 2002 May;67(1):32-8.

Papp KA, et al. Rationale, objectives, and design of PURE, a prospective registry of patients with moderate to severe chronic plaque psoriasis in Canada and Latin America. BMC Dermatol. 2019 Jun 21;19(1):9.

Pariser DM, et al. Photodynamic therapy with topical methyl aminolevulinate for actinic keratosis: results of a prospective randomized multicenter trial. J Am Acad Dermatol. 2003 Feb;48(2):227-32.

Pavlotsky F, et al. Ultraviolet-B treatment for cutaneous lichen planus: our experience with 50 patients. Photodermatol Photoimmunol Photomed. 2008 Apr;24(2):83-6.

Poliner A, Fernandez Faith E, Blieden L, Kelly KM, Metry D. Port-wine Birthmarks: Update on Diagnosis, Risk Assessment for Sturge-Weber Syndrome, and Management. Pediatr Rev. 2022 Sep;43(9):507-516.

Product Information. Levulan Kerastick (aminolevulinic acid HCl) for topical solution, 20%. Dusa Pharmaceuticals, Inc. Valhalla, New York, NY, USA, 1999.

Reynolds RV, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2024 May;90(5):1006.e1-1006.e30.

Sabeti S, et al. Consensus Statement for the Management and Treatment of Port-Wine Birthmarks in Sturge-Weber Syndrome. JAMA Dermatol. 2021 Jan;157(1):98-104.

Schmieder GJ, et al. A multicenter, randomized, vehicle-controlled phase 2 study of blue light photodynamic therapy with aminolevulinic acid HCl 20% topical solution for the treatment of actinic keratoses on the upper extremities: the effect of occlusion during the drug incubation period. J Drugs Dermatol. 2012 Dec;11(12):1483-9.

Sidbury R, et al. Guidelines of care for the management of atopic dermatitis. Jour Amer Aca Derm. 2014 Aug;71(2):327-349.

Strauss JS, et al. Guidelines of care for acne vulgaris management. J Amer Acad Derm. 2007

Apr;56(4):651-63.

Sun Y, et al. Treatment of 308-nm excimer laser on vitiligo: A systemic review of randomized controlled trials. Jour Derm Treat. 2015 Jan 30;26(4):347-353

Tangjaturonrusamee C, et al. Comparison of pneumatic broadband light plus adapalene gel 0.3% versus adapalene gel 0.3% monotherapy in the treatment of mild to moderate acne. Cutis. 2016 Jul;98(1):56-61.

Taub AF and Garretson CB. A randomized, blinded, bilateral intraindividual, vehicle-controlled trial of the use of photodynamic therapy with 5-aminolevulinic acid and blue light for the treatment of actinic keratoses of the upper extremities. J Drugs Dermatol. 2011 Sep;10(9):1049-56.

Wang L, Li L, Huang C. Efficacy of photodynamic therapy in the treatment of port wine stains: A systematic review and meta-analysis. Front Med (Lausanne). 2023 Feb;10:1111234.

Weber B, et al. Effectiveness of narrowband UVB phototherapy and psoralen plus UVA photochemotherapy in the treatment of generalized lichen planus: Results from a large retrospective analysis and an update of the literature. Photodermatol Photoimmunol Photomed. 2022 Mar;38(2):104-111.

Whitton ME, et al. Interventions for vitiligo. Cochrane Database Syst Rev 2015 Feb 24;2:CD003263.

Yones SS et al. Randomized double-blind trial of the treatment of chronic plaque psoriasis: efficacy of psoralen-UV-A therapy vs narrowband UV-B therapy. Arch Dermatol. 2006 Jul;142(7):836-42.

SEARCH TERMS

Aminolevulinic acid, BClear lamp, Excilite lamp, Levulan Kerastick, methyl aminolevulinate, Metvix, Narrow band ultraviolet B, Psoralens, PUVA, Ultraviolet light, UVA, UVB, xenon chloride laser, XeCL, XTRAC, VTRAC lamp.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Treatment of Psoriasis (NCD 250.1) [accessed 2025 Sep 16]

Treatment of Actinic Keratosis (NCD 250.4) [accessed 2025 Sep 16]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 03/23 **Revised**: 5/26 **Reviewed**: 5/24, 5/25	
Date	**Summary of Changes**
9/1/2026	• Transitioned Excimer Laser Treatment for Plaque Psoriasis policy, 1370/20.000512 to Lifetime HealthCare Companies policy.
4/1/2023	• New

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MEDICAL POLICY

Medical Policy Title	**Limb Pneumatic Compression Devices for Venous Thromboembolism Prophylaxis**
Policy Number	**1.01.51**
Current Effective Date	**September 1, 2026**
Next Review Date	**September 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Pneumatic compression device(s) are considered **medically appropriate** for venous thromboembolism (VTE) prophylaxis in the home when **ALL** the following are met:

   A. When used after major surgery (e.g. refers to procedures associated with a moderate to high risk of postoperative VTE ie: orthopedic, abdominal, pelvic, cancer, and trauma procedures and does not include minor outpatient procedures with immediate return to ambulation;

   B. When pharmacological prophylaxis is contraindicated due to an established risk factor documented in the medical records (e.g., risk for bleeding- see Policy Guidelines);

   C. Post-surgical use is up to 30 days.

II. Use of pneumatic compression device for prevention of venous thromboembolism (VTE), other than as described in Policy Statement I., is considered **not medically necessary**.

RELATED POLICIES

Corporate Medical Policy

1.01.17 Powered Compression Devices/Lymphedema Pumps

POLICY GUIDELINE(S)

I. Major orthopedic surgery includes total hip arthroplasty (THA), total knee arthroplasty (TKA), or hip fracture surgery (HFS).

II. The American College of Chest Physicians (ACCP) guidelines on prevention of venous thromboembolism (VTE) in orthopedic surgery patients list the following general risk factors for bleeding (Falck-Ytter 2012):

   A. Previous major bleeding (and previous bleeding risk similar to current risk);

   B. Severe renal failure;

   C. Concomitant antiplatelet agent; and

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D. Surgical factors: history of, or difficult-to-control, surgical bleeding during the current operative procedure, extensive surgical dissection, and revision surgery.

DESCRIPTION

Antithrombotic prophylaxis is recommended for surgical patients who are at moderate to high risk of postoperative VTE, which includes deep vein thrombosis (DVT) and pulmonary embolism (PE). Individuals may be classified as being moderate to high risk of VTE based on the surgical procedure and/or individuals characteristics. Mechanical prophylaxis using an intermittent pneumatic compression (IPC) device has been utilized as an adjunct or alternative to anticoagulation in the home setting for individuals in the postoperative period as a method to reduce VTEs.

For certain types of surgery, such as major orthopedic surgery (i.e., total knee arthroplasty, total hip arthroplasty, and hip fracture surgery), there is a particularly high risk of VTE due to the nature of the procedures and the prolonged immobility during and after surgery. Other surgical procedures vary in degree of increased risk of VTE and include abdominal surgery, pelvic surgery, cancer surgery, and surgery for major trauma. Numerous individual-related risk factors, such as increasing age, prior VTE, increasing body mass index (BMI), genetic predisposition, malignancy, pregnancy, and significant comorbidities, can be used in conjunction with the type of surgery to determine risk.

Pharmacologic prophylaxis is effective at reducing postoperative VTE, however, it has risks such as bleeding, allergic reactions, and development of heparin antibodies. Contraindications to pharmacologic prophylaxis include previous intolerance to these agents and increased risk of bleeding.

Pneumatic compression devices for prevention of DVT include various types of wraps for the arms or legs and a programmable control module. The wraps of some of these devices can provide cooling or heating to the extremity. Examples of devices that can be used in the home after discharge include the VascuTherm2 (Thermotek, Inc) and the Triple Play VT (Compression Solutions, Inc).

SUPPORTIVE LITERATURE

Studies involving the use of compression devices post-operatively are limited. The studies are often small and non-randomized, with considerable variation in comparison studies by type of compression stocking and intermittent compression device used, patient group, DVT detection method, and prophylaxis protocol. Many of the studies are in the setting of the hospital, rather than outpatient; consequently, conclusions from the hospital setting may not be able to be applied to the outpatient setting. In the outpatient setting, there are questions about the degree of compliance with the devices, including the ability to correctly use them in the absence of professional supervision.

Pneumatic Compression

Snyder et al (2017) conducted a randomized control trial that assessed the difference in the rate of deep venous thrombosis (DVT) following total knee arthroplasty (TKA) using aspirin (ASA)-based prophylaxis with or without extended use of mechanical pneumatic compression device (PCD) therapy. One hundred patients undergoing TKA, were placed on ASA for three weeks and were

randomized to receive PCD during hospitalization only or extended use at home up to six weeks post-operatively. Lower extremity Duplex venous ultrasonography was used to diagnose DVT at different time intervals. The rate of DVT was significantly lower for patients receiving extended use of PCD at 0% compared to 23.1% for those with inpatient use of PCD ($p < 0.001$).

Wang et al (2020) aimed to address the controversy whether the use of ICP is a more effective form of thromboprophylaxis than anticoagulants in individuals undergoing neurosurgery. The authors report that direct comparisons are difficult given the sparse and inconsistent studies; therefore, they summarized and compared the efficacy and safety of IPC and anticoagulants for the prevention of VTE in adults. The analysis included 18 trials comprising 2,474 patients. Both IPC and chemical prophylaxis were found to be more efficacious than the placebo in reducing the risk of DVT. Both IPC and chemical prophylaxis reduced the risk of pulmonary embolism (PE) significantly more than the placebo. Based on the available evidence of moderate-to-good quality, IPC is equivalent to anticoagulants for thromboprophylaxis in terms of efficacy. Evidence to support or negate the use of pharmacological prophylaxis in terms of safety is lacking. The results of ongoing and future large randomized clinical trials are needed.

Dietz et al (2022) conducted a randomized trial of aspirin alone (n=40) or aspirin/mobile compression pumps (n=40) after total joint arthroplasty was performed. Each group had greater than 94% compliance with aspirin use, with no difference between groups (P=0.55). Overall pump compliance during the first 14 days after hospital discharge was 51% (SD ± 33), which was significantly worse than aspirin compliance at 99% (SD ± 4.1) (P< 0.0001). Only 10 patients were compliant (>20 hr/d) with recommended pump use throughout the entire recommended period. There was no notable association between aspirin compliance and VTE within 90 days. There was no notable association between pump compliance and VTE at 90 days. However, average pump use compliance was 20% in patients with VTE and 54% in patients without VTE within 90 days. With the numbers available in this compliance study, there was no significant difference (P=0.11). The authors concluded that further study is warranted to define the duration of pump use required for clinical significance. The recommended use of compression pumps should continue to be examined.

Haykal et al (2022) report that critically ill patients (patients treated in a medical or surgical intensive care unit) are at high risk of venous thromboembolism (VTE) development (deep vein thrombosis [DVT] and/or pulmonary embolism). A meta-analysis of 5 RCTs (n=3,133 patients) evaluated the efficacy of intermittent pneumatic compression (IPC) prophylaxis in the lower limb compared with no treatment, anticoagulant use, or their combinations in reducing risk. There was a significant reduction of the incidence of VTE events when no treatment was compared with IPC, anticoagulation alone, or anticoagulation with IPC. In addition, there was a significant reduction in DVT when no treatment was compared with IPC, anticoagulation alone, or anticoagulation with IPC. However, there were no significant differences between other comparisons (IPC vs anticoagulation alone, anticoagulation alone vs anticoagulation with IPC, or anticoagulation with IPC vs IPC alone) regarding VTE or DVT incidence. Among critically ill patients, IPC alone, anticoagulation alone, and IPC with anticoagulation were associated with a significant reduction of VTE and DVT incidence compared with no treatment. However, there was no significant difference between these modalities when compared together.

Therefore, further larger studies comparing those different thromboprophylaxis modalities and their combinations are needed to provide more robust results for future clinical recommendations.

Non-Pneumatic Compression Devices

Labropoulos et al (2021) conducted a small (n=20) pilot, single-center, prospective comparative study to determine the potential ability of the Movement and Compression (MAC) System (Recovery Force USA) nonpneumatic compression device to favorably alter venous hemodynamics compared with pneumatic compression devices routinely available in clinical practice and to serve as a prequel to clinical studies evaluating its efficacy in preventing VTE. The researchers measured and compared the common femoral vein peak blood flow velocity, rise time to peak flow, and calculated peak flow velocity compared with baseline for five currently available mechanical compression devices using duplex ultrasonography in a group of subjects with different leg sizes. The peak flow velocity, compared with the baseline measurements, was significantly greater for the MAC System for three of the four comparisons (P<.001). The MAC had a significantly (P< .001) faster rise time to peak flow compared with the comparison devices. It was the only device to achieve the target peak flow velocity over baseline of at least three times in every body mass index group. Finally, the MAC System met the goal of <2.5 centimeters of device movement after ambulation in 100% of the measurements, with 75% of the measurements showing no movement of the device. The study is limited by the study design and lack of follow-up. The authors concluded that the device has promising performance, and the ability for the patient to remain mobile may allow for better compliance. Further studies are warranted.

PROFESSIONAL GUIDELINE(S)

In 2012, the American College of Chest Physicians (ACCP) published several clinical practice guidelines with recommendations on the use of postoperative intermittent pneumatic limb compression.

- Gould et al (2012) recommend the use of limb compression devices in general/non-orthopedic and abdominal-pelvic surgical patients who are at any risk for bleeding, rather than no prophylaxis or in addition to pharmacologic prophylaxis.
- Falck-Ytter et al (2012) recommended ICP for the prevention of VTE in orthopedic surgery patients for a minimum of 10-14 days rather than no antithrombotic prophylaxis (Grade 1C). The suggestion to extend prophylaxis to 35 days for patients undergoing major orthopedic surgery was a weak recommendation (Grade 2B) and did not specifically mention limb compression devices as a therapy option.
- Kahn et al (2012) suggest against the routine use of thromboprophylaxis in chronically immobilized people in a home setting.

In 2019, the American Society of Clinical Oncology (ASCO) released updates to the clinical practice guideline on VTE prophylaxis and treatment in individuals with cancer (Key 2019) recommending:

- Mechanical methods may be added to pharmacologic thromboprophylaxis but should not be

used as monotherapy for VTE prevention unless pharmacologic methods are contraindicated because of active bleeding or high bleeding risk. (Evidence quality: intermediate; Strength of recommendation: strong).

- A combined regimen of pharmacologic and mechanical prophylaxis may improve efficacy, especially in the highest-risk individuals. (Evidence quality: intermediate; Strength of recommendation: moderate)

In 2021, the American College of Obstetricians-Gynecologists (ACOG) published an updated practice bulletin on the prevention of VTE in gynecologic surgery, including the following recommendations:

- For gynecologic surgery patients who are at high risk of VTE and average risk of bleeding complications, dual thromboprophylaxis with a combination of mechanical prophylaxis (preferably with intermittent pneumatic compression) and pharmacologic prophylaxis. (Level A evidence)
- For gynecologic surgery patients at low risk of VTE, mechanical thromboprophylaxis (preferably with intermittent pneumatic compression) is recommended. Graduated compression stockings are a reasonable alternative if intermittent pneumatic compression is not available or is not preferred by the patient. Mechanical prophylaxis devices should be placed before initiation of surgery and continued until the patient is fully ambulatory. (Level B evidence)
- For gynecologic surgery patients who are at moderate risk of VTE and high risk of major bleeding complications, mechanical prophylaxis (preferably with intermittent pneumatic compression) is recommended. (Level B evidence)
- For gynecologic surgery patients at high risk of VTE for whom both LMWH and low-dose unfractionated heparin are contraindicated, or not available, mechanical prophylaxis alone (preferably with intermittent pneumatic compression) is recommended until the risk of bleeding diminishes. (Level B evidence)

In 2022, the International Consensus Meeting (ICM) brought together over 600 experts spanning a range of countries and medical professionals to conduct a comprehensive review of the literature and to generate practical recommendations for VTE prophylaxis across all type of orthopedic procedures. Published recommendations include:

- ICM-VTE general practice guidelines (2022a), 95% of the expert panel agreed that intermittent compression devices (ICD) provide protection against VTE development following orthopedic surgery. Utilizing these devices has been shown to be an effective prophylactic measure. The guideline did not address duration of use postoperatively. Noting that although portable IPC has shown effective mechanical prophylaxis for VTE after THA and TKA, the evidence is limited due to confounding variables.
- ICM-VTE hip and knee guidelines (2022b), 92% of the expert panel agreed that mechanical compressive devices can be used routinely in patients undergoing total hip arthroplasty (THA) or total knee arthroplasty (TKA) as venous thromboembolism (VTE) prophylaxis. However, further research should aim to clarify the most appropriate devices, duration of use, as well as

synergistic relationships with pharmacological agents. Furthermore, 82% of the expert panel agree that it appears that coadministration of aspirin (ASA) with pneumatic compression devices (PCD) may be more effective than ASA alone in prevention of venous thromboembolism (VTE) following total joint arthroplasty (TJA).

In 2023, the American Society of Clinical Oncology (ASCO) released an updated clinical practice guideline on VTE prophylaxis and treatment in patients with cancer (Key 2023). The guideline makes the following recommendations for thromboprophylaxis in this population:

- All patients with malignant disease undergoing major surgical intervention should be offered pharmacologic thromboprophylaxis unless contraindicated.
- Pharmacologic thromboprophylaxis for patients undergoing major surgery for cancer should be continued for at least 7-10 days.
- Extended pharmacologic thromboprophylaxis for up to 4 weeks postoperatively should be offered to patients undergoing major open or laparoscopic abdominal or pelvic surgery for cancer who have high-risk features, such as restricted mobility, obesity, history of VTE, or additional risk factors. In lower-risk surgical settings, the decision on appropriate duration of thromboprophylaxis should be made on a case-by-case basis.
- Mechanical methods may be added to pharmacologic thromboprophylaxis but should not be used as monotherapy for VTE prevention unless pharmacologic methods are contraindicated because of active bleeding or high bleeding risk (Type: evidence based; Evidence quality: intermediate; Strength of recommendation: strong).

In 2024, the American Pediatric Surgical Association Outcomes and Evidence-Based Practice Committee conducted a systematic review to describe the epidemiology of venous thromboembolism (VTE) in pediatric surgical and trauma patients and develop recommendations for screening and prophylaxis (Kelley-Quon 2024). Twenty-four manuscripts addressed mechanical prophylaxis of VTE in children.

- Recommendations for use are mostly extrapolated from adult data that support the use of sequential compression devices (SCDs) for reducing the risk of lower limb DVT; however, there is no evidence that antiembolism stockings decrease the risk of VTE in adult medical inpatients.
- For adolescents who have undergone major surgery, healthcare providers should consider SCDs in children at-risk for VTE when non-mobile only if an appropriately sized device is available.

According to the 2025 National Comprehensive Cancer Network (NCCN) guidelines for supportive care in cancer-associated venous thromboembolic (VTE) disease, hospitalized cancer patients should receive VTE prophylaxis with mechanical intermittent pneumatic compression (IPC) when anticoagulation is contraindicated. IPC for VTE prophylaxis following discharge or for at-risk ambulatory patients with cancer is not addressed in the guidelines. (V.1.2026)

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates Limb Pneumatic Compression Devices as medical devices. All Limb Pneumatic Compression Devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Aug 24]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Aug 24]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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HCPCS Codes

Code	Description
E0650	Pneumatic Compressor, nonsegmental home model
E0651	Pneumatic Compressor, segmental home model without calibrated gradient pressure
E0652	Pneumatic Compressor, segmental home model with calibrated gradient pressure
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0666	Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0673	Segmental gradient pressure pneumatic appliance, half leg

Code	Description
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins. Prevention of venous thromboembolism in gynecologic surgery: ACOG practice bulletin, number 232. Obstet Gynecol. 2021 Jul 1;138(1):e1-e15. PMID: 34259490

Badireddy M, et al. StatPearls [Internet]. Deep venous thrombosis prophylaxis. StatPearls Publishing. 2023 May 7 [accessed 2026 Aug 5]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK534865/

Crawford DA, et al. Ambulatory portable pneumatic compression device as part of a multimodal aspirin-based approach in prevention of venous thromboembolism in outpatient total knee arthroplasty. Arthroplast Today. 2020 Jun 16;6(3):378-380.

Dietz MJ, et al. Randomized trial of postoperative venous thromboembolism prophylactic compliance: aspirin and mobile compression pumps. J Am Acad Orthop Surg. 2022 Oct 15;30(20):e1319-e1326.

Falck-Ytter Y, et al. Prevention of VTE in orthopedic surgery patients: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines. Chest. 2012;141(2):278 325.

Guyatt GH, et al. American College of Chest Physicians Antithrombotic therapy and Prevention of Thrombosis Panel. Executive summary: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2012;141(2 Suppl):7S-47S. Errata to: CHEST 2021;160(6):2247-2259 and CHEST 2021;160(6):e545-e608 CHEST, 162269

Haykal T, et al. Meta-analysis of the role of intermittent pneumatic compression of the lower limbs to prevent venous thromboembolism in critically ill patients. Int J Low Extrem Wounds. 2022 Mar;21(1):31-40. Epub 2020 Jun 11.

ICM-VTE General Delegates. Recommendations from the ICM-VTE: general. J Bone Jt Surg. 2022a Mar 16;104(Suppl 1):4-162.

ICM-VTE Hip & Knee Delegates. Recommendations from the ICM-VTE: hip & knee. J Bone Jt Surg.

2022b Mar 16;104(Suppl 1):180-231.

Kahn SR, et al. Prevention of VTE in nonsurgical patients. Antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines. Chest. 2012 Feb;141(2 Suppl):e195S-e226S.

Kelley-Quon LI, et al. Screening and prophylaxis for venous thromboembolism in pediatric surgery: a systematic review. J Pediatr Surg. 2024 Oct;59(10):161585.

Key NS, et al. Venous thromboembolism prophylaxis and treatment in patients with cancer: ASCO guideline update. J Clin Oncol. 2023 Jun 01;41(16):3063-3071. PMID 37075273

Labropoulos N, et al. Comparison of a nonpneumatic device to four currently available intermittent pneumatic compression devices on common femoral blood flow dynamics. J Vasc Surg Venous Lymphat Disord. 2021 Sep;9(5):1241-1247.

Li B, et al. Effects of continuous graduated pneumatic compression and intermittent pneumatic compression on lower limb hemodynamics for VTE prophylaxis in arthroplasty. Orthop Surg. 2025 Apr;17(4):1095-1104.

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology. Cancer-Associated Venous Thromboembolic Disease. Version 1.2026 - May 05, 2026 [accessed 2026 Aug 6]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/vte.pdf

Snyder MA, et al. Efficacy in deep vein thrombosis prevention with extended mechanical compression device therapy and prophylactic aspirin following total knee arthroplasty: a randomized control trial. J Arthroplasty. 2017 May;32(5):1478-1482. Epub 2016 Dec 23.

Stevens SM, et al. Antithrombotic therapy for VTE Disease: Second update of the CHEST guideline and expert panel report. Chest. 2021 Dec;160(6):e545-e608. PMID 34352278. Epub 2021 Aug.

Tang A, et al. Discontinued use of outpatient portable intermittent pneumatic compression devices may be safe for venous thromboembolism prophylaxis in primary total knee arthroplasty using low-dose aspirin. J Knee Surg. 2022 Jul;35(8):909-915. Epub 2020 Nov 25.

Wang X, et al. Comparative efficacy and safety of pharmacological prophylaxis and intermittent pneumatic compression for prevention of venous thromboembolism in adult undergoing neurosurgery: a systematic review and network meta-analysis. Neurosurg Rev. 2021 Apr;44(2):721-729. doi: 10.1007/s10143-020-01297-0. Epub 2020 Apr 16.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Pneumatic Compression Devices (NCD 280.6) [accessed 2026 Aug 4]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 5/26 **Revised**: **Reviewed**: 11/26	
Date	**Summary of Changes**
9/1/2026	• New

MEDICAL POLICY

Medical Policy Title	**Liver Transplantation**
Policy Number	**7.02.07**
Current Effective Date	**7/1/2026**
Next Review Date	**November 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Liver transplantation for selected individuals with end-stage liver disease is considered **medically appropriate** for **ANY** of the following indications when criteria are met:

A. Hepatocellular diseases:

1. Alcoholic cirrhosis;
2. Viral hepatitis;
3. Autoimmune hepatitis;
4. Alpha-1 antitrypsin deficiency;
5. Hemochromatosis;
6. Non-alcoholic steatohepatitis cirrhosis/ metabolic dysfunction-associated steatohepatitis (MASH);
7. Protoporphyria; or
8. Wilson's disease;

B. Cholestatic liver diseases:

1. Primary biliary cirrhosis;
2. Primary sclerosing cholangitis with development of secondary biliary cirrhosis; or
3. Biliary atresia;

C. Vascular disease:

1. Budd-Chiari syndrome;

D. Primary hepatocellular carcinoma when:

1. Disease is organ confined, and the patient is not a candidate for subtotal liver resection;

E. Inborn errors of metabolism;

F. Trauma and toxic reactions;

G. Nonresectable hilar (extrahepatic) cholangiocarcinoma and as part of a neoadjuvant

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chemoradiation protocol when:

1. Absence of metastatic disease, **and**
2. For localized hilar tumors Stage I or II;

H. Nonresectable intrahepatic cholangiocarcinoma when:

1. Absence of metastatic disease confirmed by a staging laparoscopy or laparotomy; **and**
2. When combined with neoadjuvant chemoradiation;

I. Hepatoblastoma (non-metastatic):

J. Polycystic disease of the liver; **or**

K. Familial amyloid polyneuropathy.

II. Recipient Selection Guidelines

A. Cadaver Liver Recipient:

1. Model for End-stage Liver Disease (MELD) score equal to or greater than 9 (UNOS adjusts the MELD score for patients with hepatocellular cancer by adding points to their scores).
2. Patients with polycystic disease of the liver do not always develop progressive liver failure but may require transplantation due to the anatomic complications of a hugely enlarged liver. The MELD/PELD score may not apply to these cases. One of the following complications should be present:
   a. Enlargement of liver impinging on respiratory function;
   b. Extremely painful enlargement of liver; **or**
   c. Enlargement of liver significantly compressing and interfering with function of other abdominal organs.
3. The MELD/ Pediatric End-stage Liver Disease (PELD) score may apply to patients with amyloid polyneuropathy. Candidacy for liver transplant is an individual consideration based on the morbidity of the polyneuropathy. Many patients may not be candidates for liver transplant alone due to coexisting cardiac disease.

B. Living Donor Recipient:

1. MELD score equal to or greater than 9 and less than or equal to 25; and
2. Listed on the cadaveric liver transplant waiting list; **and**
3. Has suffered at least one (1) significant complication related to liver disease (e.g., variceal hemorrhage, spontaneous bacterial peritonitis, encephalopathy, or severe impairment to his or her quality of life due to, for example, fatigue, pruritis).

III. Contraindications to Liver Transplantation

A. Cadaveric Organ Recipient:

1. Relative contraindications include:

a. Major co-morbid illnesses such as ischemic heart disease, severe peripheral vascular disease, congestive cardiomyopathy, moderately severe COPD;

b. HIV infection unless **ALL** of the following criteria are met:

i. CD4 count greater than 100 cells/mm^3 for non-hepatitis C patients, greater than 200 cells/mm^3 for patients with hepatitis C;

ii. HIV-1RNA undetectable;

iii. On stable anti-retroviral therapy greater than 3 months;

iv. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections, Kaposi's sarcoma, or other neoplasm); **and**

v. Meets all other criteria for transplantation;

c. Presence of malignancy within 5 years of transplantation (other than non-melanoma skin cancers), or unless malignancy has been completely resected, or unless (upon medical review) it is determined that malignancy has been treated with small likelihood of recurrence and acceptable future risks;

d. Ongoing or recurring infections that are not effectively treated;

2. Absolute contraindications: uncontrolled behavioral health disorder that manifests in behaviors that that interfere with the patient's capacity to comply with surgical and follow-up management including but not limited to alcohol or substance abuse and major thought disorder.

B. Living Donor Organ Recipient:

1. Hepatocellular carcinoma if:

a. There is evidence of metastatic disease;

b. The recipient can expect less than a one-year disease-free outcome;

2. Simultaneous combined liver/kidney transplantation (however, in cases involving hyperoxalosis or other specific metabolic disorders, special consideration should be given to allowing simultaneous liver/kidney transplantation from two different donors).

IV. Living Donation Guidelines

A. Donor selection must be consistent with the New York State Department of Health, updates to that report, and relevant regulatory requirements.

B. Donor should be "emotionally related" to recipient (e.g., relative, previous known or current

acquaintance).

RELATED POLICIES

Corporate Medical Policy

7.02.05 Small Bowel and Multvisceral Transplants in Adults and Children

POLICY GUIDELINE(S)

I. Prior authorization is contract dependent. Approvals for all transplants, including arrangements with an approved transplant center, may be required.

II. Pre-transplant evaluation documentation could include the following clinical information. If testing is unable to be performed, the rationale for not performing the testing must be included in the documentation.

A. Clinical Evaluation:

1. Confirmation of diagnosis;
2. Identification of comorbidities;
3. Treatment of co-morbidities;
4. Current assessment of co-morbidities;
5. Consult notes (if applicable).

B. Psycho-Social Evaluation:

1. Karnofsky performance score or Palliative Performance Scale (PPS) score.
2. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol, or substance abuse).

C. Oral Health Evaluation

D. Lab Tests:

1. CBC, metabolic profile;
2. Serologies: CMV, Hepatitis B and C;
3. HIV Testing.

E. Cardiac Assessment:

1. 12 Lead EKG;
2. Stress (exercise, nuclear, or dobutamine);
3. Echo or Muga Scan.

F. Pulmonary Assessment:

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1. Chest X-ray;
2. Pulmonary function tests (PFTs) for high-risk for respiratory failure (COPD, emphysema, a-1-antritrypsin deficiency, hepatopulmonary syndrome, or significant smoking history);
3. Low dose screening CT for individuals considered high-risk for lung cancer (e.g., 20-30 pack history of smoking).

G. Age-Appropriate Screening Tests: Please refer to the U.S Preventive Services Task Force (USPSTF) website for list of age-appropriate screening guidelines. Available from: https://uspreventiveservicestaskforce.org/uspstf/ [accessed 2025 Oct 24]

III. Re-authorization

Transplant re-authorization must be completed annually while actively waiting for a transplant. Re-authorization documentation must be within the past 11 months (unless specified) and include the following clinical information (if testing is unable to be performed, the rationale must be included in the documentation). If your health condition has not changed from the previous year some testing would not be applicable.

A. Clinical Evaluation:
   1. Updated list of diagnoses to include identification of comorbidities, current assessment, and treatment plan.
   2. Specialty consultation notes (if applicable).

B. Current functional ability as evidence by current Karnofsky performance score (KPS); or Palliative Performance Scale (PPS) score.

C. Follow-up Oral Health Evaluation.

D. Lab Tests:
   1. CBC, metabolic profile;
   2. Serologies: CMV Hepatitis B and C; and
   3. HIV testing (If applicable).

E. E. Cardiac Assessment:
   1. 12 Lead EKG (If applicable); and
   2. Stress (exercise, nuclear, or dobutamine) (If applicable),
   3. Echo or Muga scan (If applicable).

F. Pulmonary Assessment:
   1. Chest x-ray (If applicable);
   2. Pulmonary function tests (PFTs) for high-risk for respiratory failure (COPD, emphysema, a-1-antritrypsin deficiency, hepatopulmonary syndrome, or significant smoking history)

(If applicable);

3. Low-dose screening CT for individuals considered high-risk for lung cancer (e.g., 20- to 30-pack history of smoking.

G. Age-appropriate Screening Tests: Please refer to the U.S Preventive Services Task Force (USPSTF) website for list of age-appropriate screening guidelines. Available from: https://www.uspreventiveservicestaskforce.org/uspstf/ [accessed 2025 Oct 24]

IV. Candidates who have end stage disease related to or impacted by alcohol consumption, including viral hepatitis, must demonstrate a period of abstinence through clinical treatment records (e.g., PCP, alcohol treatment programs). If the patient has been abstinent less than one month, a medical director consultation with the transplant center behavioral health team is required which includes an assessment by a trained Alcohol and Addiction Professional. The assessment should include history of addiction, harmful drinking patterns, awareness of harmful drinking by the patient, social environment along with family support, any identifiable psychiatric issues, and post-transplantation rehabilitation planning.

V. Candidates may be waitlisted at more than one transplant center. Since waiting time priority is first calculated among candidates at all hospitals within the local donation area, listing at transplant centers in different local allocation areas is recommended. Requirements for multiple-listed candidates may vary among transplant centers. When possible, results of tests used in the evaluation for the transplant at one center should be used at subsequent centers where the patient is listed.

DESCRIPTION

A liver transplant consists of replacing a diseased liver with a healthy liver or a segment of a healthy liver. Transplanted organs are harvested from either a cadaver (brain-dead donor) or from a living donor. In a living donor liver transplantation (LDLT) a portion of the liver is surgically removed from a healthy living person and placed into an individual whose liver is no longer working properly. The donor's remaining liver regrows and returns to its normal size, volume, and capacity within a couple of months after the surgery. At the same time, the transplanted liver portion grows and restores normal liver function in the recipient. Liver transplantation is currently the treatment of last resort for patients with end-stage liver disease.

The United Network for Organ Sharing (UNOS) uses the Model for End-stage Liver Disease (MELD) and Pediatric End-stage Liver Disease (PELD) criteria. Candidates who are less than 12 years old receive a PELD score, while candidates who are at least 12 years old receive a MELD score. These are calculated using a combination of the candidate's clinical lab values and reflect the probability of death on the waitlist within a 90-day period. Higher scores indicate a higher probability of mortality and increased urgency for transplant. Candidates that are considered urgent are assigned status 1A or 1B. MELD and PELD score ranges from six (6) to 40.

MELD calculator available from: https://optn.transplant.hrsa.gov/resources/allocation-calculators/meld-calculator/ [accessed 2025 Oct 24]

PELD calculator available from: https://optn.transplant.hrsa.gov/resources/allocation-calculators/peld-calculator/ [accessed 2025 Oct 24]

Donor morbidity and mortality are prime concerns in adult donors undergoing partial hepatectomy. Subjecting healthy donors to the risks of surgery, especially considering uncertain long-term outcomes, can be justified only in clinical circumstances in which the potential recipient has a compelling need for a living donor transplant; such as when a liver transplantation is the only therapeutic option, and a cadaveric transplantation is impossible or problematic for reasons such as anticipated waiting times. Due to the scarcity of donor organs and the success of living donation between parent and child, adult-to-adult living donor liver transplantation offers an option for appropriately screened recipients and donors.

SUPPORTIVE LITERATURE

Mazzaferro et al (1996) developed criteria to better determine which patients with hepatocellular carcinomas and cirrhosis were more likely to have better outcomes after liver transplant. They studied 48 patients with cirrhosis who had small, unresectable hepatocellular carcinomas and underwent treatment with liver transplant. The criteria for eligibility for transplantation were the presence of a tumor 5 cm or less in diameter in patients with single hepatocellular carcinomas and no more than three tumor nodules, each 3 cm or less in diameter, in patients with multiple tumors, with no evidence of macrovascular invasion or metastasis. They found that liver transplantation was an effective treatment for small, unresectable hepatocellular carcinomas in patients with cirrhosis, as their cohort demonstrated excellent long-term outcomes. Their protocol became known as the Milan Criteria and have been adopted by the American Association for the Study of Liver Diseases (AASLD).

Li et al (2025) published a meta-analysis which aimed to analyze liver transplant (LT) selection criteria through overall survival outcomes from post-operative data of patients with differing severity levels of acute-on-chronic liver failure (ACLF). They classified the severity grades according to the European Association for the Study of the Liver criteria. A total of 28,025 participants were included and the ACLF grades analysis showed that 33.7% of the patients were classified as ACLF-1, 35.1% as ACLF-2, and 31.2% as ACLF-3. Patients with ACLF-1 and ACLF-2 demonstrated favorable survival outcomes within one year, with survival rates reaching 87% [95% confidence interval (CI): 84%-91%] and 86% (95%CI: 81%-91%), respectively. Despite the relatively lower survival (73%, 95%CI: 66%-80%) and higher incidence of infection (48%, 95%CI: 29%-67%) observed in ACLF-3 patients, their survival exceeds those who do not undergo LT. Post-transplant survival was highest in North America across all ACLF grades.

PROFESSIONAL GUIDELINE(S)

The American Association for the Study of Liver Diseases (AASLD) and the American Society of Transplantation (AST) issued joint guidelines for evaluation for liver transplantation in adults (Martin 2014). "Liver transplant (LT) is indicated for severe acute or advanced chronic liver disease when the limits of medical therapy have been reached" and they make the following recommendations:

- "Evaluation for LT should be considered once a patient with cirrhosis has experienced an index complication such as ascites, hepatic encephalopathy, or variceal hemorrhage or hepatocellular dysfunction results in a MELD Score ≥15".
- "In a liver transplant candidate potentially treatable etiologies and components of hepatic decompensation such as ascites, hepatic encephalopathy, or variceal hemorrhage should be treated."
- "Potential liver transplant candidates with worsening renal dysfunction or other evidence of rapid hepatic decompensation should have prompt evaluation for liver transplant."
- Medical Comorbidities
    - "Obese patients (WHO class 1 and greater) require dietary counseling prior to LT."
    - "Class 3 obesity (BMI ≥40) is a relative contraindication to LT."
    - "Cardiac evaluation needs to include assessment of cardiac risk factors with stress echocardiography as an initial screening test with cardiac catheterization as clinically indicated."
    - "In the absence of significant comorbidities, older recipient age (>70 years) is not a contraindication to LT."
    - "Portopulmonary hypertension (POPH) should be excluded in LT candidates by routine echocardiography. For RVSP ≥45 mm Hg right heart cardiac catheterization is indicated."
    - "LT can be offered to potential recipients with POPH, which responds to medical therapy with an MPAP ≤35 mmHg."
    - "The presence of severe hepatopulmonary syndrome (HPS) is associated with increased mortality and affected individuals should undergo expedited LT evaluation."
    - "Simultaneous liver-kidney transplantation is indicated for LT candidates in whom renal failure reflects CKD with GFR <30 mL/min or acute kidney injury with dialysis >8 weeks or if extensive glomerulosclerosis is present."
- Tobacco use
    - "Tobacco consumption should be prohibited in LT candidates."
- Malignancy
    - "LT candidates with a prior extrahepatic malignancy should have received definitive treatment with adequate tumor-free survival prior to listing for LT."
    - "Candidates should undergo age and risk factor-appropriate cancer screening, e.g., colonoscopy, mammography, Papanicolaou smear."
- Infectious Diseases

- "LT candidates should be screened for bacterial, viral, and fungal infections prior to LT."
- "Treatment for latent TB should be initiated pre-LT."
- "Vaccination should be encouraged against pneumococcus, influenza, diphtheria, pertussis, and tetanus."
- "Live vaccines (mumps, measles, rubella, and varicella), if indicated, should be administered early in the evaluation process."
- "Patients with HIV infection are candidates for LT if immune function is adequate and the virus is expected to be undetectable by the time of LT."
- "LT transplant candidates with HCV have the same indications for LT as for other etiologies of cirrhosis."
- "Patients with HBV liver disease should receive antiviral therapy to suppress HBV replication pretransplant and continued surveillance for HCC."
- "LT should be considered in patients with decompensated autoimmune hepatitis who do not respond to or are not appropriate candidates for medical therapies."

- Psychosocial Evaluation
  - "Patients should be evaluated for and meet reasonable expectations for adherence to medical directives and mental health stability as determined by the psychosocial evaluation."
  - "Methadone-maintained patients should not be denied transplantation based on methadone use alone, and expectations of methadone reduction or discontinuation should not be a requirement for transplant listing."
  - "Patients should have adequate social/caregiver support to provide the necessary assistance both while waitlisted and until independently functioning in the postoperative period."
- Primary Biliary Cirrhosis (PBC)
  - "LT is indicated for decompensated PBC."
  - "Severe pruritus, refractory to medical therapy, may also be an indication for LT."
- Primary Sclerosing Cholangitis (PSC)
  - "LT is an effective therapy for decompensated liver disease due to PSC, including bouts of recurrent cholangitis and sepsis."
- Alcoholic Liver Disease
  - "Early referral of ALD patients for initiation of LT evaluation facilitates psychosocial assessment and setting addiction treatment goals."

  - "Given the chronic nature of alcohol dependence, ongoing monitoring is an important part of a comprehensive treatment plan."

- Acute Liver Failure (ALF)
  - "Patients with ALF require immediate referral to a liver transplant center."
  - "Patients with acetaminophen overdose should be evaluated for and meet reasonable expectations for adherence to medical directives and mental health stability as determined by the psychosocial evaluation."
- Hepatocellular Carcinoma
  - "LT is an effective therapy for HCC within the Milan criteria."
  - "LT may be an option for HCC in excess of the Milan criteria in combination with tumor downstaging to Milan."
- Cholangiocarcinoma
  - "Patients diagnosed with early-stage cholangiocarcinoma and deemed unresectable due to parenchymal liver disease or anatomic location may be considered for LT in combination with neoadjuvant chemoradiation."
- Metabolic Diseases
  - Nonalcoholic steatohepatitis (NASH)
    - "LT is an effective therapy for decompensated liver disease due to NASH or cryptogenic cirrhosis."
  - α-1-Antritrypsin Deficiency
    - "LT is indicated for decompensated cirrhosis due to α-1-antritrypsin deficiency."
  - Hereditary Hemochromatosis
    - "LT is indicated for decompensated cirrhosis due to hemochromatosis."
  - Wilson's Disease
    - "Urgent LT is indicated for Wilsonian acute liver failure."
    - "LT is indicated in decompensated cirrhosis due to Wilson's disease unresponsive to medical therapy."
    - "LT is not recommended as therapy for neuropsychological Wilson's disease, as LT does not reliably improve neurologic outcomes."
- Hereditary Amyloidosis
  - "LT should be considered in familial amyloid polyneuropathy (FAP) to eliminate hepatic amyloid production early in the course of disease and particularly prior to the development of cardiac and ocular complications, as these complications are not reliably

improved by LT."

- Primary Hyperoxaluria
    - "Preemptive LT (prior to the development of advanced renal disease) or combined liver and kidney transplantation in the setting of end stage renal disease (ESRD) are curative for primary hyperoxaluria and should be considered for patients who do not respond to medical therapy."
- MELD Exceptions
    - "For an LT candidate whose MELD score does not adequately reflect the severity of their liver disease, an appeal for MELD exception points should be made to the Regional Review Boards (RRB)."

The AASLD practice guidelines on diagnosis and treatment of alcohol-associated liver disease (Crabb 2020) recommend the following:

- "Patients without liver disease should be educated about safe levels of alcohol use for men (no more than two standard drinks per 24 hours) and women (no more than one standard drink per 24 hours)."
- "Patients with Alcohol-associated liver disease (ALD) or other liver diseases, in particular non-alcoholic fatty liver disease [NAFLD], NASH, viral hepatitis, and hemochromatosis, should be counseled that there is no safe level of drinking, and that they should abstain."
- "Potential LT candidates with ALD undergo evaluation by a mental health provider for full psychiatric diagnosis and adequate treatment planning."
- "Patients with decompensated alcohol-associated cirrhosis, CPT class C or MELD-Na of at least 21 should be referred and considered for liver transplantation."
- "Candidate selection for liver transplantation in alcohol-associated cirrhosis should not be based solely on a fixed interval of abstinence."
- "Liver transplantation may be considered in carefully selected patients with favorable psychosocial profiles in severe alcoholic hepatitis [AH] not responding to medical therapy."

The AASLD released a practice guideline for the prevention, diagnosis, and treatment of hepatocellular carcinoma (HCC) (Singal 2023). They state:

- "For patients with early-stage HCC who are ineligible for resection because of liver dysfunction or tumor multi-focality, LT is an optimal treatment strategy because it provides a cure for both HCC and the underlying liver disease. The Milan criteria (one lesion between 1 and 5 cm or two to three lesions between 1 and 3 cm) has been well established as the standard for optimal patient selection."
- "Liver transplantation should be the treatment of choice for transplant-eligible patients with early-stage HCC occurring in the setting of clinically significant portal hypertension and/or decompensated cirrhosis."

- "Liver transplantation should be the treatment of choice for transplant-eligible patients with HCC that recur within Milan criteria after surgical resection."

The National Comprehensive Cancer Network (NCCN) guidelines on hepatocellular carcinoma (V. 2.2025) recommend patients meeting the UNOS criteria should be considered for transplantation (cadaveric or living donation). Additionally, patients with tumor characteristics that are just outside of the UNOS guidelines may be considered for transplantation based on the institution. For those who have had successful downstaging therapy, transplantation can also be considered.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) does not regulate the transplantation of vascularized human organ transplants such as kidney, liver, heart, lung, or pancreas. The Health Resources Services Administration (HRSA) oversees the transplantation of vascularized human organs. More information available from: https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-and-tissue-product-questions-and-answers [accessed 2025 Oct 24]

HRSA information available from: https://data.hrsa.gov/topics/health-systems/organ-donation/ [accessed 2025 Oct 24]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
47133	Donor hepatectomy (including cold preservation), from cadaver donor
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age
47140	Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)
47141	Donor hepatectomy (including cold preservation), from living donor; total left lobectomy (segments II, III, and IV)
47142	Donor hepatectomy (including cold preservation), from living donor; total right lobectomy (segments V, VI, VII, and VIII)

Code	Description
47143	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe split
47144	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with trisegment split of whole liver graft into 2 partial liver grafts (i.e., left lateral segment [segments II and III] and right trisegment [segments I and IV through VIII])
47145	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with lobe split of whole liver graft into 2 partial liver grafts (i.e., left lobe [segments II, III, and IV] and right lobe [segments I and V through VIII])
47146	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; venous anastomosis, each
47147	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; arterial anastomosis, each

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
A52.15	Late syphilitic neuropathy
B15.0-B15.9	Acute hepatitis A (code range)
B16.0-B16.9	Acute hepatitis B (code range)
B17.10-B17.11	Acute hepatitis C (code range)

Code	Description
B17.8-B19.9	Other acute viral hepatitis (code range)
B25.1	Cytomegaloviral hepatitis
B66.1	Clonorchiasis
B66.3	Fascioliasis
C22.0	Liver cell carcinoma
C22.2-C22.9	Malignant neoplasm of liver and intrahepatic bile ducts (code range) (includes hepatoblastoma)
D64.0-D64.3	Sideroblastic anemia (code range)
D81.810	Biotinidase deficiency
D84.1	Defects in the complement system
E70.0-E71.30	Disorders of aromatic amino-acid metabolism (code range)
E72.00-E73.1	Other disorders of amino-acid metabolism (code range)
E74.39	Other disorders of intestinal carbohydrate absorption ~~(code range)~~
E74.4-E74.9	Other disorders of carbohydrate metabolism (code range)
E75.21-E75.3	Disorders of sphingolipid metabolism and other lipid storage disorders (code range)
E75.5-E75.6	Lipid storage disorders (code range)
E77.0-E77.9	Disorders of glycoprotein metabolism (code range)
E78.0-E78.9	Pure hypercholesterolemia (code range)
E80.0-E80.29	Disorders of porphyrin and bilirubin metabolism (code range)
E83.00-E83.19	Disorders of mineral metabolism (code range)
E88.89	Other specified metabolic disorders
E88.9	Metabolic disorder, unspecified
G60.0	Hereditary motor and sensory neuropathy
G60.2	Neuropathy in association with hereditary ataxia

Code	Description
G63	Polyneuropathy in diseases classified elsewhere
G65.0-G65.2	Sequelae of inflammatory and toxic polyneuropathies (code range)
G80.1-G80.9	Cerebral palsy (code range)
I82.0	Budd-Chiari syndrome
I99.9	Unspecified disorder of circulatory system
K71.0-K71.9	Toxic liver disease (code range)
K74.0	Hepatic fibrosis
K74.3-K74.69	Fibrosis and cirrhosis of liver (code range)
K75.2-K75.3	Other inflammatory liver diseases (code range)
K75.81-K75.89	Other specified inflammatory liver diseases (code range)
K75.9	Inflammatory liver disease, unspecified
K76.4	Peliosis hepatitis
K77	Liver disorders in diseases classified elsewhere
K80.30-K80.37	Calculus of bile duct with cholangitis (code range)
K83.0-K83.8	Other diseases of biliary tract (code range)
K87	Disorders of gallbladder, biliary tract and pancreas in diseases classified elsewhere
M34.83	Systemic sclerosis with polyneuropathy
Q44.2-Q44.3	Congenital malformations of gallbladder, bile ducts and liver (code range)
Q44.6	Cystic disease of liver
S31.609A	Unspecified open wound of abdominal wall, unspecified quadrant with penetration into peritoneal cavity, initial encounter
S36.112A	Contusion of liver, initial encounter

REFERENCES

Crabb DW, et al. Diagnosis and treatment of alcohol-associated liver diseases: 2019 practice guidance from the American Association for the Study of Liver Diseases. Hepatology. 2020 Jan;71(1):306-333.

Croome K and Taner C. The changing landscapes in dcd liver transplantation. Current Transplantation Report. 2020 Jul;7(3):194-204.

Giorgakis E, et al. Acuity circles allocation policy impact on waitlist mortality and donation after circulatory death liver transplantation: A nationwide retrospective analysis. Health Science Reports. 2023 Feb;6(2):e1066.

Kwong K, et al. Machine learning to predict waitlist dropout among liver transplant candidates with hepatocellular carcinoma. Cancer Medicine. 2022 Mar;11(6)1535-1541.

Li ZX, et al. Liver transplantation improves prognosis across all grades of acute-on-chronic liver failure patients: A systematic review and meta-analysis. World J Gastroenterol. 2025 Mar 28;31(12):102007.

Martin P, et al. Evaluation for liver transplantation in adults: 2013 practice guideline by the American Association for the Study of Liver Diseases and the American Society of Transplantation. Hepatology. 2014 Mar;59(3):1144-65.

Mazzaferro V, et al. Liver transplantation for the treatment of small hepatocellular carcinomas in patients with cirrhosis. N Engl J Med. 1996 Mar 14;334(11):693-9.

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology. Hepatocellular Carcinoma. V.2.2025. 2025 Oct 22 [accessed 2025 Oct 24]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf

Organ Procurement and Transplantation Network (OPTN) [Internet]. Policies. 2025 Oct 01 [accessed 2025 Oct 24]. Available from: https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf

Ranganathan S, et al. Hepatoblastoma and pediatric hepatocellular carcinoma: An update. Pediatr Dev Pathol. 2020 Mar-Apr;23(2):79-95.

Singal AG, et al. AASLD Practice Guidance on prevention, diagnosis, and treatment of hepatocellular carcinoma. Hepatology. 2023 Dec 1;78(6):1922-1965.

SEARCH TERMS

Hepatic transplant, Liver Transplant, Living donor liver transplant.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Adult Liver Transplantation (NCD 260.1) [accessed 2025 Oct 23]

Pediatric Liver Transplantation (NCD 260.2) [accessed 2025 Oct 23]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 3/26

Revised:

Reviewed:

Date	Summary of Changes
7/1/2026	• New

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

MEDICAL POLICY

Medical Policy Title	**Lung and Lobar Lung Transplant**
Policy Number	**7.02.10**
Current Effective Date	**July 1, 2026**
Next Review Date	**April, 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Lung transplantation is **medically appropriate** for carefully selected candidates who have irreversible, progressively disabling, end-stage pulmonary disease who meet **ALL** of the following criteria:

   A. Adequate cardiac status;

   B. Absence of infection, or absence of extrapulmonary infection in individuals with cystic fibrosis;

   C. No history of malignancy within five (5) years of transplantation, excluding non-melanomatous skin cancers; **and**

   D. Documentation of compliance with medical management.

II. Indications for a lung transplantation include, but are not limited to the following:

   A. Bilateral bronchiectasis;

   B. Congenital bronchiectasis;

   C. Alpha-1 antitrypsin deficiency;

   D. Primary pulmonary hypertension;

   E. Cystic fibrosis;

   F. Bronchopulmonary dysplasia;

   G. Idiopathic pulmonary fibrosis;

   H. Interstitial pulmonary fibrosis;

   I. Sarcoidosis;

   J. Scleroderma;

   K. Lymphangiomyomatosis;

   L. Emphysema;

   M. Eosinophilic granuloma;

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

N. Bronchiolitis obliterans;

O. Recurrent pulmonary embolism;

P. Chronic obstructive pulmonary disease (COPD);

Q. Tuberculous fibrosis of lung;

R. Pneumoconiosis and other lung diseases due to external agents;

S. Eisenmenger's syndrome.

III. Lung transplant is considered a contraindication in human immunodeficiency virus (HIV) positive individuals, unless **ALL** the following criteria are met.:

A. Cluster of Differentiation 4 (CD4) count greater than 200 cells/mm^3;

B. Undetectable HIV-1 ribonucleic acid (RNA);

C. On stable anti-retroviral therapy for greater than three (3) months; **and**

D. All other criteria for transplantation within this policy are met.

RELATED POLICIES

Corporate Medical Policy

7.02.06 Heart & Heart/Lung Transplant

POLICY GUIDELINE(S)

I. Prior authorization requirements are contract dependent. Approvals for all transplants, including arrangements with an approved transplant center, may be required.

II. Recipient Selection Guidelines

Each recipient considered for transplantation should have an evaluation completed by the transplant center, for potential difficulties that would complicate and diminish the success of transplantation. Consideration will be given to the individual's risk of death without transplantation, along with the presence and severity of potential contraindications to transplantation.

The following general medical conditions can have an impact on the long-term outcome of lung transplant recipients:

A. Current use of corticosteroids is not a contraindication to transplantation. However, all attempts to discontinue these drugs or at least reduce the dose to less than or equal to 20 mg per day of prednisolone or prednisone should be made.

B. Nutritional issues are important predictors of surgical outcome. Individuals with an ideal body weight less than 70% or greater than 130% require either weight gain or weight loss to become eligible for transplant.

C. Substance abuse issues need to be addressed prior to lung transplantation. Candidates must

have been free of substance addiction (e.g., alcohol, tobacco, narcotics) for at least six (6) months. Appropriate preoperative biochemical monitoring is recommended in at-risk individuals.

D. Psychosocial problems that are unable to be resolved and that have a high likelihood of having a negative impact on the individual's outcome (e.g., poorly controlled major psycho-affective disorder, inability to comply with complex medication regimen) are a relative contraindication. A documented history of noncompliance with medical care or treatment plans, even in the absence of a documented psychiatric condition, is a relative contraindication.

E. Colonization with fungi or atypical mycobacteria is not an absolute contraindication to transplantation. Cases should be considered on an individual basis. Special care should be taken when a unilateral transplant is considered. When possible, pre-operative attempts to eradicate colonization with antibiotic therapy are appropriate. Adequately treated mycobacterium (M) tuberculosis is not a contraindication to lung transplantation.

F. Other medical conditions, when they have not resulted in organ damage, are generally acceptable in candidates for lung transplantation (e.g., systemic hypertension, diabetes mellitus, peptic ulcer disease) and should be optimally treated and well-controlled. In the presence of any comorbid medical condition with the potential for end-organ damage, a careful search should be made for evidence of organ dysfunction.

III. Pre-transplant evaluation documentation should include the following clinical information (if testing is unable to be performed, the rationale for not performing the testing must be included in the documentation):

A. Clinical Evaluation:

1. Confirmation of diagnosis;
2. Identification of comorbidities;
3. Current assessment of co-morbidities;
4. Management of co-morbidities;
5. Consult notes (if applicable);

B. Psycho-Social Evaluation:

1. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol, or smoking/substance abuse).

C. Performance Status:

1. Karnofsky performance score;
2. Eastern Cooperative Oncology Group (ECOG) performance status;
3. Palliative Performance Scale (PPS) score; or

4. Lansky Play-Performance scale (for age 1 to 16 years);

D. Oral Health Evaluation;

E. Lab Tests:

1. Complete Blood Count (CBC), metabolic profile;
2. Serologies: Cytomegalovirus (CMV)*;* Hepatitis B and C;
3. Human Immunodeficiency Virus (HIV) Testing;

F. Cardiac Assessment:

1. 12 Lead Electrocardiogram (EKG); and
2. Echocardiogram (Echo) or Multigated Acquisition (MUGA) Scan

G. Pulmonary Assessment:

1. Chest x-ray;
2. Pulmonary function tests (PFTs) for high-risk respiratory failure (COPD, emphysema, alpha 1-antitrypsin deficiency, hepatopulmonary syndrome, or significant smoking history); and

H. Age-appropriate Screening Tests:

1. Please refer to the U.S. Preventive Services Task Force (USPSTF) [Internet] for a list of age-appropriate screening guidelines (e.g., colorectal cancer screening, cervical cancer screening for guidance). [accessed 2026 Mar 06]. Available from: https://www.uspreventiveservicestaskforce.org/uspstf/

IV. Transplant reauthorization is required annually while on the transplant waiting list, using the same criteria as pre-testing requirements (See Policy Guideline II). If the individual health condition remains unchanged from the previous year, some testing may be waived. If testing is not performed, a rationale must be provided, and documentation must be dated within the last 11 months, unless otherwise specified (e.g., age-related testing).

DESCRIPTION

The lungs are paired organs that consist of the right and left, each with different anatomical features and functions. Anatomically the right lung is divided into three lobes consisting of the upper, middle, and lower lobes. In contrast the left lung consists of two lobes, the upper and lower lobes. A lung (sometime called lobar) transplant is a surgical procedure in which a diseased or damaged lung is replaced with a healthy lung from a donor.

There are three main types of lung transplant. A single lung transplant consists of one diseased or damaged lung being removed and replaced with a donated lung. A double lung transplant consists of both lungs being removed and replaced with donated lungs. The third type of lung transplant is a heart to lung transplant which consists of a heart and both lungs being removed and replaced with a donor heart and lungs. Lungs that are suitable for transplantation are typically harvested from either

brain-dead donors or after the declaration of circulatory death. There's also the option of living donor lobar lung transplantation (LDLLT). LDLLT involves two healthy donors. The right and left lower lobes are retrieved from two healthy donors and are implanted into a single recipient. This procedure is primarily used for individuals who would not survive being on the wait list for a cadaver donor lung. Lung transplantation offers carefully selected individuals the only curative treatment for those with advanced lung disease of various nonmalignant etiologies.

Lung transplants can be performed on individuals of almost all ages from newborns to adults up to the age 65 and in certain cases over the aged 65. The indications for a lung transplant differ for adults and children. Cystic fibrosis and pulmonary arterial hypertension (PAH) have historically contributed to many young adult's lung transplants. In adults the primary indication for a lung transplant is chronic obstructive pulmonary disease (COPD) accounting for 40% of all lung transplantations perform worldwide (Kumar et al 2024). Interstitial lung disease, pulmonary vascular disease, bronchiectasis, and sarcoidosis were the other most common indications for adult lung transplants.

Lung transplantation is a major operation with significant surgical risk and a median post-transplant survival of 5.7 years (Ruck et al 2025). Advances in donor and recipient selection, improved surgical techniques, new immunosuppressive drugs, and better management of infections have improved long-term survival.

A shortage of lung donors remains a major limiting factor in the number of transplants performed. These disparities are likely due to the vulnerability of potential complications that occurred before and after brain death which can include thoracic trauma, aspiration, ventilator associated injuries, pneumonia, and neurogenic pulmonary edema. The lung allocation score (LAS) help prioritize individuals and improve outcomes. The LAS comprised of 12 physiological and demographic factors that influence mortality in individuals with advanced lung disease. LAS is determined by subtracting the predictive one-year survival without transplant from the predicted one-year survival with transplant then normalizing the score to a range of 0 to 100. Organs are allocated to individuals with the highest score before those with lower scores.

SUPPORTIVE LITERATURE

The International Society for Heart and Lung Transplantation (ISHLT) and the Organ Procurement Transplantation Network (OPTN) data registry suggest that inferior outcomes occur in adolescent lung transplant recipients. The reasons for these inferior outcomes remain undefined and they happen despite the adolescent recipients' young age and recipients lack of comorbidities. Paraskeva et al (2018) analyzed survival rates of adolescent lung transplant recipients using data from the ISHLT registry that consisted of recipients between the ages of 0 and 65 years who underwent 24,730 lung transplant procedures. Individuals between 10 and 24 years old at the time of transplant represented 9% of the registry cohort (n=2319), and they were compared with both old and young cohorts. Most adolescents (88%) were transplanted in middle to late adolescence, aged 15–24 years. The overall survival in the adolescent cohort was 65% at three years, which were like those observed in adults between 50 and 65 years of age, and significantly lower in comparison to the pediatric subgroup (73%; p=.006), and adults 25 to 34 years old (75%; p<.001) and 35 to 49 years old

(71%; p<.001). The adolescent group individuals between 15 and 19 years of age had the worst survival rates at 3 years (59%) compared with 10- to 14-year-old individual (73%; p<.001) and 20- to 24-year-old year individual (66%; p<.001). Cystic fibrosis (CF) was the main indication for transplantation in adolescent recipients (75% vs 13%; p o 0.001), whereas most adults was transplanted for emphysema and interstitial lung disease (ILD). Compared with the adult groups, more females were transplanted in adolescence. The registry study was biased towards including North American data and may contain potential data entry errors, or missing information. Additionally, there were no data reported on the differences in causes of mortality or the rates of graft dysfunction between the groups.

Mansour et al (2023) conducted a systematic review and meta-analysis comparing single lung transplant (SLT) versus bilateral lung transplant (BLT) for managing end stage chronic obstructive pulmonary disease. The study analyzed data from seven studies including 10,652 individuals and found that BLT is associated with more favorable survival rates than SLT. Subgroup analysis on survival rates of alpha-1 antitrypsin deficiency also displayed a trend favoring BLT compared with SLT at 1 year. However, the group had significant heterogeneity in baseline characteristics. The study also found that BLT recipients tend to have longer hospital stays and greater number of acute rejection events while SLT recipients tend to experience more postoperative complications. The authors concluded that BLT may be more effective approach for managing COPD, but further prospective studies are needed to confirm these findings.

Lung volume reduction (LVR) and lung transplantation (LTx) are management options for end stage COPD. Ahmad et al (2023) compared the outcomes of LVR and LTx in COPD individuals by pooling existing evidence. A meta-analysis of prospective studies on LVR and LTx published since 2000 was conducted. Baseline characteristics, perioperative variables, and clinical outcomes analysis was extracted. The analysis included 65 prospective studies comprising of 3,671 individuals. Mean age was 60 (95% confidence interval (CI): 58-62) years and comparable between the two groups. Females were 51% (95% CI: 30-71%) in the LTx group versus 28% (95% CI: 21-36%) in LVR group. Baseline 6-minute walk test (6MWT) and pulmonary function tests (PFT) were comparable except for the forced expiratory volume in 1 second (FEV1), which was lower in the LTx group (21.8% (95% CI: 16.8-26.7%) versus 27.3% (95% CI: 25.5-29.2%). Postoperatively, both groups experienced improved FEV1. However, LTx resulted in significantly higher FEV1 postoperatively (54.9% (95% CI: 41.4-68.4%) versus 32.5% (95% CI: 30.1-34.8%), but otherwise had comparable outcomes to LVR. Overall, there was no significant difference between the groups. Pooled survival overtime showed no significant difference. LTx led to greater improvement in FEV1 but had comparable outcomes to LVR.

Veno-arterial extracorporeal membrane oxygenation (V-A ECMO) has become increasingly popular for interoperative support during lung transplants even in uncomplicated cases. Pettenzuzzo et al (2024) conducted a systematic review and meta-analysis of the efficacy and safety of (V-A ECMO) and cardiopulmonary bypass (CBP) compared to an Off Pump strategy during lung transplant. The main outcomes assessed were intraoperative red blood cell (RBC) transfusion (units), fresh frozen plasma (FFP) transfusion (units), platelet (PLT) transfusion (units), postoperative invasive mechanical ventilation (IMV duration (days), intensive care unit (ICU) length of stay (LOS days), ECMO support,

and mortality (within the first 90 days after ICU admission). There were 27 observational studies with 6,113 individuals included. V-A ECMO and CBP were associated with higher blood product consumption, longer invasive mechanical ventilation (IMV) duration, prolonged ICU length of stays, longer surgical duration, and higher mortalities compared to off pump surgeries. VA ECMO overperformed CPB in nearly all other outcomes except for RBC transfusion. Older age, male gender, and body mass index >25kg/m2 negatively impacted several outcomes (RBC transfusion, ICU LOS, surgical duration, need of postoperative ECMO and mortality), regardless of the intraoperative extracorporeal support investigated. Researchers suggested that future studies are necessary to optimize and standardize the intraoperative management of lung transplants.

PROFESSIONAL GUIDELINE(S)

Idiopathic Pulmonary Fibrosis

The American Thoracic Society (ATS), European Respiratory Society, Japanese Respiratory Society, and the Latin American Thoracic Association published guidelines in 2011 for the diagnosis and management of individuals with idiopathic fibrosis. Lung transplantation was recommended for appropriately selected individuals with idiopathic pulmonary fibrosis (IPF [strong recommendation, low-quality evidence]). An update to this document was published in 2015 in which the committee did not make a recommendation regarding single versus bilateral lung transplantation for individuals with idiopathic fibrosis. The committee noted that it was unclear which option, single or bilateral lung transplantation, was preferable for long term outcomes. In 2022, the committee updated guidance on diagnosis and management of IPF and progressive pulmonary fibrosis recommending that individuals at increased risk of mortality should be referred for a lung transplantation upon diagnosis.

Chronic End Stage Lung Disease

The International Society for Heart and Lung Transplant (ISHLT) 2021 guidelines on the selection of lung transplant candidate states that "lung transplantation should be considered for adults with chronic, end-stage lung disease who meet all the following general criteria:

- High (>50%) risk of death from lung disease within 2 years if lung transplantation is not performed.
- High (>80%) likelihood of 5-year post-transplant survival from a general medical perspective if there is adequate graft function."

Cystic Fibrosis

- The Cystic Fibrosis Foundation consensus guidelines (2020) for the care of individuals with advanced cystic fibrosis lung disease recommend lung transplantation if congruent with the individual's goals.

Contraindications

ISHLT 2021 guidelines consider the following as absolute contraindications for a lung transplant:

- Malignancy with high risk of recurrence or death related to cancer.

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- Glomerular filtration rate < 40 mL/min/1.73m^2 unless being considered for multi-organ transplant.
- Acute coronary syndrome or myocardial infarction within 30 days (excluding demand ischemia).
- Stroke within 30 days.
- Liver cirrhosis with portal hypertension or synthetic dysfunction unless being considered for multi-organ transplant.
- Acute liver failure.
- Acute renal failure with rising creatinine or on dialysis and low likelihood of recovery.
- Septic shock.
- Active extrapulmonary or disseminated infection.
- HIV infection with detectable viral load.
- Limited functional status (e.g., non-ambulatory) with poor potential for post-transplant rehabilitation.
- Progressive cognitive impairment.
- Repeated episodes of non-adherence without evidence of improvement (Note: For pediatric individuals this is not an absolute contraindication and ongoing assessment of non-adherence should occur as they progress through different developmental stages.)
- Active substance uses or dependencies including current tobacco use, vaping, marijuana smoking, or intravenous (IV) drug use.

REGULATORY STATUS

Organ transplants, as surgical procedures, do not require U.S. Food and Drug Administration (FDA) approval. The Health Resources Services Administration (HRSA) oversees the transplantation of vascularized human organs through the Organ Procurement and Transplantation Network (OPTN). For more information view the OPTN website: https://www.hrsa.gov/optn [accessed 2026 March 06].

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
32851	Lung transplant, single; without cardiopulmonary bypass
32852	Lung transplant, single; with cardiopulmonary bypass
32853	Lung transplant, double (bilateral, sequential, or en bloc); without cardiopulmonary bypass
32854	Lung transplant, double (bilateral, sequential, or en bloc); with cardiopulmonary bypass
32855	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; unilateral
32856	Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; bilateral

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
D38.1	Neoplasm of uncertain behavior of trachea, bronchus and lung
D81.810	Biotinidase deficiency
D84.1	Defects in the complement system
D86.0-D86.9	Sarcoidosis (code range)
E71.41	Primary carnitine deficiency
E84.0-E84.9	Cystic fibrosis (code range)
I26.90	Septic pulmonary embolism without acute cor pulmonale
I26.99	Other pulmonary embolism without acute cor pulmonale
I27.00-I27.9	Other pulmonary heart diseases (code range)

Code	Description
J41.8	Mixed simple and mucopurulent chronic bronchitis
J43.0-J43.9	Emphysema (code range)
J44.9	Chronic obstructive pulmonary disease, unspecified
J47.9	Bronchiectasis, uncomplicated
J84.10-J84.114	Other interstitial pulmonary diseases with fibrosis (code range)
J84.2	Lymphoid interstitial pneumonia
J84.89	Other specified interstitial pulmonary diseases
J99	Respiratory disorders in diseases classified elsewhere
M32.13	Lung involvement in systemic lupus erythematosus
M33.01-M33.91	Dermatopolymyositis (code range)
M34.0-M34.9	Systemic sclerosis [scleroderma] (code range)
M35.02	Sicca syndrome with lung involvement
P27.0-P27.9	Chronic respiratory disease originating in the perinatal period (code range)
Q21.0	Ventricular septal defect
Q33.4	Congenital bronchiectasis
T80.0xxA	Air embolism following infusion, transfusion and therapeutic injection, initial encounter
T81.718A	Complication of other artery following a procedure, not elsewhere classified, initial encounter
T81.72xA	Complication of vein following a procedure, not elsewhere classified, initial encounter
T82.817A	Embolism of cardiac prosthetic devices, implants and grafts, initial encounter
T82.818A	Embolism of vascular prosthetic devices, implants and grafts, initial encounter

REFERENCES

Adler FR, et al. Lung transplantation for cystic fibrosis. Proc Am Thorac Soc. 2009 Dec;6(8):619-33.

Ahmad D, et al. Comparative outcomes of lung volume reduction surgery and lung transplantation: a systematic review and meta-analysis. J Thorac Dis. 2023 Jul 31;15(7):3627-3635.

Avdimiretz N and Benden C. The changing landscape of pediatric lung transplantation. Clin Transplant. 2022 Apr;36(4):e14634.

Benoit TM, Benden C. Pediatric lung transplantation: supply and demand. Curr Opin Organ Transplant. 2019 Jun;24(3):324-328.

Garza-Castillon R, Bharat A. Lung transplantation for coronavirus disease 2019 associated severe acute respiratory distress syndrome. Curr Opin Anaesthesiol. 2023 Feb 1;36(1):11-19.

Kapnadak SG, et al. Cystic Fibrosis Foundation consensus guidelines for the care of individuals with advanced cystic fibrosis lung disease. J Cyst Fibros. 2020 May;19(3):344-354.

Kumar A, Sharma S, Anjum F. Lung transplantation. 2024 Jun 8. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan. PMID: 33351408.

Kurihara C, et al. Clinical characteristics and outcomes of patients with covid-19-associated acute respiratory distress syndrome who underwent lung transplant. JAMA. 2022 Feb 15;327(7):652-661.

Lancaster TS, et al. Improved waitlist and transplant outcomes for pediatric lung transplantation after implementation of the lung allocation score. J Heart Lung Transplant. 2017 May;36(5):520-528.

Leard LE, et al. Consensus document for the selection of lung transplant candidates: An update from the International Society for Heart and Lung Transplantation. J Heart Lung Transplant. 2021 Nov;40(11):1349-1379.

Nakajima D, Date H. Living-donor lobar lung transplantation. J Thorac Dis. 2021 Nov;13(11):6594-6601.

Organ Procurement and Transplant Network (OPTN). [Internet]. Data. [accessed 2026 Mar 06]. Available from: https://www.hrsa.gov/optn/data-calculators

Paraskeva MA, et al. Outcomes of adolescent recipients after lung transplantation: An analysis of the International Society for Heart and Lung Transplantation Registry. J Heart Lung Transplant. Mar 2018;37(3):323-331.

Pettenuzzo T, et al. Intraoperative extracorporeal support for lung transplant: a systematic review and network meta-analysis. J Anesth Analg Crit Care. 2024 Dec 18;4(1):81.

Raghu G, et al. An Official ATS/ERS/JRS/ALAT clinical practice guideline: treatment of idiopathic pulmonary fibrosis. an update of the 2011 clinical practice guideline. Am J Respir Crit Care Med. 2015 Jul 15;192(2):e3-19.

Raghu G, et al. ATS/ERS/JRS/ALAT Committee on Idiopathic Pulmonary Fibrosis. An official ATS/ERS/JRS/ALAT statement: idiopathic pulmonary fibrosis: evidence-based guidelines for diagnosis and management. Am J Respir Crit Care Med. 2011 Mar 15;183(6):788-824.

Raghu G, et al. Idiopathic pulmonary fibrosis (an update) and progressive pulmonary fibrosis in

adults: an official ATS/ERS/JRS/ALAT clinical practice guideline. Am J Respir Crit Care Med. 2022 May 1;205(9):e18-e47.

Roach A, et al. Lung transplantation for COVID-19-related respiratory failure in the United States. N Engl J Med. 2022 Mar 24;386(12):1187-1188.

Steinman TI, et al. Clinical Practice Committee, American Society of Transplantation. Guidelines for the referral and management of patients eligible for solid organ transplantation. Transplantation. 2001 May 15;71(9):1189-204.

U.S. Preventive Services Task Force. [Internet] Recommendation topics. [accessed 2026 Mar 06]. Available from: https://www.uspreventiveservicestaskforce.org/uspstf/recommendation-topics

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Lung Transplant is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 2/26

Revised:

Reviewed: 7/26

Date	Summary of Changes
7/1/2026 * No change to effective date	• Annual review. No content change for criteria.

of policy	
7/1/2026	• New

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Policy/Procedure Name: Luxturna (voretigene neparvovec-rzyl) **Control Number: 1350/20.000587**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Inherited retinal diseases (IRDs) are a heterogeneous group of conditions that include retinitis pigmentosa (RP) and Leber congenital amaurosis (LCA) and early-onset severe retinal dystrophy (EO[S]RD), which differ in severity and age of onset. IRDs are caused by mutations in >250 genes. Variants in the *RPE65* gene account for 0.6–6% of RP and 3–16% of LCA/EORD cases.

Luxturna (voretigene neparvovec-rzyl) was FDA approved in 2017 for the treatment of retinal dystrophy associated with biallelic RPE65 mutations. It is estimated that 1000–2000 people in the United States are affected by retinal dystrophy associated with a biallelic RPE65 mutation. Luxturna is a gene therapy administered one-time via subretinal injection in patients age 12 months and older. Using an adeno-virus vector, Luxturna delivers a functional copy of the *RPE65* gene to the cell nucleus. This allows functional RPE65 protein to be produced, completing the visual cycle and potentially improving vision.

Approval was based on results from the phase 3, open-label, randomized controlled trial in patients LCA. At 1 year, mean bilateral MLMT change score was 1·8 (SD 1·1) light levels in the intervention group versus 0·2 (1·0) in the control group (difference of 1·6, 95% CI 0·72–2·41, p=0·0013). 13 (65%) of 20 intervention participants, but no control participants, passed MLMT at the lowest luminance level tested (1 lux), demonstrating maximum possible improvement. No product-related serious adverse events or deleterious immune responses occurred.

Summary

Effective Date of Policy:	2/12/2026
Indications	Treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physician
ICD10 Diagnosis Codes	Select subcodes of H35.5
HCPCS Code	J3398
Availability	$5x10^{12}$ vector genomes (vg)/mL suspension for subretinal injection, supplied in a 0.5 mL extractable volume in a single-dose 2 mL vial for a single administration in one eye
Duration	6 months

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy

Indication	Inclusion Criteria	Dosing Regimen

Indication
Treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy. Patients must have viable retinal cells as determined by the treating physician
 	
ICD10: Select subcodes of H35.5
	• Must be prescribed by an ophthalmic surgeon for administration at a certified treatment center AND
	• Must be ≥ 12 months of age based upon ongoing cell proliferation in those under 1 year of age AND
	• Must have a diagnosis of Biallelic RPE65 mutation-associated retinal dystrophy
	  ○ Diagnosis must be confirmed by genetic testing AND
	• Patient must have viable retinal cells
	  ○ Viable retinal cells must have been determined by retinal thickness on spectral domain optical coherence tomography (OCT >100 microns within the posterior pole) AND
	• Baseline full-field light sensitivity threshold (FST) test results for each eye must be submitted
		• A maximum of 1 dose of 1.5×10^{11} vg administered by subretinal injection in a total volume of 0.3 mL will be allowed per eye per lifetime

Continuation Criteria

- Not applicable – One lifetime administration per eye allowed. Authorization will be for 6 months to allow sufficient time for administration.

Considerations

- Patient must have medical drug coverage administered by CDPHP.
- Prior authorization is obtained through the CDPHP pharmacy department.

References

		Updated	Accessed
1	Luxturna [prescribing information]. Spark Therapeutics, Inc. Philadelphia, PA	5/2022	1/2026
2	Russell S, Bennett J, Wellman JA, et al. Efficacy and safety of voretigene neparvovec (AAV2-hRPE65v2) in patients with RPE65-mediated inherited retinal dystrophy: a randomised, controlled, open-label, phase 3 trial. *Lancet*. 2017;390(10097):849-860. doi:10.1016/S0140-6736(17)31868-8	7/2017	1/2026

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 2/12/2026

New: 2/2026

Revised	Reviewed

Revision Date	Changes Made

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Policy/Procedure Name: Lyfgenia (lovotibeglogene autotemcel) **Control Number: 1350/20.000497**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

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Background

Sickle cell disease (SCD) refers to a group of inherited blood disorders that are caused by a mutation in the β-globin gene, causing abnormal hemoglobin properties. The mutant hemoglobin is susceptible to continuous polymerization with other hemoglobin molecules in hypoxic environments. As the mutated hemoglobin (HbS) polymerizes, the red blood cell becomes deformed; rigid and inflexible in a "sickle" shape which leads to Vaso-occlusion and hemolysis severely affecting blood flow in these patients. Incidence of sickle cell disease is estimated at 300,000 to 400,00 live births throughout the world. It is estimated that 100,000 people are living with SCD in the United States.

Hallmark manifestations of SCD include recurrent vaso-occlusive events or crises (VOEs or VOCs) which can lead to acute pain crises. Vaso-occlusive crises can lead to episodes of severe pain as a result of decreased blood flow in microcapillaries and can include blood vessel blockage that can lead to tissue ischemia of the bone and bone marrow. These can lead to an increase in hospitalizations, and underlying medical complications such as severe infections, acute chest syndromes, acute splenic sequestration crisis, priapism, and stroke. There are several subtypes of SCD that exist that are determined by specific mutations in each hemoglobin gene. Severe SCD genotypes are listed as: βS/βS, βS/β0, and βS/β+. However, the available treatments that have been created thus far are independent of these subtypes.

America Society of Hematology guidelines recommend treating SCD based on need of complication. Guidelines exist for sickle cell disease with cardiopulmonary and kidney disease, transfusion support, cerebrovascular disease, management of acute and chronic pain, and stem cell transplantation.

Historically, Hydroxyurea has been the mainstay of treatment in SCD. This medication increases red blood cell fetal hemoglobin to reduce the amount of "sickled" cells being produced. Other available and FDA approved treatments for SCD include Endari (L-glutamine), Adakveo (crizanlizumab), and Oxybryta (voxelotor). Other interventions include hematopoietic stem cell transplantation (HSCT) which has shown to be curative in some individuals but depends on patient specific factors and compatible donor availability. Blood transfusions, and packed red blood cells may help as adjunctive therapy in unblocking blood vessels by delivering oxygen to the body. Stem cell gene therapy interventions are emerging for SCD and may offer a curative treatment for SCD complications.

Lyfgenia is approved by the FDA for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events. It utilizes a modified virus (lentivirus vector) to insert a functioning version of the HBB gene into the patient's own stem cells. The lentiviral vector in gene therapy is a method by which genes can be inserted, modified, or deleted in organisms. In comparison, exagamglogene autotemcel, (Casgevy) is known as CRISPR based technology through which gene editing increases the amount of fetal hemoglobin in red blood cells by deleting a portion of the BC11A gene.

In the pivotal Lyfgenia trial, 90% of participants achieved complete resolution of all VOEs between six and 18 months after Lyfgenia infusion and 30 of 31 patients were free of severe VOEs. The clinical trial for Lyfgenia has defined severe VOEs/VOCs as a medical event with no medically determined cause other than a vaso-occlusion requiring one of the following:

- Hospital or ED visit that exceeded 24 hours
- At least two visits to day unit or ED during a 72-hour period (with both visits requiring IV treatment)
- Priapism episode lasting more than two hours and leading to a medical facility

The Institute for Clinical and Economic Review (ICER) reviewed Lyfgenia as part of a review titled, "Gene Therapies for Sickle Cell Disease". In both trials for Lyfgenia and Casgevy, there were serious adverse events observed. These serious adverse effects were attributed to the myeloablative conditioning however were not infrequent and both therapies require chemotherapy before receiving them. ICER noted that uncertainly still remains about the long-term degree of risk of gene therapies in the real word, pointing out that at one point the FDA placed a clinical hold on Lyfgenia due to safety concerns around the hematologic malignancy risk (two cases of AML resulting in death). With Lyfgenia, in identifying the net health benefit, one needs to weigh the marked improvement in the small patient population with severe SCD alongside the potential harms of myeloablative conditioning and uncertainty in durability of benefit. **ICER noted that in those with severe SCD, Lyfgenia provides at least an incremental net benefit compared with standard of care and may provide a substantial net health benefit (B+).**

In comparing Casgevy and Lyfgenia, ICER noted the evidence as "insufficient" given the different mechanisms of action.

Summary	
Effective Date of Policy	1/1/2026
Indications	Sickle Cell Disease
ICD10 Diagnosis Codes	D57
HCPCS Code	J3394
Availability	*See FDA Prescribing Information*
Duration	Authorization will be for 6 months to allow sufficient time for administration

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy:

Specific Indication	Inclusion Criteria	Recommended Dosing Regimen

Treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events
(FDA approval)
	• Enrollee is at least 12 years of age
	• Therapy is requested by a hematologist with expertise in the management of Sickle Cell Disease
	• Enrollee has diagnosis of severe Sickle Cell Disease as defined by all of the following:
	  o Genetic confirmation of βS/βS genotype or βS/β0 or βS/β+ genotype. Additional genotypes will be considered on a case-by-case basis based on disease severity
	  o History of at least 2 severe vaso-occlusive events or crises (VOCs/VOEs) per year over the last 2 years. Severe VOC/VOE is defined as at least ONE of the following:
	  ▪ Acute pain episode that requires a visit to a medical facility and administration of pain medications (opioids or IV NSAIDs) or RBC transfusions
	  ▪ Acute chest syndrome (ACS), as indicated by presence of new pulmonary infiltrate associated with pneumonia-like symptoms, pain, or fever
	  ▪ Hepatic sequestration
	  ▪ Priapism lasting more than 2 hours and leading to a medical facility visit
	• Must have experienced ONE of the following pertaining to hydroxyurea:
	  o A therapeutic failure (ex. continued frequent and/or severe VOCs or ongoing, frequent transfusion requirements) to a ≥ 6 consecutive month trial of hydroxyurea at maximum tolerated dosing.
	  ▪ Adherence will be assess based on: Pharmacy refill history. If the patient does not have pharmacy benefits through this health plan, a recent pharmacy profile will be requested. Progress notes documenting usage of sample medication may also be requested
	  o A contraindication to hydroxyurea defined as a hypersensitivity to hydroxyurea or any component of the formulation
	  o Must have experienced two hematologic toxicity reactions with hydroxyurea that resulted in discontinuation of therapy
	  ▪ Hematologic toxicity with hydroxyurea is defined by neutrophil, platelet, hemoglobin and/or reticulocyte count abnormalities concurrent with hydroxyurea use suggestive of hematologic toxicity. After the first hematologic toxicity, hydroxyurea therapy should be stopped and can be restarted with a dose reduction upon hematologic recovery. If a second hematologic
		• The minimum recommended dose of Lyfgenia is 3 × 10^6 CD34+ cells/kg
		• Please refer to Lyfgenia FDA-approved prescribing information for complete dosage and administration instructions
		• Lyfgenia is for autologous use only

	toxicity is experienced, treatment should be discontinued • Enrollee has a Karnofsky performance status of ≥ 60 (≥ 16 years of age) or a Lansky performance status of ≥ 60 (< 16 years of age) • Must be used as a single agent therapy (not applicable to myeloablative conditioning therapy) • The patient must be eligible to undergo hematopoietic stem cell transplant (HSCT) • Patient has been screened and found negative for active infections of the following: hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus 1 &2 (HIV-1/HIV-2) in accordance with clinical guidelines prior to collection of cells (documentation of laboratory results taken within the past 3 months is required) • Patient will not receive concomitant therapy with any of the following: o Hydroxyurea for at least 2 months prior to mobilization and until all cycles of apheresis are completed o Disease-modifying agents (e.g., L-glutamine, voxelotor, crizanlizumab) for at least 2 months prior to mobilization • Prescriber must attest that the patient will not be re-started on hydroxyurea or other disease modifying therapies for SCD after receipt of Lyfgenia • For Commercial and Medicare: All requests for sickle cell gene therapy will require treatment with Casgevy (exagamglogene autotemcel)	

Exclusion Criteria

Therapy will not be approved if any of the below criteria are met:

- Enrollee has an accessible and willing 10/10 human leukocyte antigen (HLA)-matched related donor
- Enrollee has had prior treatment with an allogeneic stem cell transplant or prior treatment with gene therapy/editing product
- Enrollee has clinically significant and active bacterial, viral, fungal, or parasitic infection
- History of severe cerebral vasculopathy: defined by overt or hemorrhagic stroke; abnormal transcranial Doppler [≥ 200 cm/sec] needing chronic transfusion; or occlusion or stenosis in the polygon of Willis; or presence of Moyamoya disease
- History of advanced liver disease, defined as any of the following:
  - Persistent aspartate transaminase, alanine transaminase, or direct bilirubin value > 3× the upper limit of normal (ULN)
  - Baseline prothrombin time or partial thromboplastin time > 1.5× ULN.
  - History of cirrhosis or any evidence of bridging fibrosis, or active hepatitis
- Baseline creatinine clearance ≤ 70 mL/min/1.73 m^2 (documentation of laboratory results taken within the past 3 months is required)
- Any contraindications to the use of plerixafor during the mobilization of hematopoietic stem cells and any contraindications to the use of busulfan and any other medicinal products required during the myeloablative conditioning, including hypersensitivity to the active substances or to any of the excipients
- History of prior or current malignancy or immunodeficiency disorder, except previously treated, non-life threatening, cured tumors such as squamous cell carcinoma of the skin
- An immediate family member with a known or suspected Familial Cancer Syndrome
- Two or more α-globin gene deletions (documentation of results are required)

Continuation Criteria

- Not applicable
- Lyfgenia is indicated for one-time single-dose intravenous use only and therefore will not be authorized for retreatment.

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.

- Physician acknowledges that CDPHP will request documentation, not more frequently than biannually, of follow-up patient assessments including but not limited to the occurrence of VOE's/VOC's, laboratory findings, and other hematologic clinical events while under the care of physician.

References

		Accessed
1	Hassell KL. Population Estimates of Sickle Cell Disease in the U.S. American Journal of Preventive Medicine. 2010;38(4):S512-S521.	10/2023
2	Kato GJ, Piel FB, Reid CD, et al. Sickle cell disease. Nat Rev Dis Primers. 2018;4:18010	10/2023
3	A Study Evaluating Gene Therapy With BB305 Lentiviral Vector in Sickle Cell Disease. ClinicalTrials.gov identifier: NCT NCT04293185. Updated September 8, 2023. Accessed October 1, 2023. https://clinicaltrials.gov/ct2/show/NCT04293185	10/2023
4	Institute for Clinical and Economic Review (ICER). ICER Sickle Cell Disease Final Policy Recommendations. August 2023. Available at: https://icer.org/wp-content/uploads/2023/08/ICER_Sickle-Cell-Disease_Final-Policy-Recommendations.pdf	11/2023
5	Institute for Clinical and Economic Review (ICER). ICER Sickle Cell Disease Final Report. Published August 21, 2023. Available at: https://icer.org/wp-content/uploads/2023/08/ICER_SCD_Final_Report_FOR_PUBLICATION_082123.pdf	11/2023
6	Lyfgenia [package insert]. Somerville, MA: bluebird bio, Inc. 2023	9/2025
7	Policies and Billing Guidance for Practitioner Administered Drugs. New York Medicaid. Available at: https://www.health.ny.gov/health_care/medicaid/program/practitioner_administered/ffs_practitioner_administer.htm	11/2025

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE CHOICES:	Subject to all terms and conditions noted in above application.
SELECT/HARP PLAN:	Effective January 1st, 2026, Casgevy and Lyfgenia will be reimbursed by the NYS Medicaid fee-for-service (FFS) program for Managed Medicaid/HARP members. The prior authorization process for these medications will remain unchanged. The Plan will continue to review these medications for medical necessity.

CDPHP Pharmacy Services 1/1/2026

New: 12/2023

Policy History

Date	Note
12/2024	Changed policy name to Lyfgenia (lovotibeglogene autotemcel) following FDA approval
12/2025	Removed age limit to be at least 12 years of age or older Added criteria all requests for sickle cell gene therapy will require treatment with Casgevy (exagamglogene autotemcel) Removed criteria about being treated and followed for at least the past 24 months prior to requesting therapy in a medical center(s) that maintained detailed records on sickle cell disease history Updated inclusion criteria language for hydroxyurea use Updated exclusion criteria Updated approval duration to 6 months to allow adequate time for administration Updated language that use of Casgevy prior to Lyfgenia is applicable to Commercial and Medicare only Updated language regarding Medicaid applicability

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: LYME & OTHER TICK-BORNE DISEASES

POLICY EFFECTIVE DATE:	12/1/2023
Policy Control #:	1370/20.000474
Next Annual Review:	May, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

Intravenous infusion (CPT): 96365, 96366, 96367, 96368
Home infusion therapy (HCPCS): S9500, S9501, S9502, S9503, S9504

DESCRIPTIONS

Lyme disease (LD) is a tick-borne disease that is endemic to several regions of North America. It is caused by the bacteria, Borrelia burgdorferi (Bb), which lives in the gut of Ixodes ticks. Ticks become infected with Bb while feeding on an infected host, typically rodents. The bacteria are transmitted to humans via the saliva of a feeding tick. LD may be a progressive disease and can occur in three stages: early localized, disseminated, and late. Early localized LD, or stage I, occurs in the weeks following the bite of an infected tick. The first sign of LD is a characteristic bull's eye rash, called erythema migrans, which forms at the site of the tick bite in most cases. The second stage of LD, called disseminated LD or stage II LD, occurs in the weeks to six months after infection. The bacteria spread from the primary site via cutaneous, lymphatic, and hematogenous routes, causing general signs and symptoms of infection and organ involvement. Untreated LD that has progressed for more than six months is called late LD, late disseminated LD, or stage III LD. Late LD can have a variety of manifestations including encephalitis, encephalomyelitis, cerebral arteritis, polyneuropathy, arthritis, or musculoskeletal pain despite adequate antibiotic treatment of the initial disease. There is considerable controversy over the existence of an additional stage of LD. Various names for this stage are used in the literature, including chronic LD, post-LD syndrome (PLDS), and post-treatment LD syndrome (PLDS). This

stage refers to those few patients who experience fatigue, cognitive dysfunction, and musculoskeletal pain despite adequate antibiotic treatment of the initial disease.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policy

Home Care Services: Home Health Care/Tele-homecare/Personal Care/Personal Emergency Response System, 1370/20.000048.
Clinical Review Preauthorization List
Hyperbaric Oxygen Therapy, 2.01.07

Pharmacy Policy

Intravenous Immune Globulin (IVIG), 1350/20.000143.

POSITION STATEMENT

In accordance with the Infectious Diseases Society of America, CDPHP considers oral/intravenous antibiotic therapy medically necessary in the treatment of Lyme disease, as indicated below.

Oral Antibiotic Therapy (10-28 days)

1. For the treatment of early localized or early disseminated Lyme disease associated with erythema migrans (10-14 days depending which antibiotic is prescribed).

2. For the treatment of Lyme arthritis for patients without clinically evident neurological disease (28 days).

Benefits for oral antibiotic therapy, for the indications stated above, will only be administered if the enrollee has a prescription drug benefit. Benefits are subject to the enrollee's prescription drug formulary.

Intravenous (IV) Antibiotic Therapy (up to 28 days)

Outpatient intravenous antibiotic therapy is considered medically necessary for enrollees with the diagnosis of Lyme disease only when it is based on the clinical presentation of signs and symptoms compatible with the disease and supported by a positive serologic and/or cerebrospinal fluid (CSF) titer by indirect immunofluorescence assay (IFA), or by enzyme immunoassay (ISA), which itself is validated by a positive Western blot test.

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POLICY NAME: LYME & OTHER TICK-BORNE DISEASES

Once a diagnosis of Lyme disease is established, intravenous antibiotic therapy is considered medically necessary for any of the following indications:

1. For the treatment of early Lyme disease with evidence of either of the following:
   - Neurological involvement manifested by meningitis or radiculopathy
   - Lyme carditis requiring hospitalization with continuous EKG monitoring (i.e., patients with significant PR prolongation > 300 milliseconds, other arrhythmias, or clinical manifestations of myopericarditis)

2. For the treatment of Lyme arthritis and/or Lyme-related neurological conditions that have proved refractory to a full course of recommended oral antibiotic therapy.

3. For the treatment of late Lyme disease with evidence of either of the following:
   - Recurrent arthritis after administration of a complete course of oral antibiotics
   - Central nervous system (CNS) or peripheral nervous system involvement

Benefits for outpatient intravenous antibiotic therapy, for the indications stated above, will be administered under the medical benefit and in accordance with the CDPHP resource coordination policy, Home Care Services, 1370/20.000048.

Post-Lyme Disease Syndrome

CDPHP considers additional antibiotic therapy in post-treatment, persistently fatigued patients (post-Lyme disease syndrome) experimental and investigational because intravenous antibiotic therapy has not been shown to be effective for this indication.

Guidelines from the American Academy of Neurology (2007), the Infectious Diseases Society of America (2006), and the European Federation of Neurological Societies (2009) do not recommend antibiotic therapy for patients with chronic, persistent subjective symptoms who have already received standard treatment for Lyme disease.

POLICY CONSIDERATIONS

Because of a lack of biologic plausibility, lack of efficacy, absence of supporting data, or the potential for harm to the patient, long-term (> 28 days) antibiotic therapy is not recommended for treatment of patients with any manifestation of Lyme disease.

EXCLUSIONS

CDPHP does not cover the use of any of the following treatments for Lyme disease as they are considered experimental, investigational, or unproven for this indication (this list may not be all-inclusive):

- A course of intravenous antibiotics lasting longer than 28 days.
- Intravenous antibiotics for early Lyme disease in the absence of neurological involvement manifested by meningitis or radiculopathy, or third-degree atrioventricular block
- Repeated or prolonged courses of parenteral or oral antibiotics
- Hyperbaric oxygen therapy
- Intravenous ascorbic acid or magnesium
- Intravenous hydrogen peroxide
- Ozone therapy
- Ultraviolet blood irradiation
- Use of intravenous immune globulin (IVIG) for the treatment of chronic Lyme disease
- Use of prophylactic antibiotic therapy for individuals with no objective clinical or laboratory evidence indicative of Lyme disease.
- Lyme Borrelia Nanotrap® (0316U)

Coverage of treatment of other tick-borne "co-infections" with antibiotics beyond IDSA-recommended treatment guidelines, since there are no recognized prolonged clinical phases of these infections that would warrant prolonged antibiotic therapy.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy. Benefits for Medicare Part D prescription drugs are only available to enrollees who have elected the CDPHP Medicare Advantage product with the Part D option. The CDPHP Medicare Advantage product does not cover any prescription drugs not covered by Medicare. In addition, for those individuals enrolled in the CDPHP Medicare Advantage product who have not elected the Part D option, CDPHP only covers those prescription drugs covered by Medicare Parts A and B, not those covered by Part D.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. 1. Halperin JJ, Shapiro ED, Logigian E, et al. Practice parameter: Treatment of nervous system Lyme disease (an evidence-based review): report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology. 2007 Jul 3; 69(1): 91-102. http://www.idsociety.org/uploadedFiles/IDSA/GuidelinesPatient_Care/PDF_Library/Nerv

ous%20System%20Lyme%20Disease.pdf
2. Hayes, Inc. Medical Technology Directory. Intravenous antibiotic treatment for late-stage Lyme disease. Lansdale, PA: Hayes, Inc. August 2010.
3. Hayes, Inc. Medical Technology Directory. Long-term antibiotic therapy for chronic Lyme disease. December 2010.
4. Centers for Disease Control and Prevention: Lyme Disease Diagnosis and Treatment, http://www.cdc.gov/lyme/diagnosistreatment/index.html
5. Mygland A, Ljøstad U, Fingerle V, et al; European Federation of Neurological Societies. EFNS Guidelines on the Diagnosis and Management of European Lyme Neuroborreliosis. Eur J Neurol. 2010 Jan;17(1):8-16. https://www.eaneurology.org/fileadmin/user_upload/guidline_papers/EFNS_guideline_2010_European_lyme_neuroborreliosis.pdf
6. Other payers.
7. Wormser G, Dattwyler R, Shapiro E, et al. The Clinical Assessment, Treatment, and Prevention of Lyme Disease, Human Granulocytic Anaplasmosis, and Babesiosis: Clinical Practice Guidelines by the Infectious Diseases Society of America. Clinical Infectious Diseases. 2006;43:1089-1134. http://cid.oxfordjournals.org/content/43/9/1089.full.pdf+html
8. Cameron DJ, Johnson LB, Maloney EL. International Lyme and Associated Diseases Society. Evidence assessments and guideline recommendations in Lyme disease: the clinical management of known tick bites, erythema migrans rashes and persistent disease, Expert Review of Anti-Infective Therapy, 12:9, 1103-1135, 2014. http://www.tandfonline.com/doi/full/10.1586/14787210.2014.940900
9. Statement for the House Foreign Affairs Committee Africa, Global Health and Human Rights Subcommittee's Hearing on Global Challenges in Diagnosing and Managing Lyme Disease - Closing Knowledge Gaps Submitted by the Infectious Diseases Society of America, July 17, 2012, http://www.idsociety.org/uploadedFiles/IDSA/Topics_of_Interest/Lyme_Disease/Policy_Documents/Lyme%20Disease%20Testimony-Global%20Health%20Subcommittee.pdf
10. Wolters Kluwer UpToDate Report: Treatment of Lyme Disease, May 24, 2016.

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POLICY APPROVAL DATES

New: 05/12

Revised: 09/14, 05/16, 05/18, 5/21, 5/23, 11/23

Reviewed: 05/13, 05/14, 05/15, 05/17, 05/19, 05/20, 5/22, 5/24, 5/25, 5/26

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POLICY NAME: LYME & OTHER TICK-BORNE DISEASES

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
12/1/2023	Added to exclusions: • Lyme Borrelia Nanotrap® (0316U)
9/1/2023	Updated the recommended timeframe for oral antibiotic therapy and under IV therapy clarified treatment for Lyme carditis.
9/1/2021	Updated the recommended timeframe for oral antibiotic therapy.

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MEDICAL POLICY

Medical Policy Title	**Management of Dry Eye Syndrome and Meibomian Gland Dysfunction (e.g., LipiFlow)**
Policy Number	**9.01.19**
Current Effective Date	**November 1, 2026**
Next Review Date	**December 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. The following procedures are considered **investigational**:

A. The use of eyelid thermal pulsation therapy (e.g., LipiFlow, iLux System, TearCare, Tixel i) to treat dry eye syndrome;

B. The use of tear film imaging (i.e., LipiView Ocular Surface Interferometer) to evaluate dry eye syndrome and meibomian gland dysfunction;

C. The use of near-infrared dual imaging (i.e., LipiScan Dynamic Meibomian Imager) to evaluate meibomian glands.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Dry eye syndrome refers to a group of disorders resulting from either reduced production of the aqueous component or increased evaporation to the aqueous component of the eye. The pathophysiology of the latter condition, also known as evaporative dry eye (EDE), includes lid-related causes such as meibomian gland dysfunction (MGD) and blink problems, as well as ocular surface-related causes including mucin and contact lens dysfunction. MGD is a leading cause of dry eye throughout the world. As such, the Tear Film and Ocular Surface Society (TFOS) held an International Workshop on MGD to reach consensus on the following definition: MGD is a chronic, diffuse abnormality of the meibomian glands, commonly characterized by terminal duct obstruction and/or qualitative/quantitative changes in the glandular secretion. It may result in alteration of the tear film, symptoms of eye irritation, clinically apparent inflammation, and ocular surface disease. MGD typically results from increased keratinization of ductal epithelium, combined with increased viscosity of meibum.

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Meibomian glands are large sebaceous glands present in eyelids. They secrete lipids that form the superficial layer of tear film to protect the evaporation of the aqueous phase. Several factors, including age, diet, sex hormones, antibiotic usage, and the dysfunction of Meibomian glands, can alter the composition of lipids and proteins in meibum, resulting in altered tear film stability and function.

Treatment of MGD often involves a combination of therapies, including the application of heat to the eyelids using warm compresses, with or without manual massage to melt the abnormal meibum and facilitate its reentry into the tear film. Lipid-based artificial tears are used to restore thin or irregular lipid layers and facilitate temporary relief of symptoms. Pharmaceutical options include essential fatty acid supplementation, systemic tetracycline and azithromycin, topical antibiotics and corticosteroids, and topical tacrolimus ointment for refractory cases. Mechanical intervention involves debridement of eyelid margins and various methods to forcibly express abnormal meibum, with or without prior heating. In patients with severe terminal duct obstruction, conductive thermal pulsation treatment of the eyelids has been demonstrated to improve symptoms of MGD.

Eyelid thermal pulsation is a proposed treatment option for MGD, which is well recognized as the leading cause of dry eye syndrome. The treatment simultaneously applies heat to the palpebral surfaces of the upper and lower eyelids directly over the meibomian glands while also applying graded pulsative pressure to the outer eyelid surfaces, resulting in expression of the meibomian glands.

The LipiFlow system consists of a component that is inserted around the eyelids and a component to control the application of heat and pressure to the to the palpebral surfaces of both upper and lower eyelids. The inner portion of the apparatus applies a constant temperature of between 41°C and 43°C to the palpebral conjunctiva of the upper and lower eyelids. Simultaneously, the outer portion of the apparatus massages the outer eyelids from the base of the meibomian glands in the direction of the gland orifices, applying pulsatile pressure to the external eyelid surfaces (maximum 6 psi) for the 12-minute treatment cycle, expressing the meibomian glands during heating. The source of heat is a resistive (plastic) electric heater. Initial clinical studies revealed a single 12- minute treatment with the LipiFlow system is effective in patients with MGD.

This iLux System device consists of a hand-held instrument coupled to a single-use sterile disposable component that is positioned behind the eyelid. The iLux System allows the eye care professional (ECP) to view the eyelid margin through a magnifier, then warm the eyelid tissue to a target range of 40 to 42 ºC to melt the meibum blocking the gland orifices and then apply compression to the eyelid to express the melted meibum through the orifices. The inner eyelid temperature and amount of force applied are both displayed on the instrument allowing the ECP to titrate both heat and compression to optimize unclogging of the blocked gland. The source of heat is lime-green and infrared optical radiation produced by LEDs in the instrument. Treatment of upper and lower eyelids is sequential, and treatment time is typically between eight and twelve minutes.

The LipiView II Ocular Surface Interferometer to capture, archive, manipulate, and store digital images of the tear film, meibomian glands, ocular surface and eyelids. Using these images, the

LipiView Interferometer measures the absolute thickness of the tear film lipid layer. LipiView II, like its predicate LipiView, perform the same principal functions of ocular imaging and for specular observations of the tear film using white light interferometry. Neither device provides a diagnosis.

LipiScan Dynamic Meibomian Imager uses near infrared (NIR) illumination and an NIR-sensitive high-resolution camera to image the meibomian glands. LipiScan can be used to detect structural changes of meibomian glands.

SUPPORTIVE LITERATURE

Thermal Pulsation Therapy (e.g., LipiFlow, iLux System, TearCare, Tixel i)

A randomized controlled clinical study (Tauber 2020) was conducted to verify that the technological differences between the iLux System and the LipiFlow System do not adversely affect safety and effectiveness as it relates to indications for use. A total of 142 subjects (284 eyes) participated in the study, comprised of 101 women and 41 men, ages 19 to 86 years (mean = 54.9 ± 15.3 years). The subjects were randomized for treatment, in a 1:1 ratio into the iLux and LipiFlow treatment groups. The iLux arm of the study met the criteria for non-inferiority relative to the LipiFlow arm for the coprimary effectiveness endpoints – Meibomian Gland Score (MGS) and Tear Break-Up Time (TBUT) as well as the secondary effectiveness endpoint – Ocular Surface Disease Index (OSDI). MGS improved significantly from baseline in both treatment groups at both week 2 and week 4. MGS improvements did not differ significantly between the two treatment groups at either follow-up visit.

In a 2016 non-randomized clinical trial, Zhao and colleagues conducted a three-month single-institution trial comparing two warming methods in patients with MGD. A total of 50 patients were included in the study, 25 patients who underwent a single 12-min treatment session of thermal pulsation treatment, and 25 patients who underwent warm compresses applied for 10 min sessions twice daily for three months. Researchers concluded that in Asian patients with MGD, LipiFlow thermal pulsation demonstrated similar efficacy to twice daily warm compresses in reducing irritation symptoms and TBUT improvements. Both forms of treatment were safe and well tolerated. In addition to the low sample size, three participants from the warm compress group as well as one patient from the treatment group were lost to follow-up.

In an industry funded 2012 prospective, open label, randomized, crossover multicenter clinical trial, Lane and colleagues evaluated the safety and efficacy of the LipiFlow system compared to the iHeat Warm Compress (WC) for adults with MGD. A total of 139 patients were randomized to either the LipiFlow (n=69) and WC control group (n=70) and either received a single 12-minute LipiFlow treatment or two-week period of daily five-minute sessions of iHeat treatment, respectively. All treatment subjects were examined at day one, two weeks and four weeks, while WC subjects were given the option of entering LipiFlow cross-over arm at the two-week follow-up. Outcome measures included MG assessment, TBUT and dry eye symptoms. Additional safety outcomes such as adverse events, ocular health exam, ocular surface staining, intraocular pressure, visual acuity, and discomfort were also monitored. The results demonstrated a significant improvement in MG secretion and TBUT at two and four weeks in the LipiFlow group, as well as similar improvements in cross-over

arm at two weeks post-treatment. No such improvements were demonstrated in WC group, however. Additionally, LipiFlow resulted in a greater significant reduction in dry eye symptoms than the iHeat WC. There were no significant differences between groups in the incidence of non-serious device-related adverse effects. Researchers concluded the LipiFlow System was equally safe and significantly more effective than iHeat WC in the treatment of MGD and dry eye symptoms. As this study was funded by the manufacturer of LipiFlow and included an open-label design, the potential for investigator bias exists. Short follow-up period poses an additional limitation to this study.

Pang et al (2019) conducted a systematic review and meta-analysis of randomized controlled trials that compared the efficacy of vectored thermal pulsation treatment (VTPT) and warm compress treatment (WCT) in treating dry eye disease (DED). The primary outcome of gland function, as well as secondary outcomes of TBUT, Schirmer test, tear osmolarity, lipid layer thickness (LLT), Standard Patient Evaluation for Eye Dryness and improvement of subjective symptoms evaluated by the OSDI were examined. The study analysis consisted of four trials with a total of 385 patients. The analysis revealed a significantly greater improvement was observed in meibomian gland function, tear breakup time, and Standard Patient Evaluation for Eye Dryness at two to four weeks in the VTPT group than in the WCT group. A significantly greater decrease in OSDI was observed at two to four weeks and three months in the VTPT group than in the WCT group. Researchers concluded that a single 12-minute VTPT was more effective than traditional WCT in treating both objective and subjective measurements of DED. These findings require confirmation in randomized controlled trials with larger patient populations and longer treatment effect evaluation. Further, this meta-analysis highlights that many studies of VTPT are conducted in participants with mean age of 45-65, thus limiting the validity of data in a younger adult population. Additionally, authors acknowledged that it could not be confirmed whether WCT was conducted per protocol by participants assigned to that arm of included studies.

A Cochrane Database Systematic Review (Pucker 2024 and Yim 2025) was conducted to evaluate the effectiveness of LipiFlow for treating dry eye disease (DED) signs and symptoms and the safety of LipiFlow compared with sham or other available treatments for MGD in adults. Thirteen trials were included that randomized a total of 1,155 participants (28 to 236 participants randomized per study). There was no evidence of a difference in meibomian gland expression, meibum quality, or tear breakup time when comparing LipiFlow with basic warm compresses. When comparing LipiFlow plus eyelid hygiene with eyelid hygiene alone, there was no evidence of difference in signs or symptoms at any time point evaluated. The authors concluded the systematic review shows that LipiFlow performs similarly to other commonly used DED treatments with regards to DED signs and symptoms. The best available evidence was deemed to have a high level of bias, leading to low or very low certainty evidence. Additional research with adequate masking, a standardized testing methodology, and a sample representative of the MGD population is therefore needed before any firm conclusions can be drawn regarding comparative benefits and harms.

A systematic review and network meta-analysis (Ben Ephraim Noyman 2025) compared intense pulsed light (IPL), LipiFlow, TearCare, iLux, low-level light therapy (LLLT), and acupuncture for the treatment of dry eye disease (DED). Forty-five RCTs which included 3,455 participants were included

for analysis. Results showed TearCare combined with meibomian gland expression (MGX) demonstrated the highest efficacy for improving meibomian gland secretion (SMD - 10.08, 95% CI - 13.35 to - 6.82). IPL-based treatments, including IPL combined with diquafosol sodium or LLLT, significantly improved tear break-up time and symptom scores, with IPL alone ranking highest for symptom relief (P-score 0.811). Acupuncture was the only intervention significantly superior to conservative treatment for increasing Schirmer test values (SMD - 0.69, 95% CI - 1.06 to - 0.32). LipiFlow demonstrated modest improvements but was not significantly superior to other technologies. The authors concluded this study supports the need for standardized, long-term comparative studies.

Sadri and colleagues (2024) evaluated the safety and effectiveness of the thermo-mechanical action of Tixel C (Novoxel) compared with the thermal pulsation of LipiFlow (Johnson and Johnson) to treat MGD in a multicenter, prospective, randomized (1:1), evaluator masked study. Participants included 106 individuals (N=53 per group) with Ocular Surface Disease Index (OSDI) between 23 and 79, fluorescein tear break-up time (TBUT) <10 s and Meibomian Gland Score (MGS) ≤12 in each eye received bilateral thermo-mechanical action (TMA) or thermal pulsation (TP). The treatment consisted of three (3) sessions, two (2) weeks apart, for TMA and one (1) session for TP. TBUT, OSDI, MGS, and corneal and conjunctival staining (CCS) were assessed at baseline and at Weeks 4 and 12 post-last treatment session. The primary effectiveness endpoint was change in TBUT at Week 4. Results showed TBUT improved significantly ($p<0.001$) by 3.0±3.2 and 3.1±4.3 seconds after TMA and 2.7±2.7 and 3.3±3.6 seconds after TP, at Week 4 and Week 12, respectively. The change in TBUT for TMA was non-inferior to TP (linear mixed-effects model, $p<0.001$). OSDI, MGS and CCS significantly improved from baseline ($p<0.001$), with no significant between-group differences ($p>0.05$). OSDI improved by 26.4±21.1 and 28.6±22.4 after TMA and 18.8±21.0 and 21.9±18.5 after TP, at Week 4 and Week 12, respectively. No device-related adverse event occurred in either group. The authors concluded their study showed TMA with Tixel safely and effectively improved clinical signs and symptoms of evaporative dry eye disease associated with MGD over a 12-week period, comparable to TP with LipiFlow.

LipiView

While there are many studies employing LipiView ocular surface interferometer to assess LLT, there is little research validating its validity as a clinical tool. Zhao et al (2015) evaluated the repeatability of LipiView in measuring LLT in twenty subjects. Two investigators measured LLT of one eye of each patient three times in a single day. The results indicated similar limits of agreement for inter-observer and intra-observer measurements. Given the small sample size, repeatability of measurements in different patient subgroups could not be assessed, nor could results be generalized to patients with characteristics that vary from this small sample.

Esam et al (2025) published a review summarizing different LLT measurement techniques, normative values, and alterations in ocular surface disorders. They found advanced imaging techniques, such as LipiView, Oculus Keratograph 5M, and Tearscope, utilize interference principles, but are not interchangeable for measuring LLT. LLT ranges from 13 to 170 nm in healthy individuals, depending on the instrument and grading scale used. The reported central LLT values in DED vary from 33 to 84 nm, varying with disease severity. There are conflicting reports on the association between age,

gender, and LLT values. The significant overlap in LLT values between the normal individuals and DED patients precludes its role in the diagnosis of DED. Future studies exploring LLT variations under different environmental conditions and across larger cohorts with varying DED severity are essential to enhance clinical applicability.

LipiScan

There is a lack of evidence demonstrating the efficacy of LipiScan near-infrared dual imaging in the management of MGD.

PROFESSIONAL GUIDELINE(S)

The American Academy of Ophthalmology (AAO) published a technology assessment for thermal pulsation in the management of meibomian gland dysfunction and dry eye (Tao 2023) which states according to the current literature, a single application of thermal pulsation was safe and usually demonstrated a benefit at least comparable with standard daily warm compress therapy and eyelid hygiene in patients with MGD and dry eye. Four (4) of the included studies were sponsored and directly supported by relevant industry and raise concern over potential conflict. The three (3) level I studies without direct industry participation concluded that thermal pulsation treatment was not significantly different from eyelid hygiene control treatment. The durability beyond several months and cost efficacy remain uncertain. Because the inclusion parameters of this assessment captured only the LipiFlow system, the conclusions are limited to that product. Independent, unbiased studies of different thermal pulsation treatment frequencies and controlled studies of other thermal pulsation platforms in diverse populations are warranted to assess the long-term benefits of this intervention.

The AAO's Preferred Practice Pattern on dry eye syndrome (Amescua 2024) recommends in-office, physical heating and expression of the meibomian glands (including thermal pulsation devices) as a step 2 intervention for dry eye syndrome.

The AAO's Preferred Practice Pattern on Blepharitis (Lin 2024) stated that "there are also several in-office procedural treatments available that may theoretically unclog the inspissated meibomian gland orifices using intense pulsed light (IPL) or mechanical means (e.g., microblepharoexfoliation of the eyelid margin, meibomian gland probing, and/or devices using thermal pulsation). Although there have been industry-sponsored studies, independent, randomized, masked clinical trials have yet to be performed to assess efficacy of these costly, primarily fee-for-service treatments. (I-, Moderate, Discretionary)"

REGULATORY STATUS

The LipiFlow thermal pulsation system (TearScience Inc, Morrisville, NC) received U.S. Food and Drug Administration (FDA) approval in 2010 and is indicated for the application of localized heat and pressure therapy in adult patients with chronic cystic conditions of the eyelids, including MGD, also known as EDE or lipid deficiency dry eye.

The iLux System (Tear Films Innovations, Inc, San Diego, CA) received 510(k) marketing clearance in 2017. The iLux System is indicated for the application of localized heat and pressure therapy in adult patients with chronic diseases of the eyelids, including MGD, also known as EDE.

The Systane iLux2 (Tear Film Innovations, Inc, Carlsbad, CA) received 510(k) marketing clearance in 2020 for the application of localized heat and pressure therapy in adult patients with MGD, which is associated with evaporative dry eye, and to capture/store digital images and video of the meibomian glands.

The TearCare System (Sight Sciences, Menlo Park, CA) received 510(k) marketing clearance in 2021 for the application of localized heat and pressure therapy in adult patients with evaporative dry eye disease due to MGD, when used in conjunction with manual expression of the meibomian glands.

TearCare MGX (Sight Sciences, Menlo Park, CA) received 510(k) marketing clearance in 2023 for the application of localized heat therapy in adult patients with evaporative dry eye disease due to MGD, when used in conjunction with manual expression of the meibomian glands.

Tixel i (Novoxel Ltd, Covina, CA) received 510(k) marketing clearance in 2024 for the application of localized heat and pressure therapy in adult patients with evaporative dry eye disease due to MGD.

The LipiView II Ocular Surface Interferometer (TearScience Inc, Morrisville NC) received 510(k) marketing clearance in 2016 and is indicated for use by a physician in adult patients to capture, archive, manipulate and store digital images of…the tear film, meibomian glands, ocular surface, and eyelids.

LipiScan Dynamic Meibomian Imager (TearScience Inc, Morrisville NC) received 510K marketing clearance in 2018 and is indicated for use by a physician in adult patients to capture, archive, manipulate and store digital images of the meibomian glands.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0207T (E/I)	Evacuation of meibomian glands, automated, using heat and intermittent pressure, unilateral
0330T (E/I)	Tear film imaging, unilateral or bilateral, with interpretation and report (e.g., LipiView Ocular Surface Interferometer)

Code	Description
0507T (E/I)	Near-infrared dual imaging (e.g., simultaneous reflective and trans-illuminated light) of meibomian glands, unilateral or bilateral, with interpretation and report
0563T (E/I)	Evacuation of meibomian glands, using heat delivered through wearable, open-eye eyelid treatment devices and manual gland expression, bilateral

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
H02.8	Other disorders of eyelid (Meibomian Gland Dysfunction)
H04.121-H04.129	Dry eye syndrome (code range)

REFERENCES

Amescua G, et al; American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Panel. Dry eye syndrome preferred practice pattern. Ophthalmology. 2024 Apr;131(4): P1-P49.

American Academy of Ophthalmology [Internet]. Meibomian glands. EyeSmart eye health. 2018 Jan 19 [accessed 2025 Nov 6]. Available from: https://www.aao.org/eye-health/anatomy/meibomian-glands-list

Ben Ephraim Noyman D, et al. Dry eye disease management via technological methods: a systematic review and network meta-analysis. Ophthalmol Ther. 2025 Aug;14(8):1917-1954.

Esam S, et al. Tear film lipid layer thickness: measurement techniques, normative values, and alteration in ocular surface diseases. Curr Eye Res. 2025 Apr 2:1-15.

Hu J, et al. Efficacy and safety of a vectored thermal pulsation system (Lipiflow) in the treatment of meibomian gland dysfunction: a systematic review and meta-analysis. Graefes Arch Clin Exp Ophthalmol. 2022 Jan;260(1):25-39.

Jongyeop P, et al. Effects of Lipiflow treatment prior to cataract surgery: a prospective, randomized, controlled study. Am J Ophthalmol. 2021 Oct;230:264-275.

Lane SS, et al. A new system, the LipiFlow, for the treatment of meibomian gland dysfunction. Cornea. 2012 Apr;31(4):396-404.

Lin A, et al; American Academy of Ophthalmology Preferred Practice Pattern Cornea/External Disease Panel. Blepharitis preferred practice pattern. Ophthalmology. 2024 Apr;131(4): P50-P86.

Meng Z, et al. Efficacy and safety evaluation of a single thermal pulsation system treatment (Lipiflow) on meibomian gland dysfunction: a randomized controlled clinical trial. Int Ophthalmol. 2023 Apr;43(4):1175-1184.

Pang SP, et al. Efficacy of vectored thermal pulsation and warm compress treatments in meibomian gland dysfunction: a meta-analysis of randomized controlled trials. Cornea. 2019 June;38(12):690-7.

Pucker AD, Yim TW, Rueff E, Ngo W, Tichenor AA, Conto JE. LipiFlow for the treatment of dry eye disease. Cochrane Database Syst Rev. 2024 Feb 5;2(2):CD015448.

Sadri E, et al. Effectiveness and safety of a thermo-mechanical action device versus thermal pulsation device in the treatment of meibomian gland dysfunction. J Cataract Refract Surg. 2024 Dec 16;51(4):274–81.

Tao JP, et al. Thermal pulsation in the management of meibomian gland dysfunction and dry eye: A report by the American Academy of Ophthalmology. Ophthalmology. 2023 Dec;130(12):1336-1341.

Tauber J. A 6-week, prospective, randomized, single-masked study of Lifitegrast ophthalmic solution 5% versus thermal pulsation procedure for treatment of inflammatory meibomian gland dysfunction. Cornea. 2020;39:403-7.

Wesley G, et al. Systane iLux thermal pulsation system in the treatment of meibomian gland dysfunction: A post-hoc analysis of a 12-month, randomized, multicenter study. Clin Ophthalmol. 2022 Nov;16:3631-3640.

Yim TW, et al. LipiFlow for the treatment of dry eye disease: A Cochrane systematic review summary. Cont Lens Anterior Eye. 2025 Apr;48(2):102335.

Zhao AV, et al. Clinical trial of thermal pulsation (LipiFlow) in meibomian gland dysfunction with pretreatment meibography. Eye & Contact Lens. 2016 Nov;42(6): 339-46.

Zhao AV, et al. Intra-observer, and inter-observer repeatability of ocular surface interferometer in measuring lipid layer thickness. BMC Ophthalmol. 2015 May; 15:53.

SEARCH TERMS

Dry eye, meibomian gland secretion, eyelid thermal pulsation, near-infrared dual imaging, tear film imaging, MGD, DED

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based on our review, LipiFlow or management of meibomian gland dysfunction is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 7/26

Revised:

Reviewed:

Date	Summary of Changes
11/1/2026	• New

MEDICAL POLICY

Medical Policy Title	**Maze Procedures for Atrial Fibrillation and Flutter**
Policy Number	**7.01.27**
Current Effective Date	**January 1, 2027**
Next Review Date	**June 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

This policy does not address percutaneous transcatheter ablation procedures for the treatment of cardiac arrhythmia.

POLICY STATEMENT(S)

I. Maze procedures performed on a non-beating heart during cardiopulmonary bypass are considered **medically appropriate** for the treatment of medically refractory, chronic, symptomatic atrial fibrillation or flutter, with or without concurrent cardiac surgery.

II. Minimally invasive, off-pump Maze procedures (e.g., mini thoracotomy); including Hybrid or convergent ablation procedures (defined as a combined percutaneous catheter and thoracoscopic surgical ablation approach), are considered **investigational** as a treatment of atrial fibrillation or flutter.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia, with a prevalence estimated at 0.4% of the population, increasing with age. AF is a supraventricular tachyarrhythmia, characterized by disorganized atrial activation with ineffective atrial ejection. The underlying mechanism of AF involves an interplay between electrical triggering events and the myocardial substrate that permits propagation and maintenance of the aberrant electrical circuit. The most common focal trigger of AF appears to be located within the cardiac muscle that extends into the pulmonary veins. Atrial flutter is considered a variant of AF. Due to the necessity of long-term drug therapy and its associated potential toxicity in patients with AF, surgical techniques have been developed as part of the armamentarium of alternative non-pharmacological treatments. Literature describes patients with drug-resistant AF and flutter as having experienced their arrhythmias for an

average of seven years or more and having unsuccessful results with an average of five or more antiarrhythmic medications.

The classic Cox Maze III procedure is a complex surgical procedure that involves sequential atriotomy incisions that interrupt potential re-entrant circuits, which interrupts the aberrant atrial conduction pathways in the heart in cases of AF. It is indicated for patients who do not respond to medical or other surgical antiarrhythmic therapies and is often performed in conjunction with correction of structural conditions of the heart, such as valve repair or replacement. The procedure has become the gold standard technique for the surgical treatment of drug-resistant AF. This procedure is performed on a non-beating heart during cardiopulmonary bypass.

The Maze procedure entails making incisions in the heart that:

I. Guide an impulse from the sinoatrial (SA) node to the atrioventricular (AV) node;

II. Preserve activation of the entire atrium; and

III. Block re-entrant impulses that are responsible for AF or atrial flutter (AFl).

Despite its high success rate, the traditional "cut and sew" Maze procedure has not been widely utilized other than for those patients who also require concomitant cardiac surgery necessitating the need for cardiopulmonary bypass. Therefore, simplification of the Maze procedure, sometimes referred to as the Cox-Maze IV procedure, has evolved with the use of different ablation tools, such as microwave, cryothermy, ultrasonography and radiofrequency energy sources to create atrial ablative lesions instead of employing the incisional technique used in the traditional Maze procedure.

Due to the complexity and technical difficulty, associated with the Cox-Maze procedure, less invasive, trans-thoracic, endoscopic, off-pump procedures to treat refractory AF are also being developed and evaluated. Examples of these minimally invasive, off-pump surgical techniques include the thoracoscopic Wolf Mini-Maze and the Ex-Maze which use a paracardioscopic approach.

Studies are also starting to emerge investigating a hybrid approach that combines off- pump surgical and endocardial percutaneous catheter ablation. Hybrid ablation or convergent procedure refers to a procedure that uses both thoracoscopic and percutaneous approaches in the same patient. Ablation is performed on the outer surface of the heart (epicardial) via the thoracoscopic approach, and on the inner surface of the heart (endocardial) via the percutaneous approach. The rationale for doing a hybrid procedure is that a combination of both techniques may result in more complete ablation. Thoracoscopic epicardial ablation is limited by the inability to perform all possible ablation lines, because the posterior portions of the heart are not accessible via thoracoscopy. Percutaneous, endoscopic ablation is limited by incomplete ablation lines that often require repeat procedures. By combining both procedures, a full set of ablation lines can be performed, and incomplete ablation lines can be minimized. This convergent ablation procedure has been proposed for highly symptomatic patients with persistent AF and long-standing persistent AF for whom stand-alone surgical or endocardial ablation procedures have provided unsatisfactory outcomes.

SUPPORTIVE LITERATURE

MAZE Procedure

Sakurai et al (2025) reported long-term survival outcomes from a systematic review and meta-analysis of 38 studies (n=41,678) comparing surgical ablation with no surgical ablation during cardiac surgery. The analysis included 9 RCTs and 15 comparative observational studies. The median follow-up was 62 months. Surgical ablation was associated with decreased risk of mortality (HR=0.78; 95% CI, 0.71 to 0.84), stroke (HR=0.60; 95% CI, 0.48 to 0.76), heart failure rehospitalization (HR=0.92; 95% CI, 0.87 to 0.96) and freedom from AF (RR=1.93; 95% CI, 1.50 to 2.49). Surgical ablation was also associated with higher risk of permanent pacemaker implantation (HR=1.35; 95% CI, 1.03 to 1.77).

The Catheter Ablation (CA) Versus Thoracoscopic Surgical Ablation (SA) in Long Standing Persistent Atrial Fibrillation (LSPAF) CASA-AF trial (Haldar 2020), is the first RCT that evaluated the efficacy and safety of thoracoscopic surgical ablation versus CA as the index procedure in 120 patients with long-standing persistent AF. A reduction in AF burden of ≥ 75% was seen in 67% in the surgical ablation group versus 77% in the CA group (OR, 1.13; 95% CI, 0.67 to 4.08; p=.3). Improvements in AF symptoms were increased following CA; surgical ablation was more expensive and was associated with fewer quality-adjusted life years (p=.02) compared with CA. Long-term (up to 3 years) outcomes of the CASA-AF trial were reported by Boyalla, et al (2024). One hundred and four (104) participants (90%) completed 36-month follow-up (CA, n=57 vs SA, n=47). Seven (7) participants (12%) in the CA group and 5 (11%) in the surgical ablation group were free from atrial fibrillation/tachycardia (AF/AT) ≥ 30 seconds at 36 months (HR=1.2; 95% CI, 0.81 to 1.83; p=.41]. 33 patients (58%) in the CA group versus 26 (55%) in the surgical ablation group had their AF/AT burden reduced by ≥ 75% (HR=1.04; 95% CI, 0.57 to 1.88; p=.91). The mean quality-adjusted life years, calculated as the area under the EuroQol 5 Dimension 5 Level questionnaire index score, were 2.5 (95% CI, 2.3 to 2.6) for CA versus 2.3 (95% CI, 2.1 to 2.5) for surgical ablation. The authors concluded this long-term study showed in symptomatic LSPAF, CA and SA were equally effective at achieving arrhythmia outcomes (freedom from AF/ AT ≥ 30 seconds and ≥ 75% burden reduction) after a single procedure without antiarrhythmic drugs. However, SA is significantly more costly than CA.

Evidence from a number of prospective and retrospective studies conclude that the Maze procedure is effective in restoring sinus rhythm in up to 90% of patients with medically refractory, chronic, symptomatic AF. In addition, there is evidence that, when performed in conjunction with valve repair or replacement, the Maze procedure may reduce the risk of stroke, compared with valve replacement alone (e.g., Reston 2005, Budera 2012, and Ad 2013).

Some case series investigating minimally invasive, off-pump procedures include only patients who have failed previous catheter ablation. These studies report high success rates following thoracoscopic ablation, suggesting that patients who fail catheter ablation may still benefit from thoracoscopic ablation. However, these series are small and do not provide complete information on comparative efficacy or adverse events (e.g., Okada 2013).

Hybrid MAZE Procedure

The CONVERGE trial (Delurgio 2020) was a prospective, multi-center, randomized controlled clinical trial, longitudinal study performed from December 2013 to August 2018 to compare the effectiveness of Hybrid Convergent procedure to endocardial catheter ablation (CA) and to demonstrate its safety

for treatment of symptomatic persistent and long-standing persistent AF. The trial enrolled 153 patients at 27 locations (25 in the USA and two in the UK). Patients were randomized at a rate of 2:1 and received either the hybrid Convergent procedure or an endocardial catheter ablation alone. Of 149 evaluated patients at 12 months post-procedure, primary effectiveness was achieved in 67.7 percent (67/99) patients with Hybrid Convergent and 50.0 percent (25/50) with CA (p=0.036) on/off previously failed AADs and in 53.5 percent (53/99) versus 32.0 percent (16/50) (p=0.0128) respectively off AADs. At 18-months using a 7-day Holter monitor, 74.0 percent (53/72) Hybrid Convergent and 55 percent (23/42) CA patients experienced > 90 percent AF burden reduction. There were no deaths, cardiac perforations or atrio-esophageal fistulas reported in the trial. The major adverse events (MAEs) rate through 30-days post intervention (primarily reported as inflammatory pericardial effusions) was 7.8 percent in the treatment arm, which was lower than the protocol pre-specified performance goal of 12 percent. There was also no long-lasting safety events observed in the trial. The clinical trial data showed a greater than 23 percent advantage for the Convergent arm over the control arm.

There is limited literature related to the use of the hybrid approach in the treatment of AF. While short-term outcomes appear promising, further studies are necessary to determine whether the hybrid approach is effective, especially in patients with persistent lone or long-standing persistent, drug-resistant AF (La Meir 2012, Pison 2012, Bisleri 2013, Gehi 2013). Recent studies and reviews focusing on the convergent ablation procedure include Delurgio and colleagues (2020); Larson and colleagues (2020) and Makati and colleagues (2020). Large population studies are needed as well as comparative studies to include direct comparisons of the hybrid ablation procedures with alternative treatment options.

Eranki et al (2023) reported results of a systematic review of mid-term (at least 2 year) outcomes of hybrid ablation. The review included 1,242 individuals from 15 retrospective cohort studies and 1 RCT with sample sizes ranging from 24 to 451. Mean follow-up was 32 (SD=8) months. The mean age of patients was 62 (SD=10) years. 73% of patients were men. Five (5) studies included patients with paroxysmal AF; the majority of the studies included patients with persistent and long-standing AF. Overall, the mid-term freedom from AF was 75% (95% CI, 67 to 82). Freedom from AF at years 1, 2, and 3 was 78%, 74%, and 74%, respectively. There were 12 deaths (0.97%) overall following the hybrid procedure; 10 occurred within 30 days of the procedure. Four (4) deaths were due to a direct mechanical complication of the procedure (atrio-esophageal fistulae) and 2 patients died of stroke. The pooled complication rate was 5.5% (95% CI, 3 to 9). The authors concluded the study shows Hybrid AF ablation offers promising mid-term freedom from AF reported at a mean follow-up of 31.5 months. The overall complication rate remains low.

Mhanna et al (2021) conducted a systematic review and meta-analysis of 8 controlled studies (including the DeLurgio 2020 RCT and the Maclean 2020 nonrandomized studies) of 797 patients with AF undergoing hybrid epicardial/endocardial (convergent) ablation (n=366) or standard endocardial ablation (n=431). Across the studies, the mean age of study participants was 61 years, 77% were male, 93% had persistent AF, and 18% had undergone a previous ablation. The included studies were all assessed as having low to moderate risk of bias. Based on pooled analyses, hybrid ablation was associated with greater freedom from atrial arrhythmia, but also an increased risk of adverse events that included bleeding, pericardial effusion, and cardiac tamponade. The study authors noted

that across studies 5 deaths were reported among hybrid ablation patients while no endocardial ablation patients died, but no risk estimate was reported. The authors concluded the meta-analysis showed that although hybrid ablation was associated with a higher success rate, this should be judged for increased periprocedural adverse events and extended hospital stay.

Eranki et al (2022) conducted a systematic review and meta-analysis of 4 RCTs and propensity score-matched studies (N=422) of hybrid convergent ablation. Hybrid convergent participants had significantly higher rates of freedom from AF than endocardial ablation participants (OR=2.8; 95% CI, 1.8 to 4.2; p<.01). Major post-operative complications were also significantly higher in hybrid convergent participants (OR=5.1; 95% CI; 1.7 to 15.5; p<.01). One death was reported in the hybrid convergent participants; no deaths were reported in the in the endocardial ablation participants.

Doll et al (2023) reported results of the Combined Endoscopic Epicardial and Percutaneous Endocardial Ablation versus Repeated Catheter Ablation in Patients with Persistent and Longstanding Persistent Atrial Fibrillation (CEASE-AF, NCT02695277) RCT. CEASE-AF is a multicenter RCT comparing hybrid combined epicardial and endocardial ablation to standard endocardial CA in 9 hospitals in Germany, Netherlands, United Kingdom, Czech Republic, and Poland between 2015 and 2020 including 154 participants (102 hybrid ablation; 52 standard ablation) with symptomatic, drug refractory persistent AF and left atrial diameter > 4.0 cm or longstanding persistent AF. Participants and study physicians were not blinded to treatment assignment; the core rhythm monitoring laboratory was blinded. In the hybrid CA group, pulmonary veins and left posterior atrial wall were isolated with thoracoscopic epicardial ablation including left atrial appendage exclusion and endocardial touch-up ablation was performed 91 to 180 days afterwards. In the standard CA group, endocardial PV isolation and optional substrate ablation were performed. The primary outcome was freedom from AF, atrial flutter, or atrial tachycardia lasting > 30 seconds through 12 months without class I/III anti-arrhythmic drugs except those not exceeding previously failed doses. Rhythm status was assessed with 48-hour Holter monitoring during scheduled visits and symptom-driven monitoring during unscheduled visits. 81% of participants had persistent AF. 75% were male and the mean age was 61 (SD=8) years. Race/ethnicity was not reported. Total procedure duration was significantly longer in the hybrid group (336 minutes, SD=97) compared to the CA group (252 minutes, SD=114, p < 0.001). Through 12-months follow-up, 72% (68/95) in the hybrid group were free from AF versus 39% (20/51) in the CA group (absolute risk difference = 32% (95% CI, 14 to 48; p < 0.001). In persistent AF subgroup, freedom from AF was 73% (56/77) in the hybrid group versus 42% (18/43) in the CA group (absolute risk difference=31% (95% CI, 10 to 48). In the longstanding persistent AF subgroup, freedom from AF was 67% (12/18) in the hybrid group compared to 25% (2/8) in the CA group (absolute risk difference=42% (95% CI, 4 to 73). Composite major complication rates within 30 days after the index procedure and 30 days after the second stage hybrid ablation or repeat standard ablation were 8% (8/102) and 6% (3/52) in the hybrid versus CA groups (p = 0.751). Through 12-months post-index procedure, composite major complications occurred in 9% (9/102) in the hybrid group versus 6% (3/52) in the CA group (p = 0.752). There was one death (myocardial infarction) in the hybrid group at 93 days post-index procedure. By the 12-month follow-up visit, 4% (4/95) in the hybrid group and 35% (18/51) in the CA group had additional ablation (p < 0.001). Cardioversions (pharmaceutical and electrical) were performed in 12% (11/95) in the hybrid group and 26% (13/51) in the CA group during this time frame (p =

0.037). The authors concluded the study showed hybrid epicardial-endocardial ablation had superior effectiveness compared to catheter ablation/repeat catheter ablation in persistent atrial fibrillation and longstanding persistent atrial fibrillation without significant procedural risk increase. This study was sponsored by AtriCure, Inc.

Lee et al (2022) reported results of the Epicardial Approach in Recurred Atrial Fibrillation (EPIREAF; NCT02979847) RCT comparing a combined epicardial and endocardial ablation approach (n=50) with a conventional endocardial ablation approach (n=50). In the combined approach, subxiphoid epicardial access was obtained under fluoroscopic guidance (hybrid convergent). Participants had symptomatic, persistent AF refractory or intolerant to antiarrhythmic drugs and prior endocardial ablation. EPIREAF was a single-center, open-label, unblinded trial enrolling participants from June 2016 to November 2019. Rhythm monitoring occurred via 12-lead ECG and 24-hour Holter monitoring at 1, 3, 6, 9, and 12 months after the procedure and then every 6 months thereafter. The primary efficacy outcome was time to recurrence of sustained (> 30 seconds) AF or atrial tachycardia following the 90-day blanking period within 12 months of the procedure. The reported safety outcome was occurrence of procedure-related complications within 24 hours after the procedure. Complications included death, any event requiring emergent surgery, severe bradycardia requiring cardiac pacing, pericardial effusion with tamponade or requiring transfusion, ischemic stroke, and procedure-related hematoma or vessel injury. The median age of participants was 59 years and 16% were women. Race/ethnicity of participants was not reported. The median CHA2DS2-VASc score was 1 and the median number of prior ablations was 1. The median procedure time was 232.5 minutes in the hybrid convergent group and 226 minutes in the CA group. 93 (93%) completed the trial. Events relevant to the primary outcome occurred in 16 patients in the treatment group and in 21 patients in the control group {Kaplan-Meier estimator percentages, 32 vs. 42%; hazard ratio, 0.71 [95% confidence interval (CI): 0.37-1.37]}. The periprocedural complication rate was lower in the treatment group [2 vs. 16%; odds ratio, 0.11 (95% CI: 0.00-0.87)] with similar achievement of the procedural endpoint in the two groups. In the redo procedure for persistent atrial fibrillation, the combined approach had no significant difference of recurrence-free survival, and a lower procedural complication rate compared with the conventional approach.

van der Heijden et al (2023) reported results of the Hybrid Versus Catheter Ablation in Persistent AF (HARTCAP-AF; NCT02441738) RCT. HARTCAP-AF was a single-center, open-label, unblinded trial randomizing 41 ablation-naive adults with symptomatic, long-standing persistent AF to either hybrid ablation (n=19) or CA (n=22) between October 2016 and December 2018. All randomized participants received their allocated treatment. The hybrid ablation was performed by an experienced surgeon and electrophysiologist in a single-stage procedure. Rhythm observation was performed with a 12-lead ECG and 24-hour-Holter monitor at 3 and 6 months or following report of symptoms. A 7-day-Holter was collected at 12 months. The primary efficacy outcome was freedom from any atrial tachyarrhythmia (lasting > 5 minutes) off antiarrhythmic drugs after the 3-month blanking period until 12 months. The primary safety outcome was a composite of major adverse events and complications occurring within 12 months of follow-up. Major adverse event included death, stroke, bleeding requiring transfusion and/or reoperation, cardiac tamponade or pericardial effusion requiring intervention, empyema, myocardial infarction, pericarditis requiring pericardiocentesis or (prolongation of) (re)hospitalization, pneumothorax requiring intervention (after removal of chest

tubes), gastroparesis, symptomatic pulmonary vein stenosis > 70%, or (persistent) diaphragmatic paresis. The median age of participants was approximately 65 years; approximately 90% of participants had persistent but not long-standing AF and approximately 10% had persistent, long-standing AF. Several baseline characteristics were not balanced between the 2 treatment groups: women (5% in hybrid vs 18% in CA); median AF duration (22 months in hybrid vs 33 months in CA); CHA2DS2-VASc score > 3 (53% in hybrid vs 27% in CA); and congestive heart failure (5% in hybrid vs 27% in CA). Race/ethnicity of participants was not reported. Median procedure time (4 hours 16 minutes vs 2 hours 53 minutes; p<.001) and length of hospital stay (4 days vs 2 days; p<.001) were significantly longer in the hybrid group. Radiation dose (31 cGycm2 vs 67 cGycm2; p=.004) and radiation exposure time (23 minutes vs 1 hour 54 minutes; p<.001) were significantly higher in the CA group. After 12 months, the freedom of atrial tachyarrhythmias off antiarrhythmic drugs was higher in the HA group compared with the CA group (89% vs 41%, P = 0.002). There was 1 pericarditis requiring pericardiocentesis and 1 femoral arteriovenous fistula in the HA group. In the CA arm, 1 bleeding from the femoral artery occurred. There were no deaths, strokes, need for pacemaker implantation, or conversions to sternotomy, and the number of (serious) adverse events was comparable between groups (21% vs 14%, P = 0.685). The authors concluded the study showed Hybrid AF ablation is an efficacious and safe procedure and results in better outcomes than catheter ablation for the treatment of patients with persistent AF. The study was funded by AtriCure, Inc.

Pannone et al (2023) published results from a study to assess the long-term outcomes of hybrid ablation in a large cohort of patients after both an initial and as a redo procedure. All consecutive patients undergoing hybrid AF ablation at UZ Brussel from 2010 to 2020 were retrospectively evaluated. Hybrid AF ablation was performed in a one-step procedure: (i) thoracoscopic ablation followed by (ii) endocardial mapping and eventual ablation. All patients received PVI and posterior wall isolation. Additional lesions were performed based on clinical indication and physician judgement. Primary endpoint was freedom from atrial tachyarrhythmias (ATas). A total of 120 consecutive patients were included, 85 patients (70.8%) underwent hybrid AF ablation as first procedure (non-paroxysmal AF 100%), 20 patients (16.7%) as second procedure (non-paroxysmal AF 30%), and 15 patients (12.5%) as third procedure (non-paroxysmal AF 33.3%). After a mean follow-up of 62.3 months ± 20.3, a total of 63 patients (52.5%) experienced ATas recurrence. Complications occurred in 12.5% of patients. There was no difference in ATas between patients undergoing hybrid as first vs. redo procedure (P = 0.53). Left atrial volume index and recurrence during blanking period were independent predictors of ATas recurrence. In a large cohort of patients undergoing hybrid AF ablation, the survival from ATas recurrence was 47.5% at ≈5 years follow-up. There was no difference in clinical outcomes between patients undergoing hybrid AF ablation as first procedure or as a redo.

PROFESSIONAL GUIDELINE(S)

The Heart Rhythm Society (HRS) (2017) has stated that a hybrid approach could hold significant promise for those patients with persistent lone or long-standing persistent, drug-resistant AF, offering improved results over minimal-access surgical ablation or catheter ablation alone. It might be

reasonable to apply the indications for stand-alone surgical ablation described above to patients being considered for hybrid surgical ablation (Class IIb, LOE C).

The Society of Thoracic Surgeons 2023 Clinical Practice Guidelines for the Surgical Treatment of Atrial Fibrillation (Wyler von Ballmoos 2024) state the gold standard of surgical ablation has remained the Cox maze procedure and its iteration, based on the original work of Dr. Cox. Given stronger longitudinal evidence of efficacy and longitudinal freedom from atrial fibrillation, antiarrhythmic drugs, as well as oral anticoagulation following a full biatrial Cox Maze, the field awaits more Journal Pre-proof homogeneous or randomized evidence on hybrid or epicardial ablation procedures that adhere to the concept of the Cox Maze lesion set. Epicardial ablation with atypical lesions remain exploratory until more robust evidence becomes available.

In 2023, updated American College of Cardiology (ACC) /American Heart Association (AHA) /American College of Clinical Pharmacy (ACCP)/ Heart Rhythm Society (HRS) Guideline for the Diagnosis and Management of Atrial Fibrillation were released (Joglar 2024). These updated guidelines state that a hybrid procedure might be reasonable to reduce the risk of recurrent atrial arrhythmia citing a weak level of evidence 2B recommendation and the Level of Evidence (LOE) was B-R (moderate-quality evidence from 1 or more RCTs; meta-analyses of moderate-quality RCTs).

REGULATORY STATUS

Several ablation systems have been approved or cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process for cardiac tissue ablation (product code OCL) or PMA process (product code OCM).

Radiofrequency Ablation Approved or Cleared by the U.S. Food and Drug Administration

Device	**Manufacturer**
EPi-Sense Guided Coagulation System	Atricure
Medtronic DiamondTemp System	Medtronic
Cobra Fusion Ablation System	AtriCure
Medtronic Cardioblate and Cardioblate Gemini Systems	Medtronic
Cardima Ablation System	Cardima
Epicor Medical Ablation System	Epicor Medical
Isolator Systems	AtriCure
Estech COBRA Cardiac Electrosurgical Unit	Endoscopic Technologies

Coolrail Linear Pen	AtriCure

A number of cryoablation systems, which may be used during cardiac ablation procedures, have also been cleared for marketing.

Cryoablation Systems Approved or Cleared by the U.S. Food and Drug Administration

Device	**Manufacturer**
Cryocare Cardiac Surgery System	Endocare
SeedNet System	Galil Medical
SurgiFrost XL Surgical CryoAblation System	CryoCath Technologies; now Medtronic
Isis cryosurgical unit	Galil Medical
Artic Front Advance and Arctic Front Advance Pro and the Freezor Max Cardiac Cryoablation Catheters	Medtronic

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
33254	Operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure)
33255 (E/I)	Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); without cardiopulmonary bypass
33256	Operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure); with cardiopulmonary bypass
33257	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), limited (e.g., modified maze procedure) (List separately in addition to code for primary procedure)

Code	Description
33258 (E/I)	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., maze procedure) without cardiopulmonary bypass (List separately in addition to code for primary procedure)
33259	Operative tissue ablation and reconstruction of atria, performed at the time of other cardiac procedure(s), extensive (e.g., maze procedure) with cardiopulmonary bypass (List separately in addition to code for primary procedure)
33265 (E/I)	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, limited (e.g., modified maze procedure), without cardiopulmonary bypass
33266 (E/I)	Endoscopy, surgical; operative tissue ablation and reconstruction of atria, extensive (e.g., maze procedure), without cardiopulmonary bypass

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
I48.0-I48.92	Atrial fibrillation and flutter (code range)

REFERENCES

Abreu Filho CA, et al. Effectiveness of the maze procedure using cooled-tip radiofrequency ablation in patients with permanent atrial fibrillation and rheumatic mitral valve disease. Circ. 2005 Aug 30;112(9 Suppl):I20-5.

Ad N, et al. The effect of the Cox-maze procedure for atrial fibrillation concomitant to mitral and tricuspid valve surgery. J Thorac Cardiovasc Surg. 2013 Dec;146(6):1426-34.

Ad N, et al. The outcome of the Cox maze procedure in patients with previous percutaneous catheter ablation to treat atrial fibrillation. Ann Thorac Surg. 2011 May;91(5):1371-7.

Ballaux PK, et al. Freedom from atrial arrhythmias after classic maze III surgery: a 10-year experience. J Thorac Cardiovasc Surg. 2006 Dec;132(6):1433-40; comment pg.1253.

Barnett SD, AD N. Surgical ablation as treatment for the elimination of atrial fibrillation: a meta-analysis. J Thorac Cardiovasc Surg. 2006 May;131(5):1029-35.

Beukema WP, et al. Intermediate to long-term results of radiofrequency modified maze procedure as an adjunct to open-heart surgery. Ann Thorac Surg. 2008 Nov;86(5):1409-14.

Bisleri G, et al. Hybrid approach for the treatment of long-standing persistent atrial fibrillation: electrophysiological findings and clinical results. Eur J Cardiothorac Surg. 2013 Nov;44(5):919-23.

Boyalla V, et al.; CASA-AF Investigators. Long-term clinical outcomes and cost-effectiveness of catheter vs thoracoscopic surgical ablation in long-standing persistent atrial fibrillation using continuous cardiac monitoring: CASA-AF randomized controlled trial. Heart Rhythm. 2024 Sep;21(9):1562-1569.

Budera P, et al. Two-staged hybrid ablation of non-paroxysmal atrial fibrillation: clinical outcomes and functional improvements after 1 year. Interact Cardiovasc Thorac Surg. 2018 Jan 1;26(1):77-83.

Bulava A, et al.; SURHYB Trial Investigators. Sequential hybrid ablation vs. surgical CryoMaze alone for treatment of atrial fibrillation: results of multicenter randomized controlled trial. Europace. 2024 Feb;26(2):euae040.

Cox JL, et al. A hybrid Maze procedure for long-standing persistent atrial fibrillation. Ann Thor Surg. 2019 Feb;107(2):610-618.

Damiano RJ Jr, et al. The CURE-AF trial: a prospective, multicenter trial of irrigated radiofrequency ablation for the treatment of persistent atrial fibrillation during concomitant cardiac surgery. Heart Rhythm. 2014 Jan;11(1):39-45.

DeLurgio DB, et al. Hybrid convergent procedure for the treatment of persistent and long-standing persistent atrial fibrillation: results of CONVERGE clinical trial. Circulation: Arrhythmia and Electrophysiology. 2020 Dec;13(12).

Doll N, et al. Efficacy and safety of hybrid epicardial and endocardial ablation versus endocardial ablation in patients with persistent and longstanding persistent atrial fibrillation: a randomised, controlled trial. EClinicalMedicine. 2023 Jun 22;61:102052.

Dunnington GH, et al. A heart-team hybrid approach for atrial fibrillation: a single-centre long-term clinical outcome cohort study. European Journal of Cardio-Thoracic Surgery. 2021; 60:1343-1350.

Eranki A, et al. Hybrid convergent ablation versus endocardial catheter ablation for atrial fibrillation: a systematic review and meta-analysis of randomised control trials and propensity matched studies. J Cardiothorac Surg. 2022 Aug 13;17(1):181.

Eranki A, et al. Mid-term freedom from atrial fibrillation following hybrid ablation, a systematic review and meta-analysis. J Cardiothorac Surg. 2023 Apr 19; 18(1): 155.

Fuster V, et al. ACC/AHA/ESC 2006 Guidelines for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association. Circulation. 2006 Aug 15;114(7):e257-354.

Gaynor SL, et al. A prospective, single-center clinical trial of a modified Cox maze procedure with bipolar radiofrequency ablation. J Thorac Cardiovasc Surg. 2004 Oct;128(4):535-42.

Gaynor SL, et al. Surgical treatment of atrial fibrillation: predictors of late recurrence. J Thorac Cardiovasc Surg. 2005 Jan;129(1):104-11.

Gehi AK, et al. Hybrid epicardial-endocardial ablation using a pericardioscopic technique for the treatment of atrial fibrillation. Heart Rhythm. 2013 Jan;10(1):22-28.

Haldar S, et al. Catheter ablation vs. thoracoscopic surgical ablation in long-standing persistent atrial fibrillation: CASA-AF randomized controlled trial. Eur Heart J. 2020 Dec 14;41(47):4471-4480.

Haywood GA, et al. European multicentre experience of staged hybrid atrial fibrillation ablation for the treatment of persistent and longstanding persistent atrial fibrillation. IJC Heart & Vasculature. 2020;26:100459.

Hindricks G, et al. ESC Scientific Document Group. 2020 ESC Guidelines for the diagnosis and management of atrial fibrillation developed in collaboration with the European Association for Cardio-Thoracic Surgery (EACTS): the task force for the diagnosis and management of atrial fibrillation of the European Society of Cardiology (ESC) Developed with the special contribution of the European Heart Rhythm Association (EHRA) of the ESC. Eur Heart J. 2021 Feb 1;42(5):373-498.

Hwang SK, et al. Long-term outcomes of the maze procedure combined with mitral valve repair: risk of thromboembolism without anticoagulation therapy. Ann Thorac Surg 2015 Sep;100(3):840-3.

Je HG, et al. A systematic review of minimally invasive surgical treatment for atrial fibrillation: a comparison of the Cox-Maze procedure, beating-heart epicardial ablation, and the hybrid procedure on safety and efficacy. Eur J Cardiothorac Surg. 2015 Oct;4894):531-40.

Joglar JA, et al; Peer Review Committee Members. 2023 ACC/AHA/ACCP/HRS Guideline for the diagnosis and management of atrial fibrillation: a report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines. Circulation. 2024 Jan;149(1):e1-e156.

Kim JB, et al. Long-term outcomes of mechanical valve replacement in patients with atrial fibrillation. Impact of the maze procedure. Circulation. 2012 May;125(5):2071-80.

La Meir M, et al. Minimally invasive surgical treatment of lone atrial fibrillation: early results of hybrid versus standard minimally invasive approach employing radiofrequency sources. Int J Cardiol. 2013 Aug 20;167(4):1469-75.

Larson J, et al. Outcomes of convergent atrial fibrillation ablation with continuous rhythm monitoring. J Cardiovasc Electrophysiol. 2020;31:1270–1276.

Maclean E, et al. The convergent procedure versus catheter ablation alone in longstanding persistent atrial fibrillation: A single centre, propensity-matched cohort study. International Journal of Cardiology. 2020;303:49–53.

Makati KJ, et al. Combined epicardial and endocardial ablation for atrial fibrillation: best practices and guide to hybrid convergent procedures. Heart Rhythm. 2021 Feb;18(2):303-312.

Mhanna M, et al. Hybrid convergent ablation versus endocardial catheter ablation for atrial fibrillation: A systematic review and meta-analysis. Journal of Arrhythmia. 2021;37:1459-1467.

Nakajima H, et al. The effect of cryo-maze procedure on early and intermediate term outcome in mitral valve disease: case matched study. Circ. 2002 Sep 24;106(12 Suppl 1):I46-50.

Okada S, et al. The impact of previous catheter-based ablation on the efficacy of the Cox-maze IV procedure. Ann Thorac Surg. 2013 Sep;96(3):786-91.

Pannone L, et al. Hybrid atrial fibrillation ablation: long-term outcomes from a single-centre 10-year experience. Europace. 2023 May 19;25(5):euad114.

Pison L, et al. Hybrid thoracoscopic surgical and transvenous catheter ablation of atrial fibrillation. J Am Coll Cardiol. 2012 Jul 3;60(1):54-61.

Reston JT and Shuhaiber JH. Meta-analysis of clinical outcomes of maze-related surgical procedures for medically refractory atrial fibrillation. Eur J Cardiothorac Surg. 2005 Nov;28(5):724-30.

Sakurai Y, et al. Late survival benefits of concomitant surgical ablation for atrial fibrillation during cardiac surgery: a systematic review and meta-analysis. Am J Cardiol. 2025 Jan 15;235:16-29.

Shrestha S, et al. Hybrid Convergent ablation for atrial fibrillation: A systematic review and meta-analysis. Heart Rhythm O2. 2022 May;3(4):396-404.

van der Heijden CAJ, et al. Hybrid ablation versus repeated catheter ablation in persistent atrial fibrillation: a randomized controlled trial. JACC Clin Electrophysiol. 2023 Jul;9 (7 Pt 2):1013-1023.

Wyler von Ballmoos MC, et al. The Society of Thoracic Surgeons 2023 clinical practice guidelines for the surgical treatment of atrial fibrillation. Ann Thorac Surg. 2024 Jan:S0003-4975(24)00057-2.

Yonas E, et al. Comparison between surgical and catheter-based ablation in atrial fibrillation, should surgical based ablation be implemented as first line? A meta-analysis of studies. Indian Pacing and Electrophysiology Journal. 2020;20: 14-20.

SEARCH TERMS

COX-III, Epicardial Maze, MiniMaze, Thoracoscopic off-pump surgical ablation (TOPS).

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The Maze procedure as treatment for atrial fibrillation is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

MEDICAL POLICY

Medical Policy Title	**Medical Management Obstructive Sleep Apnea (OSA)**
Policy Number	**1.01.07**
Current Effective Date	**January 1, 2027**
Next Review Date	**October 2027**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Oral appliances therapy (OAT) is **medically appropriate** for the treatment of obstructive sleep apnea (OSA) when the severity level (e.g., mild, moderate, severe) criteria are met:

A. Mild OSA

1. Documented diagnosis of OSA with Apnea-Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) ≥ 5 and ≤ 14, confirmed by a sleep study (e.g., PSG or home sleep study); when **BOTH** of the following criteria are met:

a. At least **ONE** of the following indications:

i. Hypertension;

ii. Heart disease;

iii. Stroke;

iv. Excessive daytime sleepiness;

v. Impaired cognition;

vi. Mood disorders; **or**

vii. Insomnia;

AND

b. The individual cannot tolerate or refuses continuous positive airway pressure (CPAP) therapy; **or**

c. The physician determines that the use of positive airway pressure (PAP) therapy is contraindicated.

B. Moderate OSA

1. Documented diagnosis of OSA with a severity level indicated by an AHI or RDI ≥ 15 and < 30 confirmed by a sleep study when **EITHER** of the following criteria are met:

a. The individual cannot tolerate or refuses CPAP therapy; **or**

b. The physician determines that the use of PAP therapy is contraindicated.

C. Severe OSA

1. Documented diagnosis of OSA with a severity level indicated by AHI or RDI ≥ 30, confirmed by a sleep study when **EITHER** of the following criteria are met:
    a. The individual cannot tolerate or refuses CPAP therapy; **or**
    b. The physician determines that the use of a PAP device is contraindicated.

II. The use of Oral Appliances (OAs) is **not medically necessary** for the following indications, which include but are not limited to:
    A. Upper Airway Resistance Syndrome (UARS) with or without snoring and without a diagnosis of OSA;
    B. Primary snoring (e.g., Slow Wave Ds8, and SnoreRX);
    C. Temporomandibular joint disorders (TMJD), (refer to CMP 11.01.17 Temporomandibular Joint Disorders for other indications);
    D. Central sleep apnea;

III. Prefabricated or non-custom OAs are **not medically necessary**.

IV. Daytime neuromuscular electrical stimulation devices (e.g., eXciteOSA) is **investigational** for the treatment of OSA.

V. The use of a sleep positioning trainer with or without vibration is considered **investigational** for the treatment of positional OSA.

VI. Replacement of a medically necessary OA is **eligible for coverage** after five (5) years, unless there is documented evidence of device failure or a clinically significant change in the patient's condition that necessitates earlier replacement (e.g., tooth loss or major dental reconstruction).

VII. Replacement of a medically necessary oral appliance due to misuse or neglect (e.g., lost, or misplaced) is **ineligible for coverage**.

RELATED POLICIES

Corporate Medical Policy

#1.01.06 Positive Airway Pressure Devices: CPAP, BPAP, APAP and Noninvasive Positive Pressure Ventilators (NIPPV)

#7.01.41 Surgical Management of Sleep Disorders

#11.01.03 Experimental or Investigational Services

#11.01.17 Temporomandibular Joint Disorders (TMJD)

POLICY GUIDELINE(S)

I. Attempts at behavioral modifications and lifestyle changes (e.g., good sleep hygiene, weight loss, avoidance of alcohol consumption in evening, smoking cessation, sleep position change, treatment of nasal congestion) for individuals with UARS and sleep apnea should be an integral part of the treatment regimen for sleep-disordered breathing.

II. The decision for the use and fabrication of an OA should be made by a sleep medicine physician (e.g., somnologist or sleep specialist; ear, nose, and throat [ENT] specialist) or by an experienced dentist/orthodontist in collaboration with a sleep specialist.

III. All impressions, try-ins, and adjustments and repairs are inclusive to the lifetime of the appliance after approval of the device.

DESCRIPTION

Sleep related breathing disorders are characterized by abnormal respiration during sleep, which may or may not also occur during wakefulness. These abnormalities can include pauses in breathing, shallow breathing, or reduced airflow, often leading to fragmented sleep and reduced oxygen levels. Other symptoms can include loud snoring, gasping, choking during sleep, morning headaches, dry mouth, daytime fatigue, sleepiness, mood changes, and cognitive issues. There are several types of sleep related breathing disorders. OSA (the most common type) causes physical blockage of the upper airway typically due to relaxed throat muscles during sleep. OSA in an adult is defined as recurrent episodes of complete or partial obstruction of the upper airway leading to reduced or absent breathing during sleep for greater than 10 seconds.

Upper airway resistance syndrome (UARS) is a milder form of obstructive sleep related breathing. The airway narrows but does not fully close. This can cause sleep fragmentation and fatigue.

Central sleep apnea occurs when the brainstem, which regulates breathing, does not respond appropriately to changes in carbon dioxide levels in the blood. This results in reduced or absent respiratory effort, leading to pauses in breathing during sleep. Central apneas are often linked to heart failure or neurological conditions. The central apneas occur without any airway obstruction.

Sleep related hypoventilation disorders causes inadequate breathing during sleep which can lead to high carbon dioxide levels. Hypoventilation disorders are common in obesity, neuromuscular disorders, or medication use.

Sleep related hypoxemia is sustained low oxygen levels during sleep without elevated carbon dioxide. Often due to lung diseases or other medical conditions.

Oral Appliances (OAs)

OAs can be prefabricated, ready-made, or custom fitted device worn in the mouth during sleep to treat OSA and snoring. They work by repositioning the jaw, tongue, or soft tissues to keep the airway open, allowing for uninterrupted breathing throughout the night. The most common type of oral appliance is the mandibular advancement device (MAD), which is custom made for each individual and adjustable to allow a dentist to modify the degree of jaw advancement as needed. The goal is to achieve the most comfortable and effective position for the individual. Examples of custom oral appliances include tongue-retaining devices, non-adjustable mandibular repositioning devices (MRDs), and adjustable MRDs. These appliances may be used as an alternative to other medical (e.g., CPAP and surgical (e.g., Uvulopalatopharyngoplasty) interventions.

AIO BREATHE (AIOMEGA LLC, Texas) is a lightweight MAD that increases airway size and repositions the jaw to keep the airway more open during sleep. It is recommended for mild to moderate sleep apnea and snoring.

ProSomnus EVO PH (ProSomnus Sleep Technologies), sleep and snore devices use medical grade polymers and hinge components to reposition and stabilize the jaw during sleep. The OA causes an increase in the pharyngeal space, reducing the risk of upper airway collapse. The device is recommended for snoring and to treat mild to moderate OSA.

iNAP (Somnics Health, Inc.) uses gentle suction to move the tongue forward. No mask or headgear is required.

Vivos (Vivos Therapeutics, Inc) OAs are noninvasive, custom-made devices designed to treat OSA and snoring. They function by repositioning the hard and soft tissues of the airway to enhance airflow and improve upper airway function. The Vivos System gradually remodels the upper airway and jaw structure over time to address the underlying anatomical causes of OSA. Recently, the United States Food and Drug Administration (FDA) approved Vivos OAs the treatment of severe OSA.

Neurostimulators

eXciteOSA is an FDA approved daytime therapy designed to treat snoring and mild OSA by strengthening tongue muscles through neuromuscular electrical stimulation (NMES). It is intended for adults aged 18 and older with an AHI less than 15. The device consists of a mouthpiece with four electrodes, two above and two below the tongue that are connected to a control unit via USB. It delivers electrical pulses to stimulate both intrinsic and extrinsic tongue muscles. This stimulation strengthens the muscles, helping to prevent the tongue from collapsing backward during sleep. As a result, it supports airway patency and contributes to the reduction of snoring and apnea events.

SUPPORTIVE LITERATURE

Oral Appliances (OAs)

The consistent findings among studies support the use of OAs as an alternative treatment method for individuals with sleep-related breathing disorders. A systematic review by Lim et al (2008) concluded that there is evidence indicating oral appliance therapy improves both subjective sleepiness and sleep-disordered breathing when compared to control treatments. Lim et al (2008) also conclude that CPAP appears to be more effective in improving sleep-disordered breathing than OA. The difference in symptomatic response between these two treatments is not significant, although it is not possible to exclude an effect in favor of either therapy.

Rossi et al (2021) conducted a systematic review of 17 randomized controlled trials (RCTs) to assess the clinical effectiveness of OAs in treating OSA. The review included RCTs with at least 50 participants, comparing OAs to CPAP, placebo, surgery, or other interventions. Findings showed that OAs significantly reduced both the AHI and the Oxygen Desaturation Index (ODI), including in some individuals with severe OSA. Custom-fitted, titratable devices were found to be more effective than non-custom or non-titratable alternatives. While CPAP generally achieved greater reductions in AHI, OAs were associated with higher patient compliance and better tolerability. In cases of mild to moderate OSA, some studies showed that OAs were non-inferior to CPAP. Additionally, improvements

in daytime sleepiness (Epworth Sleepiness Scale), snoring, and quality of life were observed, although these outcomes varied across studies.

Beri et al (2023) evaluated the effectiveness of OA therapy in treating OSA, focusing on the use of mandibular advancement devices (MADs) and tongue retaining devices (TRDs). The study used the AHI as the primary outcome measure. The inclusion criteria focused on adults with an AHI greater than 5, treated with MAD or TRD, and compared it to CPAP therapy. The analysis was based on a systematic review and meta-analysis of six randomized controlled trials conducted between 1998 and 2021. OA significantly improve AHI compared to baseline (Mean Difference = 13.40; 95% CI). CPAP outperformed OA in reducing AHI (Mean Difference = 8.40; 95% CI). TRDs showed comparable results to MADs in some studies. Researchers concluded that MADs are effective alternatives for patients with mild to moderate OSA, especially those that are intolerant to CPAP.

Electrical Stimulation Appliances

The current body of evidence supporting non-surgical neuromuscular electrical stimulation for OSA remains limited. High-quality data demonstrating its safety and clinical efficacy are lacking. Well-designed, controlled studies are needed to evaluate its therapeutic effectiveness, safety profile, and long-term outcomes. Two cohort studies (Kotecha et al (2021) and Baptista et al (2021)) studied habitual snorers who were treated with eXciteOSA. Both studies reported a reduction in snoring time measured by the Watch-PAT device and bed-partner-reported snorting was also decreased. A reduction in AHI was noted in those participants with mild OSA in the Kotecha study but there was no clinically significant reduction in AHI reported in the Baptista study. Both the Epworth Sleepiness Scale (ESS) and Pittsburgh Sleep Quality Index (PSQI) test showed improvements as reported by the participants as well as the bed partners. These studies suggest that daytime tongue stimulation may improve snoring, but the effect on OSA is uncertain.

PROFESSIONAL GUIDELINE(S)

The 2015 clinical practice guidelines jointly issued by the American Academy of Sleep Medicine (AASM) and the American Academy of Dental Sleep Medicine (AADSM) recommend oral appliance therapy for adult patients with OSA who are intolerant of CPAP therapy or prefer an alternative treatment. A standard recommendation is a strong recommendation based on high-quality evidence and a guideline is a moderate recommendation based on moderate quality evidence or expert consensus. Clinicians are encouraged to follow the recommendation and that exceptions maybe applied based on the individual circumstances.

Primary Snoring (No OSA)
Sleep physicians should prescribe oral appliances instead of offering no treatment for adults seeking help for primary snoring without obstructive sleep apnea. (Standard)

- OSA – Custom Devices Preferred
  When treating adults with OSA sleep physicians should recommend that a qualified dentist provide a custom, adjustable OAs rather than a non-custom device. (Guideline)
- OSA – CPAP Intolerance or Preference
  For adults with obstructive sleep apnea who cannot tolerate CPAP or prefer another option, sleep physicians should consider prescribing OA instead of leaving the condition untreated. (Standard)
- Dental Oversight
  Qualified dentists should monitor patients using OAs for OSA to detect and minimize dental side effects or bite changes, rather than providing no follow-up. (Guideline)
- Follow-Up Sleep Testing
  Sleep physicians should conduct follow-up sleep studies to confirm or improve the effectiveness of OA therapy, rather than relying on follow-up without testing. (Guideline)

The American Academy of Dental Sleep Medicine (AADSM) released an updated position statement in October 2022, on the use of OAT for the treatment of OSA. The statement affirms that OAT is an effective treatment for both OSA and snoring, and should be considered a first-line therapy, particularly for patients who are intolerant of CPAP therapy. The guidelines emphasize that patient evaluation and appliance fitting should be conducted by qualified dentists trained in dental sleep medicine. For optimal outcomes, the use of custom-fitted, titratable OAs is recommended. Additionally, the AADSM advises that patients be offered a trial of OA therapy prior to considering surgical interventions for OSA.

The American Academy of Otolaryngology Head and Neck Surgery (AAO-HNS) position statement (2021) on the use of oral appliances for the treatment of OSA recommends OAs as a treatment option for patients with OSA, particularly those who are unable to tolerate CPAP therapy. The AAO-HNS supports the use of custom-fitted OA provided by qualified dental professionals. The Academy emphasizes the importance of interdisciplinary collaboration between otolaryngologists, sleep physicians, and dental sleep medicine providers to ensure optimal patient outcomes. The AAO-HNS encourages ongoing monitoring and follow-up to assess treatment effectiveness and manage potential side effects, such as dental or jaw changes.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates oral appliances as medical devices. All oral appliances including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Sept 11]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 Sept 11]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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CDT Codes

Code	Description
D9947	Custom sleep apnea appliance fabrication and placement (Effective 01/01/22
D9948	Adjustment of custom sleep apnea appliance (Effective 01/01/22)
D9949	Repair of custom sleep appliance (Effective 01/01/22)

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HCPCS Codes

Code	Description
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment
E0490 (E/I)	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware remote
E0491 (E/I)	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply
E0492 (E/I)	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application

Code	Description
E0493 (E/I)	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply
E0530 (E/I)	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type (01/01/24)
K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment
K1037	Docking station for use with oral device/appliance used to reduce upper airway collapsibility

ICD10 Codes

Code	Description
F51.8	Other sleep disorders not due to a substance or known physiological condition
G47.00-G47.09	Insomnia (code range)
G47.10-G47.19	Hypersomnia (code range)
G47.20-G47.29	Circadian rhythm sleep disorder (code range)
G47.30-G47.39	Sleep apnea (code range)
G47.69	Other sleep related movement disorders
G47.8-G47.9	Other and unspecified sleep disorder (code range)

REFERENCES

American Academy of Dental Sleep Medicine (AADSM) [Internet]. Dental sleep medicine standards for screening, treatment, and management of sleep-related breathing disorders in adults using oral appliance therapy. [updated 2022; accessed 2025 Sept 11]. Available from: https://www.aadsm.org/docs/jdsm.10.10.2022.sa1.pdf

American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) [Internet]. Position statement: Use of oral appliances for the treatment of obstructive sleep apnea (OSA). [updated 2021 Apr 22; accessed 2025 Sept 11]. Available from: https://www.entnet.org/resource/position-statement-use-of-oral-appliances-for-the-treatment-of-obstructive-sleep-apnea-osa/

Baptista PM, et al. Daytime neuromuscular electrical therapy of tongue muscles in improving snoring in individuals with primary snoring and mild obstructive sleep apnea. J Clin Med. 2021 Apr 27;10(9):1883

Beri A, et al. Appliances therapy in obstructive sleep apnoea: a systematic review and meta-analysis. Cureus. 2023 Nov 4;15(11):e48280.

Kotecha B, et al. A novel intraoral neuromuscular stimulation device for treating sleep-disordered breathing. Sleep Breath. 2021 Dec;25(4):2083-2090.

Lim J, et al. Oral appliances for obstructive apnea. Cochrane Database Syst Rev 2008 Aug 12;(1):CD004435.

Ng JH and Yow M. Oral appliances in the management of obstructive sleep apnea. Sleep Med Clin. 2019;14(1):109-118.

Ramar K, et al. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015. J Clin Sleep Med. 2015 Jul 15;11(7):773-827.

Rossi A, et al. Clinical evidence in the treatment of obstructive sleep apnoea with oral appliances: a systematic review. Int J Dent. 2021 May 8;2021:6676158.

Uniken Venema JAM, Doff MHJ, Joffe-Sokolova D et al., Long-term obstructive sleep apnea therapy: a 10-year follow-up of mandibular advancement device and continuous positive airway pressure: J Clin Sleep. Med 2020 March 15;16(3) 353-359.

SEARCH TERMS

Obstructive sleep apnea, OSA, Upper Airway Resistance Syndrome

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

LCD - Oral Appliances for Obstructive Sleep Apnea (L33611) [accessed 2025 Sept 11]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

MEDICAL POLICY

Medical Policy Title	**Medical Response to Contamination from Terrorist Attacks**
Policy Number	**11.01.09**
Current Effective Date	**November 1, 2026**
Next Review Date	**August 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Testing, prophylaxis, and treatment (e.g., vaccination, antimicrobial or other pharmacological treatment) for terroristic agents, whether biological, chemical, or radiological, is considered **medically appropriate** when the following are met:

   A. Local, state, or national agencies advise that such testing or treatment is medically necessary;

   B. The service, vaccine, or drug is covered under the member's subscriber contract.

II. Coverage for all medically necessary aspects of diagnosis and treatment of illness or injury resulting from terrorism is considered **medically appropriate** when contract benefits are available for the specified services.

RELATED POLICIES

Not Applicable

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

A terroristic attack is the calculated use of violence or threat of violence against people, to attain goals that are political, religious, or ideological in nature through intimidation or coercion, or by instilling fear. Terroristic attacks can be achieved through biological emergency (bioterrorism), chemical emergency, or radiological emergency.

Bioterrorism is the intentional or threatened use of viruses, bacteria, fungi, or toxins from living organisms to produce death or disease in humans, animals, or plants. Biological agents include, but are not limited to, the organisms that cause anthrax, botulism, plague, ricin, smallpox, tularemia, viral hemorrhagic fevers (e.g., Ebola, Marburg, Lassa, Machupol), as well as food or waterborne organisms (e.g., salmonella, shigella dysenteriae).

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Terroristic chemical emergency occurs when a hazardous chemical is released that has a potential for harming the health of people. Examples of chemicals that may be used in terrorist attacks include, but are not limited to, nerve agents, mustards, and choking agents. Nerve agents (e.g., sarin, VX) are highly poisonous chemicals that cause neurological disruption and may lead to convulsion, paralysis, and respiratory failure. Mustards (e.g., sulfur mustard, nitrogen mustard) are vesicants, or blistering agents, which cause severe blistering of the eyes, respiratory tract, and skin on contact, damage to the immune system, and bone marrow suppression. Pulmonary or choking agents (e.g., phosgene) are chemicals that cause severe irritation or swelling of the respiratory tract, hypotension, and cardiac failure.

Terroristic radiation emergency occurs when radioactive material is introduced into the food or water supply, explosives are used to scatter radioactive material (also known as a "dirty bomb"), a nuclear facility is bombed or destroyed, or a nuclear device is exploded. The adverse effects of radiation exposure can range from mild effects (e.g., skin reddening) to serious effects (e.g., cancer, death) depending upon the amount of radiation absorbed, the type of radiation, the route of exposure, and the duration of exposure.

SUPPORTIVE LITERATURE

Not Applicable

PROFESSIONAL GUIDELINE(S)

Not Applicable

REGULATORY STATUS

Not Applicable

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
86622	Antibody; Brucella
86668	Antibody; Francisella tularensis
86784	Antibody; Trichinella
86793	Antibody; Yersinia

Code	Description
90288	Botulism immune globulin, human, for intravenous use
90581	Anthrax vaccine, for subcutaneous or intramuscular use
90625	Cholera vaccine, live, adult dosage, 1 dose schedule, for oral use

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HCPCS Codes

Code	Description
No code(s)	

ICD10 Codes

Code	Description
A00.0-A00.9	Cholera (code range)
A20.0-A20.9	Plague (code range)
A21.0-A21.9	Tularemia (code range)
A22.0-A22.9	Anthrax (code range)
A23.0-A23.9	Brucellosis (code range)
A98.0-A98.8	Other viral hemorrhagic fevers (code range)
Y38.5x1A-Y38.5x3S	Terrorism involving nuclear weapons (code range)
Y38.6x1A-Y38.6x3S	Terrorism involving biological weapons (code range)
Y38.7x1A-Y38.7x3S	Terrorism involving chemical weapons (code range)
Z20.810	Contact with and (suspected) exposure to anthrax

REFERENCES

Bennett CL, et al. United States' regulatory approved pharmacotherapies for nuclear reactor explosions and anthrax-associated bioterrorism. Expert Opin Drug Saf. 2023 Jul-Dec;22(9):783-788.

Bower WA, et al; Centers for Disease Control and Prevention (CDC). Clinical framework and medical countermeasure use during an anthrax mass-casualty incident. MMWR Recomm Rep. 2015 Dec 4;64(4):1-22

Bower WA, et al. Center for Disease Control (CDC) [Internet]. Guidelines for the prevention and treatment of anthrax, 2023. MMWR Recomm Rep. 2023 Nov 17;72(6):1-47 [accessed 2026 Jun 29]. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10651316/pdf/rr7206a1.pdf

Centers for Disease Control and Prevention [Internet]. Bioterrorism and Anthrax: The Threat. 2025 Apr 3, updated 2026 Feb 4 [accessed 2026 Jun 29]. Available from: https://www.cdc.gov/anthrax/bioterrorism

Centers for Disease Control and Prevention [Internet]. Chemical emergencies. 2024 Apr 9, updated 2026 Jun 10 [accessed 2026 Jun 29]. Available from: http://emergency.cdc.gov/chemical/

Centers for Disease Control and Prevention [Internet]. Radiation emergencies. [accessed 2026 Jun 29]. Available from: http://emergency.cdc.gov/radiation/

Grabenstein JD. Vaccines: countering anthrax: vaccines and immunoglobulins. Clin Infect Dis. 2008 Jan 1;46(1):129-36.

Hayoun MA, et al. Biological Weapon Toxicity. 2024 Jan 1. In: Stat Pearls [Internet]. Treasure Island (FL): Stat Pearls Publishing; 2025 Jan 1 [accessed 2026 Jun 29]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK441942/

Seaton MG, et al. A framework for integrating information resources for chemical emergency management and response. J Emerg Manag. 2019;17(4):287-303.

Schorscher N, et al. Lessons learned from terror attacks: thematic priorities and development since 2001—results from a systematic review. Euro Jour of Trauma and Emer Sur. 2022;48:2613-2638.

Waselenko JK, et al. Medical management of the acute radiation syndrome: recommendations of the Strategic National Stockpile Radiation Working Group. Ann Intern Med. 2004 Jun 15;140(12):1037-51.

Williams M, Armstrong L, Sizemore DC. Biologic, Chemical, and Radiation Terrorism Review. 2023 Aug 14. In: Stat Pearls [Internet]. Treasure Island (FL): Stat Pearls Publishing; 2025 Jan [accessed 2026 Jun 29]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK493217/

Wright JG, et al. Use of anthrax vaccine in the United States: recommendations of the Advisory Committee on Immunization Practices (ACIP), 2009. MMWR Recomm Rep. 2010 Jul 23;59(RR-6):1-30.

SEARCH TERMS

Germ warfare.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medical response to acts of terrorism is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 7/26 **Revised**: **Reviewed**:	
Date	**Summary of Changes**
11/1/2026	• New

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: MEDICALLY FRAGILE CHILDREN

POLICY EFFECTIVE DATE:	12/1/2025
Policy Control #:	1370/20.000514
Next Annual Review:	November, 2026

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies
Review Process for Resource Coordination, 1370/20.000213

Behavioral Health Policies
Home and Community Based Services for Children, 1370/20.000503

POSITION STATEMENT

A medically fragile child is defined as an individual who is under twenty-one years of age and has a chronic debilitating condition or conditions*, who may or may not be hospitalized or institutionalized, and meets **one or more** of the following criteria:

- Technologically dependent** for life or health sustaining function;
- Requires a complex medication regimen or medical interventions to maintain or to improve their health status; or
- In need of ongoing assessment or intervention to prevent serious deterioration of their health status or medical complications that place their life, health, or development at risk.

*Chronic debilitating conditions include bronchopulmonary dysplasia, cerebral palsy, congenital heart disease, microcephaly, pulmonary hypertension, and muscular dystrophy. The term "medically fragile child" shall also include traumatic brain injury, the nature of which typically requires care in a specialty care center for medically fragile children, even though the child does

not have a chronic debilitating condition or also meet one of the three conditions above.

**Examples of technologically dependent include children who require the following: oxygen support, invasive and non-invasive mechanical ventilation, pacemaker, implantable cardioverter defibrillators (ICD), ventricular drains, intravenous drugs, intravenous nutrition, gastrostomy or jejunostomy, ileostomy, colostomy, urethral catheterization, and dialysis.

POLICY CONSIDERATIONS

CDPHP applies the following clinical standards when making determinations for medical necessities regrading medically fragile children:

1. CDPHP will consider as medically necessary all covered services that assist medically fragile children in reaching their maximum functional capacity, taking into account appropriate functional capacities of children the same age.

2. CDPHP will not base determinations solely on review standards applicable or designed for adults.

3. CDPHP will take into account specific needs of the child and the circumstances pertaining to their growth and development.

4. CDPHP will accommodate unusual stabilization and prolonged discharge plans, as appropriate and will consider when developing and approving discharge plans, issues including sudden reversals of condition or progress which may make discharge decisions uncertain or more prolonged than for other children or adults.

5. CDPHP will identify an available provider of needed covered services, as determined through a person-centered care plan, to effect safe discharge from a hospital or other facility.

6. CDPHP will contract with providers with demonstrated expertise in caring for medically fragile children. CDPHP will adhere to medical necessity guidelines, ensuring network providers refer medically fragile children to suitable community facilities and providers, and review out of network care when participating providers cannot meet the child's needs.

EXCLUSIONS

Duplicate services being provided by a federal or state governmental agency, by a school district, or by a developmental learning center that are sufficient in meeting the needs of an individual.

CDPHP PRODUCT VARIATIONS

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: MEDICALLY FRAGILE CHILDREN

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy. **Note**: The guidance and information contained within this policy pertain to any child determined to be medically fragile based on the definition and not only Medically Fragile Waiver Children identified under the NYS DOH Children Waiver. Additionally: • CDPHP will cover services until a medically fragile child achieves age-appropriate functional capacity. • Payment will not be denied to a discharging hospital or other facility due to lack of an available post-discharge provider as long as they have worked with the utilization review agent to identify an appropriate provider. • When rendering or arranging for care or payment, CDPHP along with the provider will inquire of and consider the desires of the family, including the availability and capacity of the family, the needs for the family to simultaneously care for family's other children, and the need for parents to continue employment. • CDPHP will pay for all days of inpatient hospital care at a participating specialty care center for medically fragile children when CDPHP and the facility mutually agree that the patient is ready for discharge to home but requires specialized home care services not available or in place, or when the patient is awaiting discharge to a residential facility but no residential facility bed is available. • CDPHP will pay for all days of residential care at a participating specialty care center when CDPHP and the facility mutually agree that the patient is ready for discharge to home but required care services are not available or in place. These services will be covered until CDPHP can identify and secure admission to an alternate provider rendering the necessary level of services.

SOURCES

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: MEDICALLY FRAGILE CHILDREN

1. Public Health Law §4406-I and §4903-a
2. Insurance Law §§ 3217-j and 4306-i
3. Other payers

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POLICY APPROVAL DATES

New: 7/23

Revised: 11/23 11/25

Reviewed: 11/24

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
12/1/2025	Policy updated to include language regarding review of out-of-network care when in plan providers cannot meet the needs of the medically fragile child.
9/1/2023* * No change to effective date for this update	Added clarification for who qualifies as a medically fragile child Select Plan/HARP section. Added exclusion regarding duplicate services.
9/1/2023	New

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MEDICAL POLICY

Medical Policy Title	**Medically Necessary Services**
Policy Number	**11.01.15**
Current Effective Date	**November 1, 2026**
Next Review Date	**October 2027**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. The Health Plan provides benefits for services that are considered **medically necessary,** that are included in the member's contract (institutional care, medical care and services, technology, tests, treatments, drugs, dental care and supplies).

II. Services will be deemed **medically necessary** only when **ALL** of the following criteria are met:

- A. Services are appropriate and consistent with the diagnosis and treatment of the patient's medical condition;
- B. Services are required for the direct care and treatment or management of the patient's condition;
- C. If not provided, the patient's medical condition would be adversely affected;
- D. Services are provided in accordance with standards of generally accepted medical practice;
- E. Services are not primarily for the convenience of the patient, the patient's family, the provider of services, or another provider;
- F. They are the most appropriate service(s), rendered in the most efficient and economical way and at the most economical level of care that can safely be provided.

III. Inpatient level of care is only **medically necessary**, when the medical symptoms or conditions are such that diagnosis and treatment cannot safely be provided in any other setting (e.g., outpatient, physician's office, or at home).

IV. **Medical necessity** of a service is determined by the Health Plan and may consider **ANY or ALL** of the following criteria:

- A. Review of the patient's medical records. When no medical records are received (e.g., clinical note from requesting provider, lab tests, imaging studies, non-operative management if appropriate), the request will be denied not medically necessary;
- B. Reports in peer-reviewed medical literature;
- C. Reports and guidelines, published by nationally recognized health care organizations, which include supporting scientific data;
- D. Professional standards of safety and effectiveness that are generally recognized in the

United States for diagnosis, care or treatment;

E. Opinions of health professionals in the generally recognized health specialty involved;

F. Opinions of the attending professional providers;

G. Any other relevant information brought to the attention of the Health Plan.

V. A prescription, order or recommendation by a provider does **NOT** make a service:

A. Medically necessary;

B. The most appropriate treatment; or

C. That it will be covered by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Under the New York Insurance Law, if a service has been authorized as medically necessary through the prior authorization process, the Health Plan may not deny a claim for the service unless the member is no longer covered on the date of service; the claim was not submitted in accordance with the contractual timeframes for submitting claims; the member's benefits are exhausted at the time the claim is received; the prior authorization was based on incomplete or inaccurate information; or there is a reasonable basis to believe that the member or provider has engaged in fraud. In the event that the Health Plan authorizes as medically necessary a course of treatment limited by number, time period or otherwise, then a request for treatment beyond the authorized course of treatment shall be deemed to be a new request, and any denial of such a request shall not be governed by the preceding sentence.

II. Determination as to a service being considered medically necessary or not medically necessary is made only through the Health Plan by an appropriate clinical peer reviewer. In most cases, a physician who is a Health Plan Medical Director acts as the clinical peer reviewer. Medical opinions of professional societies, peer review committees or other groups of physicians that are submitted for review will be evaluated. A clinical peer reviewer is a practitioner in the same profession and same or similar specialty as the practitioner who manages the care or provides the service.

III. Medical necessity determination will be based on documentation of clinical information available to provider at the time the order was created for the service. Documentation needs to support the requested service (please refer to the specific Corporate Medical Policy for the service).

DESCRIPTION

The purpose of this medical policy is to define the term "medically necessary" or "medical necessity"

and to provide clarification as to the criteria utilized by the Health Plan in determining whether requests for pre-service (e.g., prior authorization), concurrent, or post-service (e.g., initial determination, reconsideration, or appeal) approval are medically necessary.

Medically necessary, or medical necessity, is defined as health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

I. In accordance with generally accepted standards of medical practice, which are based on:
   A. Credible scientific evidence published in peer-reviewed medical literature and generally recognized by the relevant medical community when available;
   B. Physician specialty society recommendations;
   C. The views of prudent physicians practicing in relevant clinical areas;
   D. Any other clinically relevant factors; and

II. Clinically appropriate in terms of type, frequency, extent, site, and duration; and considered effective for the patient's illness, injury or disease; and

III. Not primarily for the convenience of the patient, patient's family, patient's physician, or any other health care provider; and

IV. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the patient's illness, injury or disease.

SUPPORTIVE LITERATURE

Not Applicable

PROFESSIONAL GUIDELINE(S)

Not Applicable

REGULATORY STATUS

New York Insurance Law § 3224-a establishes clear standards to ensure that health care claims are processed and paid promptly and fairly by insurers.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Multiple Codes	

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HCPCS Codes

Code	Description
Multiple Codes	

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

American Academy of Pediatrics. Essential contractual language for medical necessity in children. Policy statement. Pediatrics 2013 Aug;132(2):398-401.

Health Plan contracts.

New York State Legislature [Internet]. Insurance Law § 3224-a: Standards for prompt, fair and equitable settlement of claims for health care and payments for health care services. N.Y. Ins. Law § 3224-a (2025). [accessed 2025 Jul 30] Available from: https://www.nysenate.gov/legislation/laws/ISC/3224-A

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Medically Necessary Services.

Medicare Benefit Policy Manual [accessed 2025 Jul 30]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.

- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 7/26 **Revised**: **Reviewed**:	
Date	**Summary of Changes**
11/1/2026	• New

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

MEDICAL POLICY

Medical Policy Title	**Minimally Invasive Treatments for Benign Prostatic Hyperplasia (BPH)**
Policy Number	**7.01.104**
Current Effective Date	**October 1, 2026**
Next Review Date	**October 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Minimally invasive treatment for benign prostatic hyperplasia (BPH) is **medically appropriate** when **ALL** of the following criteria are met:

   A. Symptomatic benign prostatic hyperplasia (BPH);

   B. As an alternative to Transurethral Resection of the Prostate (TURP) when **EITHER** of the following are met:

      1. Non-surgical methods have been tried (e.g., alpha blocker, PDE5 Inhibitor, finasteride/dutasteride) for at least three (3) months; **or**

      2. The patient is unable to tolerate non-surgical treatments;

   C. With **ANY** of the following minimally invasive BPH treatments when associated criteria are met:

      1. Prostatic Urethral Lift (PUL) (i.e., UroLift)

         a. Prostate volume 30-80cc;

         b. Absence of **ANY** of the following contraindications;

            i. Obstructive middle lobe verified by cystoscopy;

            ii. Urethral conditions that may prevent insertion of delivery system into the bladder;

            iii. Signs and symptoms of a urinary tract infection;

            iv. Urinary incontinence due to incompetent sphincter; **or**

            v. Current gross hematuria;

      2. Transurethral Water Vapor Thermal Therapy II (i.e., Rezūm)

         a. 50 years of age or older; **and**

         b. Prostate volume between 30-80cc;

      3. Waterjet Ablation Therapy (Aquabeam)

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a. 45-80 years old; **and**
b. Prostate volume 30-150cc; **or**

4. Prostate Artery Embolization (PAE)
   a. Contraindication to general anesthesia must be well documented; **or**
   b. Gross hematuria from the prostate; **and**
   c. Performed by an interventional radiologist trained in this procedure.

II. The following BPH treatments are considered **investigational**, including but not limited to:
   A. Transperineal Laser Ablation (TPLA);
   B. Temporary Implantable Nitinol Device (iTIND);
   C. Drug coated balloons (e.g. Optilume).

RELATED POLICIES

Corporate Medical Policy

7.01.01 Focal Therapies for Prostate Cancer

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. The number of prostatic urethral lift implants will vary due to the unique characteristics of the prostate and prostatic urethra, but clinical data support an average of four (4) to five (5) implants per procedure.

II. PUL devices do contain nickel, patients that have a known allergy to nickel should have a discussion with their provider before consenting to the procedure.

DESCRIPTION

Benign prostatic hyperplasia (BPH) is one of the most common afflictions in the aging man. It is a histologic diagnosis defined as the proliferation of smooth muscle and epithelial cells within the transition zone of the prostate gland. The enlarged gland has been proposed to contribute to the overall lower urinary tract symptoms (LUTS) complex through direct bladder outlet obstruction (BOO) from enlarged tissue and from increased smooth muscle tone and resistance within the enlarged gland. Voiding symptoms have often been attributed to the physical presence of BOO. BPH does not necessarily require treatment. The decision to treat is based on an assessment of the impact of the symptoms on quality of life, which can be significant. Patients with persistent symptoms despite medical management may be considered for surgical treatment. The traditional standard treatment is transurethral resection of the prostate (TURP).

Prostatic Urethral Lift (PUL) (e.g. UroLift System)

Prostatic urethral lift (PUL) system (e.g. UroLift System) is a minimally invasive, that provides anterolateral mechanical traction of the lateral lobes of the prostate, opening the urethral lumen and reducing urinary obstruction. The delivery device contains a preloaded implant that deploys a permanent tensioning suture. The suture runs from the urethra to the outer prostatic capsule and serves to pull the lateral lobe of the prostate away from the urethra. Implants are delivered bilaterally to separate the encroaching lobes. Four to five implants are typically inserted, but this varies with the size and shape of the prostate. The UroLift System may be used to treat prostate glands measuring less than 80 milliliters (mL) and is implanted by a urologist in an outpatient or inpatient setting. The transurethral procedure to insert the UroLift is performed with the use of local or general anesthesia and oral sedation.

Transurethral Water Vapor Thermal Therapy (e.g. Rezūm System)

Transurethral water vapor thermal therapy has been investigated as a minimally invasive alternative to transurethral resection of the prostate. Transurethral water vapor thermal therapy is a transurethral needle ablation technique which injects radiofrequency-generated, sterile water vapor (~103 degrees C) into enlarged prostate tissue. As the steam encounters the prostatic tissue, it condenses back into water, releasing large amounts of thermal energy, disrupting the prostatic cell membranes, and leading to cell death and necrosis. It takes approximately three months for the body to reabsorb dead tissue, decreasing prostate volume and relieving LUTS. The thermal energy is confined to the prostrate, which reduces the risk of injury to other parts of the body. The procedure is performed under local anesthesia in an office or outpatient setting.

Prostate Artery Embolization (PAE)

Prostate artery embolization (PAE) is a minimally invasive outpatient procedure that involves the release of microscopic, plastic beads into the arteries that feed the prostate gland. The beads travel to the patient's prosthetic arteries, and once there, they permanently block off the blood flow that is causing the swelling in the prostate.

Transperineal Laser Ablation (TPLA)

Transperineal Laser Ablation (TPLA) is a minimally invasive procedure that involves use of a diode laser light which is passed through 300 µm optical fibers which are introduced transperineally and placed at a secure distance from urethra and bladder neck. EchoLaser Smart Interface assists easing needle positioning and increases safety. Several clinical trials are currently enrolling members for data collection.

Temporary Implantable Nitinol Device (iTIND)

Temporary implantable nitinol device (iTIND) is implanted cystoscopically and is designed to remodel the bladder neck and prostatic urethra through ischemic tissue necrosis and permanent mucosal incisions. iTIND was developed to be a truly minimally invasive, non-ablative therapy that does not carry the possible risks of leaving a permanent implant within the prostatic urethra. The iTind device expands and exerts pressure on prostatic tissue, causing ischemic necrosis, the creation of compression channels, and a remodeling of the prostatic urethra and the bladder neck. This stent-like device is left in place for only five to seven days before being removed.

Transurethral Waterjet Ablation (e.g. Aquablation)

Transurethral Waterjet Ablation (Aquablation) uses a specialized system that combines image guidance and robotics for the targeted heat-free removal of prostate tissue. The procedure is usually done with the patient under general or spinal anesthesia. Transrectal ultrasound is used throughout the procedure. A handpiece with an integrated cystoscope and ablation probe is inserted through the urethra and into the bladder. Positioning is confirmed by using visual markers on a computer screen, and the surgeon is able to plan the depth and angle of resection using the system software. Once the surgical mapping is complete, a high-speed jet of saline is delivered to the prostate at various flow rates, according to the depth of penetration needed. The ablated tissue is aspirated through ports in the handpiece and can be used for histological analysis.

Transurethral Balloon Dilatation (e.g. Optilume)

Transurethral balloon dilatation involves the insertion of a balloon catheter through the urethra into the prostatic urethra where it is inflated, theoretically pushing back prostate tissue and stretching the urethra where it has been narrowed by the prostate. An example of this includes but may not be limited to the Optilume Basic. The Optilume drug-coated balloon combines urethral dilation with circumferential topical delivery of paclitaxel.

SUPPORTIVE LITERATURE

Prostatic Urethral Lift

Roehrborn et al (2013) reported results of the L.I.F.T. (Luminal Improvement Following Prostatic Tissue Approximation for the Treatment of LUTS secondary to BPH) trial, which was the first multicenter, randomized, double-blinded trial of the prostatic urethral lift (PUL) for the treatment of LUTS secondary to BPH. Nineteen centers in three countries (United States, Canada, and Australia) enrolled 206 men, who were randomized 2:1 to treatment with either the PUL (n=140) or sham control (n=66) consisting of rigid cystoscopy. The primary endpoint was the reduction in AUASI at three months. Secondary measures included QOL, Benign Prostatic Hyperplasia Impact Index (BPHII), International Index of Erectile Function (IIEF), Male Sexual Health Questionnaire for Ejaculatory Dysfunction (MSHQ-EjD), Maximum urinary flow rate (Qmax), and PVR. Participants were followed for 12 months, with 123 PUL subjects included in the 12- month analysis. The primary endpoint was met with the PUL AUASI reduction 88% greater than sham control, 11.1 versus 5.9, respectively (p=0.003) and sustained at one year. Qmax increased 4.4 ml per second at three months and was sustained at 4.0 ml per second at 12 months, which was both clinically and statistically significant. Erectile function remained stable after the procedure. There were two serious adverse events, one clot retention and one bladder stone. Less serious adverse events (AE) (postoperative dysuria, hematuria, pain/discomfort, and urgency) were typically mild to moderate and resolved within two weeks. The authors concluded the prostatic urethral lift provides a clinically meaningful improvement in LUTS secondary to BPH and urinary flow and can be performed under local anesthesia with low morbidity and preservation of sexual function.

Sønksen et al (2015) conducted a randomized trial known as the BPH6 study, comparing PUL to TURP to determine LUTS improvement, recovery, worsening of erectile and ejaculatory function,

continence, and safety. A total of 80 men across 10 European centers received either PUL (n=45) or TURP (n=35). One patient in the PUL group was excluded from analysis for violation of the active urinary retention exclusion criteria. At 12-month follow-up, the PUL group demonstrated an average decrease of 11.4 in IPSS, while IPSS improvement after TURP was 15.4. PUL patients consistently had more rapid recovery than TURP patients (82% vs. 53% respectively). Significant improvements in IPSS, IPSS QoL, BPH II, and Qmax were observed in both groups over time. Erectile function was preserved in both PUL and TURP groups as measured by SHIM scores. The PUL group experienced an improvement in average ejaculatory score (MSHQEjD) from baseline ($p = 0.03$), but the TURP group suffered from a significant decline. For the BPH6 ejaculatory assessment, the response for the PUL group was 100%, significantly better than the 60.6% response for the TURP group ($p < 0.0001$). Continence preservation was comparable between the groups. The number of patients who experienced grade 2 and 3 adverse events was similar between groups. Of the participants who met the original BPH6 primary endpoint, 34.9% were in the PUL group and 8.6% were in the TURP group. Of the participants who met the modified BPH6 primary endpoint, 52.3% were in the PUL group and 20.0% were in the TURP group. Reintervention for failure to cure occurred in 6.8% (3/44) of PUL patients and 5.7% (2/35) of TURP patients (not significant). The authors concluded that both the PUL and TURP groups achieved significant symptom relief compared to baseline, with a superior symptom relief rate for TURP and a superior quality of recovery and preservation of ejaculatory function for PUL. Limitations include the short-medium follow-up, small sample size, and lack of blinding.

Roehrborn et al (2017) reported five-year results of the L.I.F.T. study. At five years of follow-up, data were available for 104 of 140 PUL subjects (74.3%). A total of 18 were lost to follow-up, nine died of unrelated causes; nine exited the study for other reasons. Surgical retreatment for failure to cure was 13.6%, with 4.3% receiving additional PUL implants and 9.3% undergoing TURP or laser ablation. The authors reported on two analyses, a per-protocol (PP) analysis and an intention-to-treat (ITT) analysis. A total of 72 patients were included in the PP analysis, after exclusions for protocol violations, additional BPH procedures, or treatment with BPH medication. Sustained improvements were reported based on the PP analysis in symptoms (36% IPSS), quality of life (50% QOL, 52% BPHII) and urinary flow rate (44% Qmax). No differences were seen between ITT and PP populations.

Gratzke et al (2017) reported two-year follow-up results from the BPH6 study. Over the two-year follow-up, six patients (13.6%) in the PUL group and two (5.7%) in the TURP group underwent secondary treatment for LUTS. Three additional patients discontinued study participation, resulting in 37 PUL patients and 32 TURP patients included in the two-year analysis. Significant improvements in International Prostate Symptom Score (IPSS), IPSS quality of life (QoL), BPH Impact Index (BPHII), and maximum urinary flow rate (Qmax) were observed in both groups throughout the two-year follow-up. Changes in IPSS and Qmax in the TURP group were superior to the PUL group. Improvements in IPSS QoL and BPHII score were not statistically different between the study groups. PUL resulted in superior quality of recovery, ejaculatory function preservation, and performance on the composite BPH6 index. Ejaculatory function bother scores did not change significantly in either treatment group. TURP significantly compromised continence function at two weeks and three

months. Only PUL resulted in statistically significant improvement in sleep.

Rukstalis et al (2019) reported on the MedLift study, an U.S. Food and Drug Administration (FDA) IDE extension of the L.I.F.T. randomized study designed to examine safety and efficacy of PUL for treatment of obstructive middle lobes (OML). Compared to lateral lobe subjects from the historical L.I.F.T. study, the 45 enrolled OML subjects' symptoms improved at least as much at every time point (OML range 13.5–15.9, LL range 9.9–11.1, p=0.01). The observed rate of post-procedure, device-related, serious complications was 0%, thereby achieving the primary safety composite endpoint. Published evidence, which includes the BPH6, L.I.F.T., and MedLift studies, support a clinically meaningful improvement in net health outcome.

Transurethral Water Vapor Thermal Therapy

McVary et al (2016) reported the results of a multi-center, randomized, controlled study (Rezum II study) using transurethral prostate convective water vapor thermal energy to treat LUTS associated with BPH. A total of 197 men aged 50 years and older were randomized 2:1 to thermal therapy, n=136, and control (insertion of a rigid cystoscope), n=61. The primary endpoint was an IPSS reduction at three months greater than 125% in the treatment group as compared to the control. Results showed IPSS was reduced by 50% compared with 20% reduction for control. Therapy outcomes for the treatment group, including Qmax, QoL ($p < 0.0001$) and BPHII ($p= 0.0003$), were significantly improved compared to control and sustained throughout 12 months. Two treatment subjects had three serious AEs adjudicated as procedure-related: extended urinary retention, nausea, and vomiting. The authors concluded that convective water vapor energy ablation of prostate adenomas provides statistically significant and clinically meaningful improvements within two weeks after treatment for LUTS due to BPH. Limitations of the study include the short follow-up period and small sample size.

McVary et al (2019) reported four-year outcomes of the randomized controlled trial of water vapor thermal therapy study. Out of the original 135 subjects who underwent water vapor therapy, 90 (66.7%) were included in the 48-month per protocol analysis. IPSS improvements from baseline remained consistent from the early response at three months (49.9%) to year 1 (52.2%), year 2 (50.7%), year 3 (49.7%), and year 4 (46.7%). Flowrate improvements were sustained relative to baseline, remaining significant, although an increase of 5.5 at one year to a mean 4.2 mL/s at four years was noted. Men with moderate and severe LUTS had symptomatic relief with similar IPSS improvements at four years of 46.1% and 46.9% and Qmax of 45% and 51.3%, respectively. QOL and BPH Impact Index remained improved at 43% and 52% respectively, $P <.0001$. Throughout the four years, urinary incontinence scores decreased significantly. Sexual function throughout two years after treatment shows that erectile function (IIEF) and ejaculatory function (MSHQ-EjD) scores remained unchanged but worsened at four years. At four years, surgical intervention was performed in six of 135 subjects (4.4%) including four subjects in whom a median lobe was identified but not treated. Comparatively, surgical retreatment rates for TUNA are 19.1% at three years and 14%-51% at five years. TUMT retreatment at five years is 8.9%-21%, and prostatic urethral lift procedure has a reported surgical retreatment of 10.6% at three years and 13.6% at five years. The authors concluded that water vapor thermal therapy provides effective symptom relief and improved QOL that remained durable throughout four years.

McVary et al (2021) reported his final five-year outcomes of the randomized controlled trial for water vapor thermal therapy for treatment of moderate to severe lower urinary tract symptoms secondary to benign prostatic hypertrophy (BPH). Significant improvement of lower urinary tract symptoms was observed at <3 months post-thermal therapy, remaining durable through 5 years in the treatment group. At five years, the International Prostate Symptom Score reduced 48%, quality of life increased 45%, maximum flow rate improved 44%, and the Benign Prostatic Hyperplasia Impact Index decreased 48%. Surgical re-treatment rate was 4.4% with no reports of device or procedure related sexual dysfunction or sustained de novo erectile dysfunction.

In addition, the efficacy and safety of Rezum water vapor thermal therapy was further supported through a prospective pilot study, a crossover study, and two retrospective studies where outcomes demonstrated improvements in patients International Prostate Symptom Score (IPSS), quality of life (QoL), Qmax and post void residual (PVR) without causing deterioration of sexual function.

Evidence for transurethral water vapor thermal therapy mostly consists of one small, short-term, sham controlled RCT with a five-year uncontrolled follow-up phase. LUTS improved more in the intervention group (50%) compared to sham (20%) at three months. Improvements were sustained through four years of follow-up. No adverse events of erectile or ejaculatory function were observed with scores unchanged through two years of follow-up. Based on the single, short-term, sham-controlled study with a five-year uncontrolled follow-up phase, BPH treatment with water vapor thermal therapy resulted in improved health outcomes which remained stable throughout the five years.

Prostate Artery Embolization (PAE)

Bhatia et al (2025) conducted a retrospective study evaluated the mid- to long-term safety and effectiveness of prostatic artery embolization (PAE) in 1,075 patients treated at a single center between January 2014 and July 2023. Patients had moderate-to-severe lower urinary tract symptoms (LUTS) or urinary retention who had undergone PAE. They were followed for a mean of 458.4 days and assessed at 1, 3, 6, and 12 months after PAE and thereafter. Mean prostate volume (PV) was 107 grams, and the median preprocedural IPSS was 23, QoL was 5, and IIEF-5 score was 17 and PSA level was 4.7ng/ml. In the LUTS subgroup, at 1–3, 6–12, and 48–60 months, the median IPSS values were 7, 6, and 9, respectively. Of 126 patients in the retention cohort, 119 (94%) were catheter-free at the 3-month follow-up. Up to 60 months after PAE, 90 patients (16% of reintervention eligible patients) required a second prostatic intervention. After PAE, 65.5% of patients were BPO medication–free at 1 year. Adverse events were rare, in 7 patients and resolved without lasting effects, including prostate sloughing, urosepsis and transient ischemic attacks. Overall, PAE demonstrated durable symptom relief, improved quality of life, and a favorable safety profile with sustained relief up to 60 months.

Brown et al (2024) conducted a randomized controlled trial to assess PAE as a first line therapy compared to medication in treatment of naïve men with prostate enlargement known as the P-EASY ADVANCE trial. The trial consisted of at 39 men with enlarged prostates, moderate-severe lower urinary tract symptoms and obstructed/equivocal urodynamic studies (UDS), and who had no prior treatment for BPH. They were randomized to receive either combined medical therapy or PAE.

Follow-up was conducted by assessing UDS, International Prostate Symptom Score (IPSS), uroflowmetry and ultrasound at short- to medium-term intervals and compared to baseline. Both interventions improved voiding and bladder outflow obstruction from baseline (unobstructed after PAE 63%, medication 28%). PAE patients had greater reduction in prostate size, incomplete emptying, total IPSS, and quality of life. In the medication group, altered ejaculation, erectile dysfunction and nauseas were more common. Although PAE showed to be more effective than the combined medical therapy, authors state that "further randomized comparative trials are planned to validate the role of PAE in mitigating obstructive BPH."

Müllhaupt et al (2024) conducted a randomized, open-label, single center trial of 103 patients with refractory LUTS/benign prostatic obstruction (BPO). They aimed to compare the safety and efficacy of PAE and TURP treatment at 5-year follow up. Primary outcome was the change in IPSS after PAE versus TURP. Secondary outcome included patient-reported outcomes, functional measures and adverse events. The outcomes were measured at 3, 6, 12, 24, and 60 months. Of the randomized patients with LUTS/BPO, 18/48 in the PAE group and 38/51 in the TURP group completed 5-year follow-up. Mean IPSS reduction was -7.78 for PAE and -11.57 for TURP (difference 3.79; 95% CI -0.66 to 8.24). TURP showed superior patient-reported outcomes except erectile function. At 5 years, TURP was more effective than PAE in improving urinary flow (9.30 vs 3.59 ml/s; difference -5.71) and reducing postvoid residual volume (219.97 vs 27.81 ml; difference 192.15). The study had notable limitations. Blinding of patients and physicians wasn't possible, and five patients per group were lost to follow-up. Additional dropouts left only 18 PAE and 38 TURP patients for analysis, reducing statistical power and preventing subgroup analysis. This likely contributed to the loss of significance in some comparisons at the 5-year follow-up. Furthermore, five of 20 patients who required TURP after unsatisfactory PAE outcomes could only undergo unilateral embolization, which may have impacted results. The authors state "the improvements in subjective and objective outcomes are more pronounced after TURP and thus PAE is not a definitive treatment in the long term for a relevant proportion of patients, especially those with advanced LUTS/BPO stage requiring maximum relief of bladder outlet obstruction."

Marchi et al (2023) conducted a retrospective single-center with the primary objective to assess long-term outcomes of PAE in 88 patients with acute urinary retention related to BPH. Urinary catheter was attempted at two weeks post PAE, success was defined as the absence of acute urinary retention recurrence. In the month following catheter removal 82% of patients were successful and 16% had immediate recurrence. Clinical success persisted for 66% of patients at long term follow-up (mean follow-up: 19.5 months ±16.5 [SD]; range: 2−74 months). Recurrence occurred at a mean of 16.2 months ±12.2 (SD) (range: 1.5−43 months) post-PAE. Overall, 24% patients of the cohort underwent prostatic surgery, at a mean of 10.4 months ± 12.2 (SD) (range: 1.2−42.4 months) from initial PAE. No correlations between patient variables or bilateral PAE and long-term clinical success were identified. Kaplan-Meier analysis showed a three-year catheter free probability of 60%. They state that further investigation is needed in patients with acute urinary retention (AUR) recurrence during long-term follow-up.

Carnevale et al (2020) conducted a retrospective single center study in 317 patients with moderate to severe BPH. Participants were followed for 96 months to evaluate the efficacy, and long-term results

of PAE for BPH. Participants received PAE, 94% received bilateral and 6% received unilateral. Over a median follow-up of 72 months, early clinical failure occurred in 1.9%, and 23% experienced symptom recurrence significantly higher in the unilateral group (42% vs. 21%). Average improvements included a 16-point drop in IPSS, 4-point improvement in quality-of-life score, 39 cm^3 reduction in prostate volume (39%), a 6 mL/sec increase in urinary flow (155%), and a 70 mL decrease in postvoid residual volume (48%), all statistically significant ($P < .05$). Higher baseline PSA levels were linked to lower recurrence risk (HR 0.9; 95% CI: 0.8–0.9; $P < .001$). Embolization with mixed particle sizes (100–500 µm group vs 300-500 µm group) showed no significant impact on recurrence. No patients reported urinary incontinence or erectile dysfunction. Limitations included, that early PAE procedures lacked cone-beam CT, cone-beam CT has since enhanced pelvic anatomy visualization and reduced both procedure and radiation time. Baseline IPSS was missing for men with catheters. Over 10 years, varied techniques and embolic agents were used, limiting consistency. Few patients had over five years of follow-up. The authors state that "although long-term results for PAE are promising, further investigations regarding optimal technical aspects of the procedure and patient selection are still required" stating that the data indicates it is a safe and effective procedure and has the potential to become an alternative procedure for BPH.

Transperineal Laser Ablation (TPLA)

Bianco et al (2021) presented at the 2021 American Urological Association annual meeting, the six month and twelve-month results of a study called transperineal laser ablation for benign prostatic hyperplasia (BPH): Feasibility and safety. This study was a Phase I trial, trial, whose objective was to evaluate feasibility, safety as well as three-, six- and twelve-months outcomes for TPLA. Twenty subjects were enrolled in this study. All subjects had complete lower urinary tract evaluation with pressure flow studies, international prostate symptom scores (IPSS) and sexual health inventory for men (SHIM) scores and ultrasonographic prostate volume measurements. Renal function biomarkers as well as PSA were collected. The protocol called for 2-4 Echolaser4 (Elesta Els, Italy) TPLA applications in the prostate under ultrasound guidance aided by the ELS tracing system. Although functional outcomes are pending, a 4-point median improvement in IPSS scores was seen at thirty days.

Temporary Implantable Nitinol Device (iTIND)

Kadner et al (2020) reported on the results of a single-arm, multicenter, international, prospective study that was conducted at nine sites from December 2014 to December 2016 under clinical trial NCT02145208. 81 men with symptomatic BPH (IPSS≥10, peak urinary flow <12mls/s and prostate volume < 75mls) were enrolled in this study. Kadner, et al., notes that a wash-out period of one month for alpha-blockers and six months for 5-alpha reductase inhibitors (5-ARIs) was mandatory to avoid variable confusion. The procedure was performed under light sedation with device implanted and removed five to seven days later with topical sedation. A total of 51 men completed follow up after two years. Mean Qmax and PVR were 7.62 ± 2.25 ml/s and 65.84 ± 38.46 ml at baseline, and IPSS and QoL scores were 20.51 ± 4.58 and 3.96 ± 0.87, respectively. Implantation procedures elicited average pain VAS scores of 3.2 ± 1.6 and were all technically successful with no intraoperative complications. Implants were retrieved 5.7 ± 0.9 days after deployment. All objective and subjective measures showed statistically significant improvements (p <

0.0001) from baseline levels at all assessment points. IPSS urinary symptoms were reduced by 12.00 ± 6.12 points at the end of the follow-up period. Quality of life scores reflected symptomatic relief, with patients reporting a mean reduction of 2.4 points from baseline. Maximum urinary flow rate (Qmax) rose to 16.00 ± 7.43 ml/s, an average increase of 8.38 ± 7.93 ml/s. No deterioration in PVR was observed by the end of the follow-up period. Results suggest, that iTind implantation for treatment of LUTS secondary to BPH is associated with minimal perioperative morbidity and provides rapid symptomatic and functional outcomes that are durable through 24 months follow-up. The need for reoperation or de-novo-medication is very low, except in patients with median lobes, who so far cannot be recommended for treatment. In contrast to medical and surgical alternatives, there is an indication that treatment with iTind does not pose a risk to ejaculatory and sexual functions, but this finding must be supported with further studies. The European Association of Urology guidelines acknowledge the emerging role of this device, no specific recommendation is given, and its formal role is therefore yet to be defined.

Transurethral Waterjet Ablation (Aquablation)

Aquablation for treatment of BPH has been assessed in a single RCT, known as WATER (Waterjet Ablation Therapy for Endoscopic Resection of Prostate Tissue). WATER was a noninferiority trial comparing aquablation with TURP in 181 participants at 17 sites in 4 countries. Participants were men ages 45 to 80 years with moderate-to-severe LUTS, defined as an IPSS 10 score ≥12, and prostate size between 30 and 80 cc. The primary efficacy endpoint was the difference between groups in the change in IPSS at 6 months, and the primary safety endpoint was the development of Clavien-Dindo persistent grade 1, or 2 or higher operative complications at 3 months. Primary endpoint results were reported by Gilling et al in 2018, 12-month results in Gilling et al (2019), and 3-year results in Gilling et al (2020). Additionally, a synthesis of the trial results up to 12 months was reported in a Cochrane systematic review conducted by Hwang et al (2019). On the primary efficacy outcome, aquablation was noninferior to TURP. At 6 months, mean IPSS decreased from baseline by 16.9 points for aquablation and 15.1points for TURP (mean difference 1.8 points; p<.0001 for noninferiority and p=.1347 for superiority). The primary safety endpoint rate was lower in the aquablation group compared to the TURP group (26% versus 42%, p=.0149). The rate of grade two (2) and greater events was similar in the two groups (20% for aquablation and 23%for TURP; p=.3038).

Berjaoui et al (2024) conducted a study to compare the long-term outcomes of Aqublation for small-to-moderate prostates (30-80 mL) in the WATER clinical trial, with the outcomes for large prostates (80-150 mL) in the WATER II clinical trial at a 5-year follow-up. Participants that made it to the 5-year follow up were 60 subjects from WATER II and 58 participants from WATER, just under half did not make it to the 5-year mark. Patients completed IPSS and Incontinence Severity Index (ISI) questionnaires. Also measured was uroflowmetry, PVR measurements, and standard laboratory testing. These questionnaires were repeated at months 1, 3, 6, 12, 24, 36, 48, and 60 months. PSA was repeated and 6 months and annually thereafter. Results demonstrated improvement in from baseline to 60 months in IPSS: WATER (22.9 to 7.0) and WATER II (23.2 to 6.8), Qmax: WATER (9.4 to 17.3 cc/s) and WATER II (8.7 to 17.1 cc/s). At the 5-year follow-up, patients that were medication-free for BPH (WATER: 99% and WATER II: 94%) and free from surgical retreatment

(WATER: 95%; WATER II: 97%).

Optilume

DeLong et al (2025) reported the 5-year study closeout results for the ROBUST I trial that evaluated the safety and efficacy of the Optilume drug-coated balloon (DCB) for men with short, recurrent bulbar urethral strictures. The trial consisted of 53 men with recurrent bulbar urethral strictures. The strictures were less than or equal to 2cm long and a lumen or greater that 12 French and have undergone between 1 and 4 prior endoscopic procedures, who all received the Optilume DCB. The outcomes were measured by symptom questionnaires, maximum urinary flow rate, postvoid residual, and freedom from repeat intervention. Of the 53 men, 31 completed all follow-up requirements, 58% achieved functional success at 5 years. Average IPSS improved from a mean of 25.2 at baseline to 7.2 at 5 years. 71.7% of the patients were free from repeat interventions throughout the 5 years. Urinary flow rate improved from 5.0 mL/s at baseline to 19.9mL/s. The average post void residual was reduced from 141.4 mL to 59.5 mL at 5 years. There was no serious treatment related adverse events, including erectile dysfunction. For men that wish to avoid urethroplasty based on this study Optilume is a safe and effective treatment option for appropriately selected men with recurrent bulbar urethral stricture.

Kaplan et al (2024) reported the 2-year long-term follow up from the PINNACLE study, a prospective, multicenter, randomized study that was evaluating the safety and effectiveness of the Optilume BPH catheter system. The study consisted of 148 men with symptomatic BPH, who were randomized in a 2:1 fashion to Optilume or a Sham. Success was measured by IPSS, peak urinary flow rate (Qmax), post void residual (PVR) urine, quality of life and sexual function, follow-up beyond 1 year was limited to those treated with the Optilume product. At 2 years 67.5% of participants treated with Optilume were considered symptomatic responders. Symptomatic responders are defined by ≥30% improvement in IPSS without medical or surgical retreatment. IPSS improved from 23.4 to 11.0, Qmax improved by 116.8% to 19%, PVR had a reduction (83.7 ± 70.3 (n = 99) to 65.9 ± 74.5 (n = 65)).

Kaplan et al (2024) reported the 4-year results of the prospective single arm, open-label, multicenter EVEREST clinical study. The study aimed to gather initial safety and efficacy data of the Optilume BPH Catheter System for the treatment of lower urinary tract symptoms (LUTS) secondary to BPH. The study consisted of 80 men with moderate-to-severe LUTS secondary to BPH who were treated with Optilume. Symptoms were assessed using IPSS, BPH Impact Index, Qmax and PVR. Previously reported symptom improvements were maintained through 4-year follow-up, which included reduction in IPSS and IPSS quality of life. Qmax was maintained in majority of men, with an average improvement from baseline and no adverse events were reported. Some limitations of the study include the lack of a control group and small number of participants.

PROFESSIONAL GUIDELINE(S)

The American Urological Association (AUA) guidelines for Management of Lower Urinary Tract Symptoms Attributed to BPH (Goueli 2026) state:

- TURP should be offered as a treatment option for patients with LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)
- Transurethral incision of the prostate (TUIP) should be offered as an option for patients with prostates ≤30g for the surgical treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)
- PVP should be offered as an option using 120W or 180W platforms for the treatment of LUTS/BPH. (Moderate Recommendation; Evidence Level: Grade B)
- PUL should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80g and verified absence of an obstructive middle lobe. (Moderate Recommendation; Evidence Level: Grade C)
- PUL may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)
- Water Vapor Thermal Therapy (WVTT) should be considered as a treatment option for patients with LUTS/BPH provided prostate volume 30-80g. (Moderate Recommendation; Evidence Level: Grade C)
- WVTT may be offered as a treatment option to eligible patients who desire preservation of erectile and ejaculatory function. (Conditional Recommendation; Evidence Level: Grade C)
- Robotic waterjet treatment (RWT) may be offered as a treatment option to patients with LUTS/BPH provided prostate volume 30-80g. (Conditional Recommendation; Evidence Level: Grade C)
- PAE may be offered for the treatment of LUTS/BPH. PAE should be performed by clinicians trained in this interventional radiology procedure for prostate volume of ≥50cc following a discussion of the potential risks and benefits. (Conditional Recommendation: Evidence level: Grade B)

The National Institute for Health and care Excellence (NICE) 2021 guidelines for Transurethral water jet ablation for LUTS/BPH states that evidence on transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia raises no major safety concerns. The evidence on efficacy is limited in quality. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.

The Society of Interventional Radiology (SIR) provides broader indications, recommending PAE for patients with very large prostates (>80 cc), urinary retention, desire to preserve sexual function, prostatic hematuria, and patients who are poor surgical candidates. The SIR's 2026 updated practice guidance document notes increased acceptance of PAE and its inclusion in multiple international guidelines.

REGULATORY STATUS

The Rezūm System (NxThera, Inc., Maple Grove, MN) received Section 510(k) approval from the FDA in August 2015.

The FDA indications for Rezūm System are:

- Men ≥ 50 years of age;
- Prostate volume ≥ 30 cm^3 and ≤ 80 cm^3;
- Intended to relieve symptoms, obstructions;
- Reduce prostate tissue associated with BPH;
- Treatment of prostate with hyperplasia of the central zone and/or median lobe.

In 2013, the FDA granted a de novo classification clearance for the UroLift System.

In January 2017, the FDA granted Section 510(k) clearance for the UroLift System (UL400 and UL500) for the treatment of symptoms due to urinary outflow obstruction secondary to BPH, including lateral and median lobe hyperplasia, in men 45 years of age or older.

In December 2019, the FDA modified the list of contraindications for the UroLift System (UL400) from prostate volume greater than 80 cc to prostate volume greater than 100 cc. The FDA indicated that its decision was based on clinical review of both sponsored and independent clinical studies that included men with prostate volumes greater than 80 cc, which showed that the symptom response, quality of life, uroflowmetry, adverse events, and catheterization rates were equivalent to the outcomes of patients with prostate volumes less than 80cc.

In June 2020, the FDA granted section 510(k) clearance for the UroLift Advanced Tissue Control (ATC) System. A modification of the UroLift UL400 System, where the primary difference is the addition of a wing component on the distal tip of the UL400 which provides a larger footprint. This design feature is intended to provide better mobilization of tissue when performing the UroLift System procedure.

In July 2020, the FDA granted Section 510(k) clearance for the UroLift 2 System (UL2) for the treatment of urinary outflow obstruction secondary to BPH, including lateral and median lobe hyperplasia in men 45 years of age and older. The UL2 system is substantially equivalent to previous cleared generation devices. Minor device modifications have been made to the UL2 Delivery System (Delivery handle and implant cartridge) that do not affect the overall safety and effectiveness of the UroLift procedure. No modifications have been made to the UroLift Implant.

In 2020, the FDA expanded coverage of the UroLift system to treat prostates between 80-100 ccs.

The FDA Contraindications for the UroLift System are:

- Prostate volume of >100 cc;
- Urinary tract infection (UTI);
- Urethra conditions that may prevent insertion of delivery system into bladder;
- Urinary incontinence due to incompetent sphincter;

- Current gross hematuria.

Optilume was FDA approved in 2021 for the treatment of men with urethral strictures.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0714T (E/I)	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume less than 50 mL
0867T (E/I)	Transperineal laser ablation of benign prostatic hyperplasia, including imaging guidance; prostate volume greater or equal to 50 mL
37242	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; arterial, other than hemorrhage or tumor (eg, congenital or acquired arterial malformations, arteriovenous malformations, arteriovenous fistulas, aneurysms, pseudoaneurysms) (e.g., PAE)
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction (e.g., PAE)
52284 (E/I)	Cystourethroscopy, with mechanical urethral dilation and urethral therapeutic drug delivery by drug-coated balloon catheter for urethral stricture or stenosis, male, including fluoroscopy, when performed (e.g., Optilume)
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant (e.g., PUL)

Code	Description
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure) (e.g., PUL)
52443 (E/I) 0619T Termed 12/31/25	Cystourethroscopy with initial transurethral anterior prostate commissurotomy with a nondrug-coated balloon catheter followed by therapeutic drug delivery into the prostate by a drug-coated balloon catheter, including transrectal ultrasound and fluoroscopy, when performed (Effective 01/01/26) (Replacing code 0619T) Cystourethroscopy with transurethral anterior prostate commissurotomy and drug delivery, including transrectal ultrasound and fluoroscopy, when performed
53854	Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy (e.g., Rezum)
53865 (E/I)	Cystourethroscopy with insertion of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate (effective 01/01/2025) (e.g., iTIND)
53866 (E/I)	Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate (effective 01/01/2025) (e.g., iTIND)
52597 Effective 01/01/26 0421T Termed 12/31/25	Transurethral robotic-assisted waterjet resection of prostate, including intraoperative planning, ultrasound guidance, control of postoperative bleeding, complete, including vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy, when performed (Effective 01/01/26) (Replacing code 0421T) Transurethral waterjet ablation of prostate, including control of post-operative bleeding, including ultrasound guidance, complete (vasectomy, meatotomy, cystourethroscopy, urethral calibration and/or dilation, and internal urethrotomy are included when performed)

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HCPCS Codes

Code	Description
C2596	Probe, image guided, robotic, waterjet ablation

Code	Description
C9739	Cystourethroscopy, with insertion of transprostatic implant; one to three implants
C9740	Cystourethroscopy, with insertion of transprostatic implant; four or more implants

ICD10 Codes

Code	Description
N40.1	Benign prostatic hyperplasia with lower urinary tract symptoms

REFERENCES

Abt D, et al. Prostatic artery embolisation versus transurethral resection of the prostate for benign prostatic hyperplasia: 2-yr outcomes of a randomised, open-label, single-centre trial. Eur Urol. 2021 Jul;80(1):34-42.

American Urological Association [Internet]. Benign Prostatic Hyperplasia: Surgical management of benign prostatic hyperplasia/lower urinary tract symptoms [amended 2023; accessed 2025 Sep 26]. Available from: https://www.auanet.org/guidelines-and-quality/guidelines/benign-prostatic-hyperplasia-(bph)-guideline

Arezki A, et al. Reasons to go for Rezūm steam therapy: an effective and durable outpatient minimally invasive procedure. World J Urol. 2021 Jul;39(7):2307-2313.

Bach T, et al. Aquablation Outcomes in men with LUTS due to BPH following single versus multi-pass treatments. Urology. 2022 Nov;169:167-172.

Berjaoui MB, et al. WATER versus WATER II 5-year update: Comparing Aquablation therapy for benign prostatic hyperplasia in 30-80-cm^3 and 80-150-cm^3 prostates. BJUI Compass. 2024 Sep 9;5(11):1023-1033.

Bhatia S, et al. Prostatic artery embolization: mid- to long-term outcomes in 1,075 patients. J Vasc Interv Radiol. 2025 Mar;36(3):456-466.

Bhojani N, et al. Aquablation Therapy in Large Prostates (80-150 mL) for Lower Urinary Tract Symptoms Due to Benign Prostatic Hyperplasia: Final WATER II 5-Year Clinical Trial Results. J Urol. 2023 Jul;210(1):143-153.

Bianco et al. V06-05: Transperineal laser ablation for Benign Prostatic Hyperplasia (BPH): Feasibility and safety. American Urological Association. 2021 Sept.

Brown N, et al. The 'Prostate Embolisation AS first-line therapY compAred to meDication in treatment naïVe men with prostAte eNlargement, a randomised ControllEd trial' (P-EASY ADVANCE): a randomised controlled trial of prostate embolisation vs medication for BPH. BJU Int. 2024 Dec;134 Suppl 2(Suppl 2):38-46.

Burdziak H, et al. Efficacy and safety of photoselective vaporization of the prostate using the

Greenlight XPS 180W laser and simple prostatectomy for high-volume prostate hypertrophy: a comparative analysis. Cent European J Urol. 2024;77(1):64-76.

Carnevale FC, et al. Prostatic artery embolization for the treatment of lower urinary tract symptoms due to benign prostatic hyperplasia: 10 years' experience. Radiology. 2020 Aug;296(2):444-451.

Cerrato C, et al. Prostatic stents: a narrative review of current evidence. Ther Adv Urol. 2024 May 30;16

Chughtai B, et al. The iTind temporarily implanted nitinol device for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia: A multicenter, randomized, controlled trial. Urology. 2021 Jul;153:270-276.

Davis C, et al. Development of Research Agenda in Prostate Artery Embolization: Summary of Society of Interventional Radiology Consensus Panel. J Vasc Interv Radiol. 2020 Jan;31(1):108-113.

DeLong J, et al. Long-Term Outcomes of Recurrent Bulbar Urethral Stricture Treatment with the Optilume Drug-Coated Balloon: Five-Year Results from the ROBUST I Study. J Urol. 2025 Jan;213(1):90-98.

de Rienzo G, et al. Transperineal interstitial laser ablation of the prostate, a novel option for minimally invasive treatment of benign prostatic obstruction. Eur Urol. 2021 Jul;80(1):95-103.

Dixon CM, et al. Two-year results after convective radiofrequency water vapor thermal therapy of symptomatic benign prostatic hyperplasia. Res Rep Urol. 2016 Nov 21;8:207-216.

Doppalapudi, S.K., Gupta, N. What is new with Rezūm water vapor thermal therapy for LUTS/BPH. Curr Urol Rep. 2021;22(4).

Eure G, et al. Real-world evidence of prostatic urethral lift confirms pivotal clinical study results: 2-year outcomes of a retrospective multicenter study. J Endourol. 2019 Jul;33(7):576-584.

Foster H.E, et al. Surgical management of lower urinary tract symptoms attributed to benign prostatic hyperplasia. AUA Guideline. J Urol. 2018;200:612.

Gilling P, et al. Three-year outcomes after Aquablation therapy compared to TURP: results from a blinded randomized trial. Can J Urol. 2020 Feb;27(1):10072-10079.

Gilling PJ, et al. Five-year outcomes for Aquablation therapy compared to TURP: results from a double-blind, randomized trial in men with LUTS due to BPH. Can J Urol. 2022 Feb;29(1):10960-10968.

Goueli R, et al. Management of lower urinary tract symptoms attributed to benign prostatic hyperplasia: AUA Guideline (2026) Part III: procedural/surgical management. J Urol. 2026 Aug;216(2):161-170.

Gratzke C, et al. Prostatic urethral lift vs transurethral resection of the prostate: 2-year results of the BPH6 prospective, multicentre, randomized study. BJU Int. 2017 May;119(5):767-775.

Gravas S, et al. EAU guidelines on non-neurogenic male lower urinary tract symptoms (LUTS), including benign prostatic obstruction (BPO). European Association of Urology. 2017;129–146.

Gupta N, et al. Three-year treatment outcomes of water vapor thermal therapy compared to doxazosin, finasteride and combination drug therapy in men with benign prostatic hyperplasia: Cohort data from the MTOPS trial. J Urol. 2018 Aug;200(2):405-413.

Habib E, et al. Holmium laser enucleation versus bipolar resection in the management of large-volume benign prostatic hyperplasia: A randomized controlled trial. Int J Urol. 2022 Feb;29(2):128-135.

Haroon, U.M., et al. Introduction of Rezum system technology to Ireland for treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia: a pilot study on early outcomes and procedure cost analysis. Ir J Med Sci. 2021.

Higazy A, et al. Rezum: a novel minimally invasive treatment for lower urinary tract symptoms secondary to benign prostatic hyperplasia. A review article. Int Urol Nephrol. 2021 Sep;53(9):1747-1756.

Insausti I, et al. Randomized comparison of prostatic artery embolization versus transurethral resection of the prostate for treatment of benign prostatic hyperplasia. J Vasc Interv Radiol. 2020 Jun;31(6):882-890.

Jiang YL and Qian LJ. Transurethral resection of the prostate versus prostatic artery embolization in the treatment of benign prostatic hyperplasia: a meta-analysis. BMC Urol. 2019 Jan;19(1):11.

Jung JH, et al. Prostatic urethral lift for the treatment of lower urinary tract symptoms in men with benign prostatic hyperplasia. Cochrane Database Syst Rev. 2019 May 25;5:CD012832.

Kadner G, et al. Second generation of temporary implantable nitinol device (iTind) in men with LUTS: 2-year results of the MT-02-study. World J Urol. 2020 Dec;38(12):3235-3244.

Kaplan SA, et al. Long-term outcomes after treatment with Optilume BPH Four-year results from the EVEREST study. Can Urol Assoc J. 2024 Nov;18(11):E319-E325.

Marchi A, et al. Long-term outcomes of prostate artery embolization for acute urinary retention: An analysis of 88 patients. Diagn Interv Imaging. 2023 Jun;104(6):292-296.

McVary KT, et al. Minimally invasive prostate convective water vapor energy ablation: A multicenter, randomized, controlled study for the treatment of lower urinary tract symptoms secondary to benign prostatic hyperplasia. J Urol. 2016 May;195(5):1529-1538.

McVary KT and Roehrborn CG. Three-year outcomes of the prospective, randomized controlled Rezūm system study: convective radiofrequency thermal therapy for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. Urology. 2018 Jan;111:1-9.

McVary KT, et al. Rezūm water vapor thermal therapy for lower urinary tract symptoms associated with benign prostatic hyperplasia: 4- year results from randomized controlled study. Urology. 2019 Apr;126:171-179.

McVary KT, et al. Final 5-year outcomes of the multicenter randomized sham-controlled trial of a water vapor thermal therapy for treatment of moderate to severe lower urinary tract symptoms secondary to benign prostatic hyperplasia. J Urol. 2021 Sep;206(3):715-724.

Mouli S, et al. Society of Interventional Radiology (SIR) 2026 practice guidance document for prostatic artery embolization. J Vasc Interv Radiol. 2026 Jun 1:108771.

Müllhaupt G, et al. Prostatic artery embolisation versus transurethral resection of the prostate for benign prostatic obstruction: 5-year outcomes of a randomised, open-label, noninferiority trial. Eur Urol Focus. 2024 Sep;10(5):788-795.

National Institute for Health and Clinical Excellence (NICE) [Internet]. Transurethral water jet ablation for lower urinary tract symptoms caused by benign prostatic hyperplasia. IPG770. 2023 September 14 [accessed 2025 Sep 26]. Available from: https://www.nice.org.uk/guidance/ipg770/evidence/overview-final-pdf-13136516461

National Institute for Health and Clinical Excellence (NICE) [Internet]. Insertion of prostatic urethral lift implants to treat lower urinary tract symptoms secondary to benign prostatic hyperplasia. IPG 475. 2014 Jan [accessed 2025 Sep 26]. Available from: https://www.nice.org.uk/Guidance/IPG475

National Institute for Health and Clinical Excellence (NICE) [Internet]. UroLift for treating lower urinary tract symptoms of benign prostatic hyperplasia. MTG28. 2021 May 4 [accessed 2025 Sep 26]. Available from: https://www.nice.org.uk/guidance/mtg58/resources/urolift-for-treating-lower-urinary-tract-symptoms-of-benign-prostatic-hyperplasia-pdf-64372122962629

Patel NH, et al. Device malfunctions and complications associated with benign prostatic hyperplasia surgery: Review of the manufacturer and user facility device experience database. J Endourol. 2019 Jun;33(6):448-454.

Pisco JM, et al. Randomised clinical trial of prostatic artery embolisation versus a sham procedure for benign prostatic hyperplasia. Eur Urol. 2020 Mar;77(3):354-362.

Roehrborn CG, et al. The prostatic urethral lift for the treatment of lower urinary tract symptoms associated with prostate enlargement due to benign prostatic hyperplasia: the L.I.F.T. Study. J Urol. 2013 Dec;190(6):2161-7.

Roehrborn CG, et al. Convective thermal therapy: Durable 2-year results of randomized controlled and prospective crossover studies for treatment of lower urinary tract symptoms due to benign prostatic hyperplasia. J Urol. 2017 Jun;197(6):1507-1516.

Roehrborn CG, et al. Five-year results of the prospective randomised controlled prostatic urethral L.I.F.T. study. Can J Urol. 2017 Jun;24(3):8802-8813.

Rukstalis D, et al. Prostatic Urethral Lift (PUL) for obstructive median lobes: 12-month results of the MedLift Study. Prostate Cancer Prostatic Dis. 2019 Sep;22(3):411-419.

Salem R, er al. Prostate artery embolization for lower urinary tract symptoms secondary to benign prostatic hyperplasia: results from a prospective FDA-approved investigational device exemption study. Urology. 2018 Oct;120:205-210.

Shoji S, et al. Functional outcomes of transurethral thulium laser enucleation versus bipolar transurethral resection for benign prostatic hyperplasia over a period of 12 months: a prospective randomized study. Int J Urol. 2020 Nov;27(11):974-980.

Sønksen J, et al. Prospective, randomized, multinational study of prostatic urethral lift versus transurethral resection of the prostate: 12- month results from the BPH6 study. Eur Urol. 2015 Oct;68(4):643-52.

Suarez-Ibarrola R, et al. Reasons for new MIS. Let's be fair: iTIND, Urolift and Rezūm. World J Urol. 2021 Jul;39(7):2315-2327.

Thomas JA, et al. A multicenter randomized noninferiority trial comparing greenlight-xps laser vaporization of the prostate and transurethral resection of the prostate for the treatment of benign prostatic obstruction: two-yr outcomes of the GOLIATH study. Eur Urol. 2016 Jan;69(1):94-102

Tutrone RF and Schiff W. Early patient experience following treatment with the UroLift prostatic urethral lift and Rezum steam injection. Can J Urol. 2020 Jun;27(3):10213-10219.

Tzeng M., New Endoscopic In-office Surgical therapies for benign prostatic hyperplasia: A systematic review. Eur Urol Focus. 2021 Mar 1:S2405-4569(21)00056-0.

Userovici M., et al., Prostatic urethral lift using Urolift system for benign prostatic hyperplasia: 7 years' experience. Prog Urol. 2020 Mar;30(3):147-154.

Worthington J, et al. Thulium laser transurethral vaporesection versus transurethral resection of the prostate for benign prostatic obstruction: the UNBLOCS RCT. Health Technol Assess. 2020 Sep;24(41):1-96.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Fluid Jet System Treatment for LUTS/BPH (LCD L38367) [accessed 2025 Sep 26]

Fluid Jet System Treatment for LUTS/BPH (Billing and Coding A56797) [accessed 2025 Sep 26]

Therapeutic Embolization (NCD 20.28) [accessed 2025 Sep 26]

Prostatic urethral lift is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare

coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 09/17 **Revised**: 05/21, 9/24, 1/26, 11/26 **Reviewed**: 09/18, 09/19, 9/20, 9/21, 09/22, 9/23, 9/25	
Date	**Summary of Changes**
10/1/2026	• Policy edit, Professional Guidelines section updated to reflect 2026 AUA update; PAE grade changed from C to B.
1/1/2026	• Transitioned Prostatic Urethral Lift policy, 1370/20.000493 to Lifetime HealthCare Companies policy template.
10/1/2024	• Added Exclusions section for contraindications.
6/1/2021	• Criteria updated and exclusions removed to align with American Urological Association.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

MEDICAL POLICY

Medical Policy Title	**Molecular Testing in the Management of Pulmonary Nodules**
Policy Number	**2.02.58**
Current Effective Date	**January 1, 2027**
Next Review Date	**October 2027**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Molecular testing in the management of undiagnosed pulmonary nodules by plasma-based proteomic screening, gene expression of bronchial brushings or nasal swab, and flow cytometry of sputum, are considered **investigational** in **ALL** circumstances including, but not limited to, the following tests:

   A. CyPath Lung (0406U)

   B. EarlyCDT Lung (83520)

   C. LungLB (0317U)

   D. Nodify CDT (0360U)

   E. Nodify XL2, (including the following prior generations of this test: Xpresys Lung, Xpresys Lung 2 [BDX-XL2]) (0080U)

   F. OncobiotaLUNG (0395U)

   G. ReVeal Lung Nodule Characterization (0092U)

   H. Protein Assays Utilizing Lung Cancer Analytes (PAULA's Test)

   I. Percepta Genomic Sequencing Classifier

   J. Percepta Nasal Swab

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. The Health Plan and its employees adhere to all State and Federal laws concerning the confidentiality of genetic testing and the results of genetic testing. All records, findings and results of any genetic test performed on any person shall be deemed confidential and shall not be disclosed without the written informed consent of the person to whom such genetic test relates. This information shall not be released to any person or organization not specifically authorized by the individual subject of the test or in compliance with applicable law.

II. Genetic testing is appropriate only when performed by a qualified laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and offered in a setting with adequately trained health care professionals who are qualified to provide appropriate pre- and post-test counseling.

III. Genetic testing is contract dependent. Coverage only applies to members with a valid contract; coverage is not provided for family members without a valid contract.

DESCRIPTION

Pulmonary nodules are a common clinical problem that may be found incidentally on a chest x-ray or computed tomography (CT) scan or during lung cancer screening studies of smokers. The primary question after the detection of a pulmonary nodule is the probability of malignancy, with subsequent management of the nodule based on a range of factors such as the radiographic characteristics of the nodules (e.g., size, shape, density) and patient factors (e.g., age, smoking history, previous cancer history, family history, environmental/occupational exposures). The key challenge in the diagnostic workup for pulmonary nodules is appropriately ruling in patients for invasive diagnostic procedures and ruling out patients who should forego invasive diagnostic procedures. However, due to the low positive predictive value of pulmonary nodules detected radiographically, many unnecessary invasive diagnostic procedures and/or surgeries are performed to confirm or eliminate the diagnosis of lung cancer.

Plasma-based proteomic screening, gene expression profiling of bronchial brushing or nasal swab, and flow cytometry analysis of sputum are molecular tests available for the diagnostic workup of pulmonary nodules. To rule out malignancy, invasive diagnostic procedures such as computed tomography-guided biopsies, bronchoscopies, or video-assisted thoracoscopic procedures are often required. Invasive procedures carry risk for complications ranging from post-procedure pain to pneumothorax. Molecular diagnostic tests have been proposed to aid in risk-stratifying patients to determine the need for subsequent invasive diagnostic procedures.

<u>CyPath Lung, Precision Pathology</u>

CyPath Lung is a non-invasive, sputum-based test for the early diagnosis of lung cancer. It uses a fully automated flow cytometric platform to analyze the cellular content of sputum for patients whose computed tomography (CT) results in a suspicious finding. Patients collect sputum at home over three days with the assistance of a patient coach. CyPath Lung test results stratify the patient into one of two risk groups. Those patients deemed "likely or very likely" to have cancer may benefit from aggressive intervention. Those "unlikely or very unlikely" to have a malignancy may continue imaging surveillance. CyPath Lung reveals the lung micro-environment by automated analysis of sputum using flow cytometry to characterize cell populations indicative of cancer in the lung. CyPath Lung labels a person's sputum sample with fluorescent antibodies that uniquely identify different cell types and a fluorescent porphyrin called TCPP that preferentially binds to cancer cells and cancer-related cells. TCPP fluoresces a bright red color when attached to cancer cells and cancer-associated cells that are visible when the sample is run through a flow cytometer. CyPath Lung uses automated analysis that looks for pre-set parameters that are predictive of cancer, one of which is the presence of cells that

have taken up greater amounts of the TCPP porphyrin label. This test is intended for use after lung cancer screening to improve early-stage lung cancer diagnosis.

EarlyCDT Lung, Oncimmune

EarlyCDT-Lung is a serum-based test that measures autoantibodies (p53, NY-ESO-1, CAGE, GBU4-5, HuD, MAGE A4, and SOX2) associated with small cell and non-small cell lung cancer (NSCLC). Positive results are reported as 'positive-moderate' if at least one (1) of the seven (7) autoantibodies is elevated above a predetermined 'low' threshold, but all are below the 'high' threshold. If at least one (1) of the seven (7) autoantibodies is elevated above the 'high' predetermined threshold, the test is reported as 'positive-high'. EarlyCDT Lung is proposed as a 'rule-in' test to be used in addition to standard care for the detection of lung cancer. The estimated post-test risk is intended to help clinicians make decisions about further testing or intervention. High-risk individuals with a positive EarlyCDT-Lung would have additional testing such as a CT scan or the test would be used as a follow-up test for indeterminate lung nodules identified by CT.

LungLB, LungLife AI

The LungLB test is a 4-color fluorescence in-situ hybridization (FISH) assay employed to detect early circulating tumor cells (CTCs) from peripheral blood draw. This assay was developed as a FISH-based liquid biopsy test utilizing DNA FISH to validate identification of CTC to assist in the clinical assessment of individuals with indeterminate nodules suspicious for lung cancer. LungLB uses a predictive algorithm to generate an evaluation reported as a decreased or increased risk for lung cancer.

Nodify CDT, Biodesix

Nodify CDT test aims to detect early-stage lung cancer in an individual who is at moderate to high-risk. The test measures seven (7) autoantibodies (CAGE, GBU4-5, HuD, MAGE A4, NY-ESO-1, p53 and SOX-2) that are claimed to be associated with tumor antigens to help detect lung cancer. The test aims to help physicians identify lung nodules that are likely malignant or at higher risk of cancer. Invasive diagnostic procedures would be indicated for patients with a "high level" Nodify CDT test result.

Nodify XL2, Biodesix
(including prior generations of this test: Xpresys Lung, Xpresys Lung 2 [BDX-XL2])

Nodify XL2 test aims to identify those patients whose pulmonary nodules have a high likelihood of being benign, and those who may be better candidates for non-invasive computed tomography (CT) surveillance versus surgical resection. This test utilizes plasma and an integrated classifier that measures the ratio of two (2) proteins (LG3BP and C163A) combined with several clinical and radiological factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location) to report a categorical probability of malignancy.

The Nodify XL2 and Nodify CDT tests are therefore only used in the management of pulmonary nodules to rule out or rule in, invasive diagnostic procedures; they do not diagnose lung cancer. These tests are offered together as Biodesix's Nodify Lung testing strategy, but physicians may also choose to order each test independently.

OncobiotaLUNG, Micronoma

OncobiotaLUNG is a blood test used to measure microbial DNA by NGS, carcinoembryonic antigen and osteopontin by immunoassay. It is purported to detect malignancy risk for lung nodules in early-stage disease by microbiome-driven, liquid biopsy assay and categorize nodules as being high-risk or low-risk.

ReVeal Lung Nodule Characterization, MagArray

ReVeal Lung Nodule Characterization is a plasma-based protein biomarker test that may aid clinicians in characterizing indeterminate pulmonary nodules (4-30 mm) in current smokers aged 25 years and older. The test uses immunoassay, microarray, and magnetic nanoparticle detection techniques. The ReVeal Lung Nodule Characterization score is presented on a scale from 0 to 100 with a single cut point at 50, and the score is calculated using an algorithm based on the measurement of 3 clinical factors (smoking history, individual age, nodule size) and 3 blood proteins (epidermal growth factor receptor [EGFR], prosurfactant protein B (ProSB), tissue inhibitor of metalloproteinases 1 (TIMP1)) associated with the presence of lung cancer. This result may aid in making the decision to perform a biopsy, or to consider routine monitoring. REVEAL Lung Nodule Characterization is a risk assessment tool, which is to be used only in conjunction with standard clinical assessments. The test is not intended to be a screening or stand-alone diagnostic assay.

Protein Assays Utilizing Lung Cancer Analytes (PAULA's Test), Genesys Biolabs

PAULA's Test is a biomarker blood test for lung cancer. It is for people at high-risk for lung cancer due to a long term smoking history. This test aims to provide a risk score for lung cancer by measuring serum levels of several cancer markers. These marker tests include CEA (carcinoembryonic antigen), CA 125 (carbohydrate antigen 125), CYFRA 21-1 (cytokeratin-19 fragment 21-1) and NY-ESO-1, an autoantibody (New York esophageal cancer-1). A risk calculating algorithm utilizes machine learning technology to combine the tumor biomarker test values with relevant clinical factors (age, smoking history, and prior lung ailments) to generate a composite score categorizing the risk that the patient has LC. This risk score correlates to the likelihood of having cancer as low, medium, and high.

Percepta Genomic Sequencing Classifier, Veracyte

The Percepta Bronchial Genomic Classifier is a 23-gene, gene expression profiling test that analyzes genomic changes in the airways of current of former smokers to assess an individual's risk of having lung cancer, without the direct testing of a pulmonary nodule. The test is performed with the bronchial brushings collected during bronchoscopy for the diagnosis of suspected lung cancer following indeterminate cytology results. The test aim is to stratify the clinical risk for malignancy and eliminate the need for invasive diagnostic procedures.

Percepta Nasal Swab, Veracyte

The Percepta Nasal Swab test is a nasal genomic classifier that aims assess risk of malignancy in current or former smoking individuals with lung nodules found on CT. The test results are reported as low risk for cancer and continue to monitor with LDCT, moderate risk and to consider non-surgical tissue sampling, or high-risk for cancer and to consider sending patients for surgery and/or

treatment. The Percepta Nasal Swab test was built upon foundational "field of injury" science - through which genomic changes associated with lung cancer can be found in the airways of current and former smokers. Veracyte began making the test available to a limited number of medical centers in October 2021.

SUPPORTIVE LITERATURE

Plasma-Based Proteomic Screening

Silvestri et al (2018) reported the validation of the Xpresys Lung version 2/Nodify XL2 (BDX-XL2) in a prospective multicenter observational study (PulmonAry NOdule Plasma proTeomIc Classifier [PANOPTIC]) that enrolled 685 patients with eight (8) to 30 mm lung nodules. After exclusions, 178 patients remained with a low pretest probability of malignancy ≤50% and were included in the study population. There were 149 benign lung nodules and 29 malignant lung nodules in the study. Of these, 66 were classified as "likely benign", 65 of which had a benign nodule, resulting in 44% of benign lung nodules (65 of 149) being correctly labeled "likely benign," while one (1) of 29 malignant nodules (3%) was misclassified as "likely benign". Of the 71 patients who had invasive procedures, 42 had benign nodules. Use of the integrated proteomic classifier would have reduced the number of patients undergoing an invasive procedure to 27, a 36% relative risk reduction, with one (1) malignant nodule misclassified as benign. Of note, 88 patients were reported to be without follow-up CT scan data at one (1) year and the investigators called for a two (2) year follow up.

Tanner et al (2021) performed an extended analysis and 2-year follow-up of the 392 patients included in the PANOPTIC study. Of the 178 patients with a physician pretest probability of malignancy < 50%, 149 (84%) were benign at year one (1). At year two (2), 17 patients who were categorized as benign previously, were lost to follow up and were excluded reducing the number of patients with benign nodules to 132 at the two (2) year interval and leaving a total of 161 patients (90%) with data available for analysis. All nodules designated as benign at year one (1) remained benign by imaging (e.g., stable or resolved) at year two (2) with no change in pathologic diagnoses or nodule size by CT. Additionally, the area under the curve of the integrated classifier was 0.76 (95% CI, 0.69 to 0.82), which outperformed the physician pretest probability for malignancy (0.69; 95% CI, 0.62 to 0.76) and the Mayo (0.69; 95% CI, 0.62 to 0.76), Veterans Administration (0.6; 95% CI, 0.53 to 0.67), and Brock (0.71; 95% CI, 0.63 to 0.77) models in the lower risk pretest probability (≤ 50%) cohort.

Tahvilian et al (2023) conducted a prospective correlational study of 151 participants from Mount Sinai Hospital (n = 83) and MD Anderson Cancer Center (n = 68), who were scheduled for a pulmonary biopsy and then enrolled to have a LungLB blood test. Participants enrolled in this study were followed for nine (9) to 24 months following biopsy to confirm malignant or benign diagnosis using standard of care procedures at each site, including CT-based surveillance, repeat biopsy, and/or surgery. Of these 151 participants, 112 participants were diagnosed with malignant lung lesions and 39 participants with benign lung lesions based on blinded nodule biopsy results. LungLB achieved 77% sensitivity and 72% specificity with an AUC of 0.78 for predicting lung cancer in the associated needle biopsy. The clinical trial was limited due to small sample size and COVID-related diagnostic delays. The researchers noted one of the two study sites, MD Anderson Cancer Center, is

in a region with higher incidence of fungal histoplasmosis infections. In this cohort 11 (28.2%) of 39 participants with benign lesions had infectious etiology. Additional studies of the LungLB test are warranted.

Gene Expression Analysis

Vachani et al (2016) reported on rates of invasive procedures from two multicenter trials of patients undergoing bronchoscopy for suspected lung cancer, Airway Epithelium Gene Expression in the Diagnosis of Lung Cancer cohorts (AEGIS I and II). Of 222 patients with low and intermediate pretest probability of cancer, 188 (85%) had an inconclusive bronchoscopy and follow-up procedure data available for analysis. Seventy-seven (41%) patients underwent an additional 99 invasive procedures, which included surgical lung biopsy in 40 (52%) patients. Benign and malignant diseases were diagnosed in 62 (81%) and 15 (19%) patients, respectively. Among those undergoing surgical biopsy, 20 (50%) were performed in patients with benign disease. If the classifier had been used to guide decision-making, procedures could have been avoided in 21 of 42 (50%) of patients undergoing further invasive testing. Among 35 patients with an inconclusive index bronchoscopy who were diagnosed with lung cancer, the sensitivity of the classifier was 89%, with 4 (11%) patients having a false-negative classifier result and may have experienced a delayed diagnosis. The study was limited to 12 months of follow up after the index bronchoscopy. In addition, physicians were blinded to results of the classifier so the impact of the classifier on their decision making was unable to be evaluated. In some patients with a negative classifier result, physicians may still choose to proceed with further invasive testing.

Mazzone et al (2022) conducted a prospective, multicenter, blinded, clinical validation study of 412 patients who were current or former smokers and were undergoing bronchoscopy for suspected lung cancer from the AEGIS I and II trails and the Percepta Registry. The prevalence of malignancy was 39.6% and the ability of the classifier to decrease unnecessary invasive procedures was estimated. Overall, 29% of intermediate-risk lung lesions were down-classified to low-risk with a 91.0% negative predictive value (NPV) and 12.2% of intermediate-risk lesions were up-classified to high-risk with a 65.4% positive predictive value (PPV). In addition, 54.5% of low-risk lesions were down-classified to very- low-risk with > 99% NPV and 27.3% of high-risk lesions were up-classified to very high risk with a 91.5% PPV. If the classifier results were used in nodule management, 50% of patients with benign lesions and 29% of patients with malignant lesions undergoing additional invasive procedures could have avoided these procedures. The study was limited to patients with a history of smoking and the follow up period was only 12 months to determine benign status. Additional prospective clinical utility studies would be helpful to further establish the benefits and performance of the classifier in real-world settings.

Flow Cytometry Analysis of Sputum

Lemieux et al (2023) conducted a prospective, multicenter clinical trial of CyPath Lung that evaluated sputum of smokers or former smokers enrolled in a cancer cohort and a non-cancer cohort. Initially 171 sputum samples were analyzed but the study only reports on 150 samples that passed quality control. An analysis pipeline combining automated flow cytometry data processing with machine learning was developed to distinguish cancer from non-cancer samples from 150 patients at high risk of whom 28 had lung cancer. Flow data and patient features were evaluated to identify predictors of

lung cancer. The final model was evaluated on a second, independent group of 32 samples, including six (6) samples from patients diagnosed with lung cancer. Automated analysis combined with machine learning resulted in a predictive model that achieved an area under the ROC curve (AUC) of 0.89 (95% CI 0.83–0.89). The sensitivity and specificity were 82% and 88%, respectively, and the negative and positive predictive values 96% and 61%, respectively. Importantly, the test was 92% sensitive and 87% specific in cases when nodules were < 20 mm (AUC of 0.94; 95% CI 0.89–0.99). Testing of the model on an independent second set of samples showed an AUC of 0.85 (95% CI 0.71–0.98) with an 83% sensitivity, 77% specificity, 95% negative predictive value and 45% positive predictive value. This manufacturer's clinical trial is limited by the small, non-diverse sample size and a lack of long term follow up of the non-cancer cohort to confirm they were cancer-free.

Based on the review of the peer reviewed literature, while trial results are promising, further clinical trials are indicated to assess the impact on population health outcomes and clinical decision making. Long-term follow up is needed on these tests to be able to assess their effectiveness in detecting early cancer and risk stratifying indeterminate pulmonary nodules to prevent unnecessary invasive procedures.

PROFESSIONAL GUIDELINE(S)

Currently, professional societies including the American Lung Association, the National Comprehensive Cancer Network (NCCN), and the National Institute for Health and Care Excellence (NICE) do not recommend the use of molecular testing in the management of pulmonary nodules.

U.S. Preventive Service Task Force recommendations (2021) state potential screening modalities that are not recommended because they have not been found to be beneficial include sputum cytology, chest radiography, and measurement of biomarker levels. The paper notes that research is needed to identify biomarkers that can accurately identify persons at high-risk is needed to improve detection and minimize false-positive results.

The American Thoracic Society (ATS) published a position statement on the evaluation of molecular biomarkers for the early detection of lung cancer (Mazzone 2017). They state to support the application of molecular biomarkers in these clinical settings there must be evidence that the molecular biomarker leads to clinical decisions whose benefits outweigh their harms. Although it is tempting to apply novel testing based on promising discovery or validation level studies, the lung cancer community should insist on additional evidence of clinical utility before changing practice. In 2021, ATS published their Core Curriculum adult pulmonary medicine update regarding thoracic oncology which states the use of artificial intelligence with radiomics or integrating artificial intelligence into analysis of genomic, plasma biomarker, biopsy staining pattern, and other patient-derived data are currently under investigation (Garrison 2021). Recent studies have focused on molecular biomarkers to further risk-stratify nodules, but additional clinical utility studies are needed.

REGULATORY STATUS

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service; laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA). Xpresys Lung 2, now Nodify XL2 (BDX-XL2; Integrated

Diagnostics [Indi], purchased by Biodesix); Nodify CDT (Biodesix); REVEAL Lung Nodule Characterization (MagArray); and Percepta Genomic Sequencing Classifier (Veracyte) are available under the auspices of the CLIA. Laboratories that offer laboratory-developed tests must be licensed by the CLIA for high-complexity testing. To date, the U.S. Food and Drug Administration (FDA) has chosen not to require any regulatory review of these tests.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0080U (E/I)	Oncology (lung), mass spectrometric analysis of galectin-3-binding protein and scavenger receptor cysteine-rich type 1 protein M130, with five clinical risk factors (age, smoking status, nodule diameter, nodule-spiculation status and nodule location), utilizing plasma, algorithm reported as a categorical probability of malignancy (BDX-XL2, Biodesix, Inc) [Nodify XL2]
0092U (E/I)	Oncology (lung), three protein biomarkers, immunoassay using magnetic nanosensor technology, plasma, algorithm reported as risk score for likelihood of malignancy (REVEAL Lung Nodule Characterization, MagArray, Inc)
0317U (E/I)	Oncology (lung cancer), four-probe FISH (3q29, 3p22.1, 10q22.3, 10cen) assay, whole blood, predictive algorithm-generated evaluation reported as decreased or increased risk for lung cancer (LungLB, LungLife AI)
0360U (E/I)	Oncology (lung), enzyme-linked immunosorbent assay (ELISA) of 7 autoantibodies (p53, NY-ESO-1, CAGE, GBU4-5, SOX2, MAGE A4, and HuD), plasma, algorithm reported as a categorical result for risk of malignancy (Nodify CDT, Biodesix, Inc)
0395U (E/I)	Oncology (lung), multi-omics (microbial DNA by shotgun next-generation sequencing and carcinoembryonic antigen and osteopontin by immunoassay), plasma, algorithm reported as malignancy risk for lung nodules in early-stage disease (OncobiotaLUNG, Micronoma)
0406U (E/I)	Oncology (lung), flow cytometry, sputum, 5 markers (meso-tetra [4-carboxyphenyl] porphyrin [TCPP], CD206, CD66b, CD3, CD19), algorithm reported as likelihood of lung cancer (CyPath Lung, Precision Pathology Services)

Code	Description
83520 (*E/I)	Immunoassay for analyte other than infectious agent antibody or infectious agent antigen; quantitative, not otherwise specified *E/I when utilized for EarlyCDT lung
81599	Unlisted multianalyte assay with algorithmic analysis
81479 (*E/I)	Unlisted molecular pathology procedure *E/I when utilized for Genesys Biolab's Protein Assays Utilizing Lung Cancer Analytes (PAULAs Test), Veracyte's Percepta Genomic Sequencing Classifier, and Veracyte's Percepta Nasal Swab

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
R91	Abnormal findings on diagnostic imaging of lung
R91.1	Solitary pulmonary nodule
R91.8	Other nonspecific abnormal finding of lung field
Z12.2	Encounter for screening for malignant neoplasm of respiratory organs

REFERENCES

American Lung Association [Internet]. Lung Cancer Screening Resources. [accessed 2025 Sep 9]. Available from: https://www.lung.org/lung-health-diseases/lung-disease-lookup/lung-cancer/screening-resources

Feng X, et al. Lung cancer risk discrimination of prediagnostic proteomics measurements compared with existing prediction tools. J Natl Cancer Inst. 2023 Sep;115(9):1050-1059.

Garrison GW, et al. ATS Core Curriculum 2021. Adult Pulmonary Medicine: Thoracic Oncology. ATS Sch. 2021 Sep;2(3):468-483.

Lemieux ME, et al. Detection of early-stage lung cancer in sputum using automated flow cytometry and machine learning. Respir Res. 2023 Jan 21;24(1):23.

Marmor HN, et al. Biomarkers in lung cancer screening: a narrative review. Curr Chall Thorac Surg. 2023 Feb 25;5:5.

Mazzone P, et al; AEGIS Study Team; Percepta Registry Investigators. Clinical validation and utility of Percepta GSC for the evaluation of lung cancer. PLoS One. 2022 Jul 13;17(7):e0268567.

Mazzone PJ, et al; ATS Assembly on Thoracic Oncology. Evaluating molecular biomarkers for the early detection of lung cancer: when is a biomarker ready for clinical use? an official American Thoracic Society Policy Statement. Am J Respir Crit Care Med. 2017 Oct 1;196(7):e15-e29.

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology. Lung cancer screening. V1.2025. October 14, 2024 [accessed 2025 Sep 9]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/lung_screening.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology. Non-Small Cell Lung Cancer. V.8.2025. 2025 Aug 15 [accessed 2025 Sep 9]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology. Small cell lung cancer. V1.2026. July 25, 2025 [accessed 2025 Sep 9]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf

National Institute for Health and Care Excellence (NICE) [Internet]. Diagnostics guidance: EarlyCDT Lung for assessing risk of lung cancer in solid lung nodules (DG46). 2022 Feb 23 [accessed 2025 Sep 9]. Available from: https://www.nice.org.uk/guidance/dg46/chapter/1-Recommendations

Ostrin EJ, et al. Biomarkers for lung cancer screening and detection. Cancer Epidemiol Biomarkers Prev. 2020 Dec;29(12):2411-2415.

Pritchett MA, et al.; ORACLE Study Investigators. Assessing a biomarker's ability to reduce invasive procedures in patients with benign lung nodules: results from the ORACLE study. PLoS One. 2023 Jul;18(7):e0287409.

Silvestri GA, et al; PANOPTIC Trial Team. Assessment of plasma proteomics biomarker's ability to distinguish benign from malignant lung nodules: results of the PANOPTIC (pulmonary nodule plasma proteomic classifier) trial. Chest. 2018 Sep;154(3):491-500.

Tahvilian S, et al. The presence of circulating genetically abnormal cells in blood predicts risk of lung cancer in individuals with indeterminate pulmonary nodules. BMC Pulm Med. 2023 Jun 5;23(1):193.

Tanner NT, et al. Assessment of integrated classifier's ability to distinguish benign from malignant lung nodules: Extended analyses and 2-year follow-up results of the PANOPTIC (pulmonary nodule plasma proteomic classifier) trial. Chest. 2021 Mar;159(3):1283-1287.

US Preventive Services Task Force; Krist AH, et al. Screening for lung cancer: US preventive services task force recommendation statement. JAMA. 2021 Mar;325(10):962-970.

Vachani A, et al. Clinical utility of a bronchial genomic classifier in patients with suspected lung cancer. Chest. 2016 Jul;150(1):210-8.

SEARCH TERMS

CyPath Lung, Early CDT Lung, Nodify CDT, Nodify XL2, Xpresys Lung, Xpresys Lung 2, BDX-XL2, OncobiotaLUNG, ReVeal Lung Nodule Characterization, Protein Assays Utilizing Lung Cancer Analytes (PAULAs Test), Percepta Genomic Sequencing Classifier, Percepta Nasal Swab

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based upon review, molecular testing for the management of pulmonary nodules is not addressed in a National or Regional Medicare coverage determinations or policies.

Please refer to the Medicare Managed Care Manual [accessed 2025 Sep 9] Available from: 100-16 | CMS Medicare Managed Care Manual

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	Original effective date

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: MOMETASONE FUROATE SINUS IMPLANTS

Policy Effective Date:	8/1/2022
Policy Control #:	1370/20.000501
Next Annual Review:	July, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

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PROCEDURE CODES

31299 - Unlisted procedure, accessory sinuses (when specified as insertion of drug-eluding implant)

31237 - Nasal/sinus endoscopy, surgical; with biopsy, polypectomy or debridement (separate procedure)

J7402 - Mometasone furoate sinus implant, 10 micrograms (Sinuva™)

C2625, S1091 - Stent, non-coronary, temporary, with delivery system (Propel™)

DESCRIPTION

Sinuva® is a second-generation, bioabsorbable, corticosteroid-releasing sinus implant. It is composed of 1,350 micrograms mometasone furoate that is gradually released over 90 days. It is inserted into the ethmoid sinus by physicians trained in otolaryngology. The insertion procedure is performed during an office visit, and is considered an alternative to revision surgery for the treatment of recurrent nasal polyps in adults who have undergone previous ethmoid sinus surgery. Over time, as the implant softens and polyps decrease, the implant may be expelled out of the nose on its own or with actions such as sneezing or forceful nose blowing. The implant can be removed 90 days after placement, or earlier at the physician's discretion.

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The Propel sinus implant is composed of a bioabsorbable co-polymer and contains 370 micrograms of mometasone furoate, an anti-inflammatory steroid. The implant is inserted by a physician under endoscopic visualization using a proprietary delivery system to access the frontal or maxillary sinus ostium and deploy the implant. The Propel Contour implant is designed to be self-retaining against the mucosa of the sinus ostium in order to maintain sinus patency. Propel Contour releases mometasone furoate directly to the mucosa; the implant is completely bioabsorbable.

POSITION STATEMENT

CDPHP considers mometasone furoate sinus implant (Sinuva®) medically necessary when *all* of the following criteria are met:

- The member must have a diagnosis of recurrent nasal polyps.
- The member has had ethmoid sinus surgery and has nasal obstruction/congestion symptoms despite use of intranasal steroid irrigations or sprays.
- The member must be 18 years of age or older.
- The member has had previous treatment, contraindication, or intolerance to conventional nasal polyp therapy (such as leukotriene receptor antagonist, steroid taper, and/or intranasal steroids).
- The member has documented nasal allergies, or if allergy testing is negative, evaluation for aspirin-exacerbated respiratory disease (AERD) has been considered.

The use of a mometasone furoate sinus implant (Propel™) is considered medically necessary following functional endoscopic sinus surgery (FESS) when the following criteria are met:

- Patient is ≥ 18 years of age; *and*
- Ethmoid sinus surgery is planned

POLICY CONSIDERATIONS

The mometasone furoate implantation procedure will be covered under the medical portion of the contract.

The Sinuva/Propel sinus implant is loaded into a delivery system and placed under endoscopic visualization by a trained otolaryngologist in an office setting, ambulatory surgery center or hospital setting.

To report endoscopic placement of Sinuva™ in the ethmoid sinus in conjunction with biopsy, polypectomy, or debridement, report CPT code 31237, nasal endoscopy, surgical, with biopsy, polypectomy, or debridement.

EXCLUSIONS

CDPHP considers a mometasone furoate sinus implant experimental and investigational for

POLICY NAME: MOMETASONE FUROATE SINUS IMPLANTS

indications other than those stated in this policy due to insufficient evidence in peer-reviewed literature.

The use of a mometasone furoate nasal implant should be avoided in individuals with a known hypersensitivity to mometasone furoate or with nasal ulcers or trauma**.**

According to the Food and Drug Administration (FDA) approved labeling and Sinuva package insert, repeat administration of Sinuva has not been studied and therefore, is not covered.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy. The mometasone furoate sinus implant is not Part D-eligible.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. CDPHP Board Certified Consultants
2. American Academy of Otolaryngology-Head and neck Surgery Position Statement: The Use of Biomaterials in Sinonasal Procedures, September 26, 2015 https://www.entnet.org/content/position-statement-use-biomaterials-sinonasal-procedures
3. American Rhinologic Society Position Statement on Drug –Eluding Implants, September 14, 2016, https://www.american-rhinologic.org/index.php?option=com_content&view=article&id=32:drug-eluting-implants&catid=26:position-statements&Itemid=197
4. Hayes, Inc., Search & Summary Report: Sinuva (Intersect ENT, Inc.) Bioabsorbable Steroid-Releasing Sinus Implant for the Treatment of Nasal Polyps after Ethmoid Sinus Surgery, February 26, 2019
5. Food & Drug Administration (FDA) Approval & Labeling: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/209310Orig1s000ltr.pdf https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/209310Orig1s001ltr.pdf https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/209310lbl.pdf
6. Intersect ENT, Inc., Sinuva (mometasone furoate) implant. Manufacturer Prescribing Information, https://www.intersectent.com/technologies/
7. Other payers
8. Bhattacharyya N. Clinical presentation, diagnosis, and treatment of nasal obstruction. Up-to-date [online serial]. Waltham, MA: Up-to-date; reviewed May 2018.
9. Kern RC, Stolovitzky JP, Silvers SL, et al; RESOLVE II study investigators. A phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps. Int

Forum Allergy Rhinol. 2018;8(4):471-481. https://www.ncbi.nlm.nih.gov/pubmed/29350840

10. Forwith KD, Han JK, Stolovitzky JP, et al. RESOLVE: bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis after sinus surgery: 6-month outcomes from a randomized, controlled, blinded study. Int Forum Allergy Rhinol. 2016;6(6):573-81. https://www.ncbi.nlm.nih.gov/pubmed/26992115

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POLICY APPROVAL DATES

New: 07/19

Revised: 09/19, 01/20, 7/20, 09/20, 5/21, 7/22

Reviewed: 7/21, 7/23, 7/24, 7/25, 7/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update

8/1/2022	Clarified in the exclusions that repeat use of Sinuva is not covered.
	
	Under Propel, removed the following criteria:
	• Patient has one or more of the following conditions:
	  • Mucosal inflammation
	  • Failed prior surgery and/or restenosis
	  • Absolute or relative contraindication to systemic steroids

4/1/21	Removed termed code J7401 and replaced with new code J7402. Removed termed code C9122. Added new code S1091 for Propel®

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POLICY NAME: MOMETASONE FUROATE SINUS IMPLANTS

1/1/21	Policy updated to reflect mometasone furoate sinus implant may be performed in an office, ambulatory surgery center, or hospital setting.
7/1/2020	New HCPCS code C9122 (mometasone furoate sinus implant, 10 micrograms, Sinuva®) added to policy.
51/2020	Added statement in Policy Considerations regarding the proper reporting of endoscopic placement of Sinuva™ in conjunction with biopsy, polypectomy, or debridement.
1/1/2020	Propel™ sinus implant added to Description section. Criteria for coverage of Propel™ added to Application section. Statements regarding correct placement and place of service for the Propel™ and Sinuva® sinus implants added to the Policy Considerations section.

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Background

Hemophilia is an X-linked recessive genetic bleeding disorder that decreases the number of clotting factors to decrease the ability of the person to clot during a bleed. Although the majority of the population affected is male passed on from the mother, if she is a carrier of the gene, about 1/3 of all new cases are also caused by a spontaneous mutation or change in gene.

Hemophilia A is associated with a decrease in the production of clotting factor VIII and is the more common of the two types, affecting about 95% of all hemophiliacs. Hemophilia B is associated with a decrease in clotting factor IX that affects only about 5% of hemophiliacs. Hemophilia can vary from mild to severe depending on the amount of decreased factor levels and resulting bleeding complications can lead to long-term morbidity from joint damage due to recurrent bleeds. Standard treatment of hemophilia is usually with an infusion of factor VIII or IX and can either be in response to a bleeding event (episodic) or scheduled to prevent bleeds (prophylactic).

In 30-35% of patients with hemophilia A and in 1-5% of patients with hemophilia B, a neutralizing antibody, known as an inhibitor (against factor VIII in hemophilia A, and factor IX in hemophilia B) forms as an immune-based response to attack the infused factor and puts patients at increased risk of complications and death from uncontrolled bleeding. Testing for inhibitors in patients with hemophilia should always be done at least twice a year or after any treatment with factor replacement that inadequate response.

Treatment Overview

The cornerstone of management for both hemophilia A and B is to replace the deficient coagulation factor either through episodic (on-demand) treatment which is replacement factor given at the time of bleeding or through continuous prophylaxis which is replacement factor given to prevent bleeding. Patients can develop antibodies to factor products, known as inhibitors. Inhibitors render factor inactive (infused factor is seen as a foreign protein). Inhibitor development (both low and high titer inhibitors) can greatly interfere with the ability to treat bleeding and achieve adequate hemostasis. High titer inhibitors bind to exogenously administered replacement factor and prevent it from achieving hemostasis.

According to the 2020 World Federation of Hemophilia (WFH) guidelines for the management of hemophilia, prophylaxis with factor products are considered standard of care for those with severe hemophilia A to prevent bleeding. Hemlibra is noted alongside traditional factor replacement concepts for management, and importantly notes that it is not intended to treat acute bleeding episodes, which do require treatment with factor replacement (as this therapy does not replace the missing coagulation factor). The aforementioned guidelines do also note that caution is required when treating breakthrough bleeding episodes while on Hemlibra, as several patients developed either venous thromboembolism or thrombotic microangiopathy with concomitant administration of activated prothrombin complex concentrate (aPCC), in accordance with the above noted FDA Black Box Warning.

Since the most recent World Federation of Hemophilia guidelines were published, two new non-factor therapies have been approved by the FDA for the prevention of bleeding events in patients with both hemophilia A and hemophilia B.

Episodic versus Prophylactic Therapy

Episodic (on-demand) treatment has been shown to be clinically inferior to prophylactic therapy with respect to bleeding prevention, joint preservation, and long-term outcomes. Clinical trials and observational studies consistently demonstrate higher bleeding rates, progressive joint damage, and worse functional outcomes in patients managed with episodic therapy compared to those receiving routine prophylaxis. Episodic therapy fails to prevent subclinical and micro-bleeding events that drive irreversible joint damage and does not adequately mitigate disease progression. Therefore, prophylactic therapy is the established standard of care for individuals with moderate to severe hemophilia or a high-risk bleeding phenotype. Episodic treatment is not considered an appropriate long-term management strategy or qualifying pathway for coverage under this policy. Routine use of episodic therapy alone suggests a disease course or bleeding phenotype that is inconsistent with the severity and risk profile required for coverage of the treatments addressed in this policy.

Coverage Intent and Scope

This policy applies to monoclonal antibody therapies for the management of hemophilia A and hemophilia B in individuals with moderate to severe disease or a high-risk bleeding phenotype for whom routine prophylaxis is clinically indicated. Coverage is intended for patients who demonstrate a disease course associated with recurrent clinically significant bleeding, elevated risk of spontaneous hemorrhage, or

progressive joint damage. Eligibility for coverage is not based on diagnosis alone and is determined by satisfaction of the clinical criteria described below.

Table 1: Available products per indication and inhibitor status

	Hemlibra (emicizumab-kxwh)	Hympavzi (marstacimab-hncq)	Alhemo (concizumab-mtci)	Qfitlia (fitusiran)
Congenital FVIII deficiency (hemophilia A)				
With Inhibitors	X	X	X	X
Without Inhibitors	X	X	X	X
Congenital FIX deficiency (hemophilia B)				
With Inhibitors		X	X	X
Without Inhibitors		X	X	X
FDA Approved Age Requirement				
All indications	Any Age	≥ 6 years of age	≥ 12 years of age	≥ 12 years of age

Table 2: Sites of Bleeding in Hemophilia

Serious	• Joints (hemarthrosis) • Muscles, especially deep compartments (iliopsoas, calf, forearm) • Mucous membranes of the mouth, nose, and genitourinary tract
Life-threatening	• Intracranial • Neck/throat • Gastrointestinal

Summary	
Effective Date of Policy	7/13/2026
Indications	Severe hemophilia A (congenital factor VIII deficiency) Severe hemophilia B (congenital factor IX deficiency)
ICD10 Diagnosis Codes	D66, D67
Availability	Hemlibra: single-dose vials for injection: 30 mg/mL, 60 mg/0.4 mL, 105 mg/0.7 mL, 150 mg/mL Hympavzi: 150 mg/mL in a single-dose prefilled syringe and a single-dose prefilled pen Alhemo: 60 mg/1.5 mL in a single-patient-use prefilled pen, 150 mg/1.5 mL in a single-patient-use prefilled pen, and 300 mg/3 mL in a single-patient-use prefilled pen Qfitlia: 50 mg/0.5 mL in a single-dose prefilled pen, 20 mg/0.2 mL in a single-dose vial
HCPCS Codes	Hemlibra: J7170 Hympavzi: J7172 Alhemo: J7173 Qfitlia: J7174
Duration	Managed Medicaid/HARP/CHP: • Initial: 6 months • Recertification: 12 months Commercial/Medicare Part B: • Initial and Recertification: 2 years

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy:

1. The prescribed medication must be used for the indication(s) consistent with the population outlined in Table 1 above
2. Must be prescribed by, or in consultation with, a hematologist
3. Must be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes

4. Inhibitor Status Requirements
    a. For patients WITH inhibitors, there must be documentation of inhibitors (e.g., history of inhibitor titer ≥ 5 Bethesda units per mL)
        i. For Hemophilia A, Bethesda assay must have been completed within 8 weeks of the request
        ii. For Hemophilia B, Bethesda assay must have been completed within 6 months of the request is acceptable unless recent immune-tolerance induction or clinical change that suggest assessment is warranted
    b. For patients WITHOUT inhibitors:
        i. Patients must have severe hemophilia A (factor VIII < 1%) or hemophilia B (IX ≤ 2%) as evidenced by documentation of baseline (untreated) factory activity level AND
    c. Must have documentation of a recent (within 6 months of the request) inhibitor test confirming absence of factor VIII (for hemophilia A) or factor IX (for hemophilia B) inhibitors
5. Bleed History Requirements
    a. Documentation of the patient's baseline annualized bleed rate
        i. Only bleeds requiring medical intervention or treatment should be counted in ABR calculations AND
    b. The patient must have a history of two or more episodes of spontaneous bleeding episodes into joints or muscles consistent with moderate to severe hemophilia AND
    c. There must be documentation of inadequate bleed control despite ≥ 80% adherence (based on refill history or infusion logs) of prophylactic therapy as evidenced by:
        i. Two or more clinically significant spontaneous bleeding events within the past 12 months requiring medical intervention or treatment (e.g., factor infusion, bypassing agent, or clinical evaluation) while adherent to prophylactic factor replacement or bypassing agents OR
        ii. Inability to achieve or maintain appropriate trough factor activity level ≥ 3% as evidenced by at least two pre-dose levels < 3% obtained ≥ 4 weeks apart within a 6-month period, despite appropriate dosing
6. Patients with Hemophilia A must have had a trial and failure of Hemlibra prior to consideration of coverage for another hemophilia monoclonal antibody therapy.
    a. An adequate trial of Hemlibra is defined as the completion of the 4-week loading dose in addition to at least 24 weeks of maintenance therapy at an approved dose with confirmed adherence, unless discontinued earlier due to serious side effects or documentation of neutralizing antibodies
    b. Failure of Hemlibra is defined as any of the following:
        i. An increase in treated spontaneous or joint bleeds compared to pre-treatment baseline (e.g., increase in ABR, return to pre-treatment bleeding frequency) OR
        ii. Bleeding requiring additional factor or bypassing agent therapy (beyond what is typical for minor trauma or surgery) OR
        iii. Failure to prevent target joint bleeds or new joint damage
7. Transition to non-factor therapies may be considered medically necessary when there is documented clinical ineffectiveness associated with factor replacement therapy as described in the criteria above.
    a. Use of these therapies reduce treatment burden (for convenience), in the absence of such clinical factors, does not meet medical necessity criteria and will not be authorized.

Exclusion Criteria

- Hemlibra, Hympavzi, Alhemo, and Qfitlia will not be authorized in combination with another monoclonal antibody used for Hemophilia or, when used for prophylaxis, with factor products or bypassing agents except for intermittent use to manage breakthrough bleeds
- Patient must not have received previous treatment with a gene therapy product for hemophilia, due to insufficient evidence on safety and/or efficacy of subsequent use with non-factor agents
- Use in acquired hemophilia is excluded from coverage, as there is no clinical evidence or guideline support for the safety and/or efficacy of these agents in this population

Continuation Criteria

- Recertification will require documentation that the patient has had a beneficial response to therapy (e.g., reduction in frequency and/or severity in spontaneous bleeding events, decreased need for intermittent factor or bypassing therapy, etc.)

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department
- See Prescribing Information for approved dosing
- Quantity Limits:
  - Alhemo: 1 pen per 28 days
    - Upon each review the requested pen strength and quantity will be reviewed in accordance with FDA-approved weight-based dosing. Approval will be limited to the minimum number of pens needed to obtain the appropriate dose and pen strength that provides the least amount of waste.
  - Hemlibra
    - The most efficient vial and strength combination should be used to minimize drug waste, consistent with the FDA-approved dosing regimen and the patient's prescribed dose.
  - Hympavzi: 4 syringes/pens per 28 days
  - Qfitlia: 0.5 mL/56 days

References

		Updated	Accessed
1	Hemlibra prescribing information. San Francisco, CA: Genentech, Inc.	1/24	1/25
2	World Foundation of Hemophilia: Guidelines for the management of hemophilia 3rd edition. Montreal, QC, Canada: Blackwell Publishing Ltd.; 2020.	2020	1/24
3	Oldenburg J, Mahlangu JN, Kim B, et al. Emicizumab prophylaxis in hemophilia A with inhibitors. N Engl J Med. 2017;377:809–18.		9/18
4	Emicizumab for Hemophilia A with Inhibitors: Effectiveness and Value Final Evidence Report. Institute for Clinical and Economic Review. April 16, 2018.		9/18
5	FDA Approves Genentech's Hemlibra (Emicizumab-kxwh) for Hemophilia A Without Factor VIII Inhibitors [news release]. Genentech's website. https://www.gene.com/media/press-releases/14749/2018-10-04/fda-approves-genentechs-hemlibra-emicizu. Accessed October 4, 2018.		10/18
6	HAVEN 3: Mahlangu J, Oldenburg J, Paz-Priel I, Negrier C, Niggli M, Mancuso ME, Schmitt C, Jiménez-Yuste V, Kempton C, Dhalluin C, Callaghan MU, Bujan W, Shima M, Adamkewicz JI, Asikanius E, Levy GG, Kruse-Jarres R. Emicizumab Prophylaxis in Patients Who Have Hemophilia A without Inhibitors. N Engl J Med. 2018 Aug 30;379(9):811-822. doi: 10.1056/NEJMoa1803550.		10/18
7	A Study to Evaluate the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of Emicizumab Given Every 4 Weeks in Participants With Hemophilia A (HAVEN 4). Retrieved from http://clinicaltrials.gov/ct2 (Identification No. NCT03020160). August 2018.		10/18
8	Krumb E, et al. Adoption of emicizumab (Hemlibra®) for hemophilia A in Europe: Data from the 2020 European Association for Haemophilia and Allied Disorders survey. Haemophilia. 2021; 1-8.	2021	2/23
9	Young G, et al. A multicenter, open-label phase 3 study of emicizumab prophylaxis in children with hemophilia A with inhibitors. Blood. 2019; 134(24):2127-2138.	12/19	2/23
10	Pierce GF , Hart DP , Kaczmarek R . WFH Coagulation Product Safety, Supply, and Access (CPSSA) Committee of the World Federation of Hemophilia (WFH). Safety and efficacy of emicizumab and other novel agents in newborns and infants [letter to the editor]. Haemophilia. 2019 ; 25 (5): e334 - e335.	2019	2/23
11	Wieland I. Emicizumab for All Pediatric Patients with Severe Hemophilia A. Review Article. Hamostaseologie 2022; 42:104-115.	1/22	2/23
12	Hympavzi prescribing information. New York, NY: Pfizer Inc.	10/24	1/26
13	Alhemo prescribing information. Plainsboro, NJ: Novo Nordisk Inc.	12/24	1/25
14	Qfitlia prescribing information. Cambridge, MA: Genzyme Corporation	3/25	1/26

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application if administered under the medical benefit.

Not applicable if obtained through pharmacy under Part D.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application if administered under the medical benefit.

Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program.

CDPHP Pharmacy Services 7/13/2026

New: 10/18

Revised	Reviewed
4/21, 12/22, 4/23, 2/25, 2/26, 4/26, 7/26	9/19, 9/20, 4/22, 4/24

Date	Note
12/2022	Revised to remove State Program applicability (Select/HARP) and indicate that therapy is fulfilled under the Prescription Benefit.
4/2023	Amended age requirement from 12 years and above to 1 year and above, references updated.
2/2025	Renamed policy to accommodate the inclusion of new drugs Hympavzi and Alhemo. Removed age requirement for Hemlibra along with change in criteria regarding inhibitor requirement.
2/2026	Reformatted policy and made applicable to Medicare Part B Added Qfitlia Made timeframes for criteria clearer for getting certain labs Removed language about specific benefit coverage for Hemlibra Added quantity limits
4/2026	Updated approval durations per LOB
7/2026	Age & Label Expansion for Hympavzi

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BEHAVIORAL HEALTH
RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: NEUROPSYCHOLOGICAL TESTING

POLICY EFFECTIVE DATE:	1/1/2025
Policy Control #:	1370/20.000416
Next Annual Review:	12/2025

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

96116, 96121, 96132, 96133, 96136, 96137, 96138, 96139, 96146

DESCRIPTION

Neuropsychological testing involves using a standardized battery of tests or an individualized approach that focuses on cognitive functions that are specific to a patient's reported problems. It is usually done in connection with neurological diagnoses rather than related to behavioral health conditions. Neuropsychological testing is intended to describe and diagnose the neurocognitive effects of medical disorders that impinge directly or indirectly on the functional integrity of the brain.

RELATED POLICIES/DOCUMENTS

Psychological Testing, 1370/20.000461

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: NEUROPSYCHOLOGICAL TESTING

POSITION STATEMENT

CDPHP administers benefits for neuropsychological testing, under the medical portion of the contract, to include but not limited to the following indications:

- To detect neurologic disease based on quantitative assessment of neurocognitive abilities.
- To differentiate between a psychiatric disorder and a neurological or neuro-endocrine medical condition with cognitive and psychiatric symptoms.
- To rule in or out diagnostic conditions when known or suspected neurological disease is not detected or is not certain following the use of standard psychiatric and medical neurodiagnostic procedures.
- To determine the enrollee's baseline neurocognitive functioning capabilities and/or changes in status/functioning when it is necessary to assist with treatment planning to assess neurocognitive functions for the formulation of rehabilitation and/or management strategies among individuals with neurologic disorders.

Neuropsychological testing is performed by a licensed psychologist, board certified in neuropsychology, neurologist, or psychiatrist with specialized training and expertise in the types of tests/assessment being requested, and who can perform them at a level proficient to interpret testing data.

POLICY CONSIDERATIONS

Neuropsychological testing should be preceded by adequate mental status examination, review of the individual's pertinent history, and appropriate medical and/or neurological consultation. The testing is considered necessary when there has been significant mental status change, cognitive function change, memory loss, or behavior change as a result of suspected organic brain dysfunction resulting from illness or injury.

Examples of neurologic disease/injury in which neuropsychological testing may be indicated are:

- Dementia of various etiologies (i.e., primary neurodegenerative, infectious, etc.)
- Delirium/confusional state
- Hydrocephalus
- Intracranial neoplasm
- Seizure disorders
- Stroke or cerebral vascular injury (e.g., brain aneurysm, subdural hematoma)
- Traumatic brain injury
- Vascular or hereditary disorders
- Multiple sclerosis
- Neurotoxin exposure
- Acquired immunodeficiency syndrome (AIDS) encephalopathy
- Lyme disease encephalopathy including neuroborreliosis
- Extrapyramidal disease (i.e., Parkinson's Disease, Huntington's Disease); or
- Developmental delay (Note: testing for pervasive developmental disorder is addressed in

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POLICY NAME: NEUROPSYCHOLOGICAL TESTING

resource coordination policy, Psychological Testing).
- Depression and other psychiatric conditions presenting with neurologic symptomatology making differential diagnosis difficult but imperative to
- formulating a treatment plan
- Dyslexia

EXCLUSIONS

Neuropsychological testing is not considered reasonable and necessary for the following conditions:

- Routine monitoring of chronic disorders such as cerebrovascular disease, HIV infection, etc. unless significant clinical change is documented.
- Evaluation when abnormalities of the brain function are not suspected.
- When a person has been diagnosed previously with brain dysfunction and there is no expectation that the testing would impact the individual's treatment.
- When neuropsychological assessments can be obtained through the clinical evaluation alone.
- When used as a screening test given to the individual or to the general population.
- For periodic re-testing of stable members.
- For members who have had surgery for epilepsy within the last twelve months.
- When required for vocational purposes or ordered by the court or legal system.
- When related to adult or child ADHD hyperactivity, autism spectrum disorder, Tourette's Syndrome, intellectual developmental disorder or school-related services unless secondary to one of the aforementioned indications.
- When related to educational or vocational assessment or training, including to assess improvement of academic functioning, to diagnose specific learning disabilities, reading disorders, developmental disorders of scholastic skills, and alexia.
- When related to assessment or diagnosing of pervasive developmental disorders or other disorders or psychological development.
- When the member has a history of substance abuse, and the member continues to use mood altering substances and/or when the member is < 10 days post-detoxification.
- When a person is on certain medications that may confound interpretation of results, and drug effects have not been ruled out.
- For pre-procedure work-up, unless neuropsychological testing is required to determine if the member is cognitively able to benefit from the procedure and is able to cooperate with all aspects of the treatment plan and the member meets all other criteria for the proposed procedure.
- When administered or scored by technicians not meeting the requirements outlined in the NYS Office of the Professions Education Law.

CDPHP considers computerized neuropsychological testing [96146] (e.g., ImPACT™, CogState Sport®) experimental/investigational for all indications, including sports related injuries, as it

does not require a physician, psychologist or licensed mental health provider to provide interpretation and preparation of the report; and overall impact on health outcomes is unproven at this time.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP:	Subject to all terms and conditions noted above in application with the exception that neuropsychological testing is covered when ordered by the court or legal system.

SOURCES

1. Board Certified Consultants
2. Contract Clarification.
3. CDPHP Exclusions & Mixed Services Protocol Document, 9/28/06.
4. Other Payers.
5. Sharfstein, S.; Webb, W.; Stoline, A.: 50.2 Economics of Psychiatry. Kaplan Textbook of Psychiatry, 6th Edition.
6. NYS Education Department, Office of the Professions License Requirements for Psychologist, http://www.op.nysed.gov/prof/psych/psychlic.htm
7. ~~7.~~ NYS Education Department, Office of the Professions, Use and Supervision of a Testing Technician by a Licensed Psychologist, http://www.op.nysed.gov/prof/psych/psychsupertesttech.htm
8. Hannay, Bieliauskas, Crosson, Hammeke, Hamsher, & Koffler, The Houston Conference on Specialty Education and Training in Clinical Neuropsychology, 1998, http://www.theaacn.org/position_papers/houston_conference.pdf
9. Hayes Inc. Directory Report: Computerized Neurocognitive Testing (CNT) for Sports-Related Head Injury, 1/30/14.
10. American Academy of Clinical Neuropsychology (AACN) Practice Guidelines for Neuropsychological Assessment and Consultation, The Clinical Neuropsychologist, 21: 209-231, 2007.
11. American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (*DSM-5*).
12. InterQual® (Version 2024), BH:Behavioral Health Services Neuropsychological and Developmental Testing

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POLICY NAME: NEUROPSYCHOLOGICAL TESTING

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Date 1/6/25

CDPHP Behavioral Health

POLICY APPROVAL DATES

New:	07/04
Revised:	12/07, 01/09, 01/10, 01/11, 01/13, 01/15, 01/18, 12/24
Reviewed:	03/05, 12/05, 11/06, 09/09, 01/12, 09/13, 07/14, 01/16, 01/17, 01/19, 09/19, 01/21, 9/21, 12/22, 12/23,

BEHAVIORAL HEALTH
RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: NEUROPSYCHOLOGICAL TESTING

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
12/25	Added coverage for dyxlexia. Removed from exclusions.
11/1/2021	Hourly limitation removed for neuropsychological testing.
1/1/2020	Application section: • Added requirement that psychologists be board certified in neuropsychology • Increased neuropsych testing hours from 6 to 12. • Clarification on how units should be billed on claims Added additional examples of indications for neuropsych testing in the Policy Considerations section. Updated the Exclusions section.

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: NON-COVERED TECHNOLOGIES

POLICY EFFECTIVE DATE: 9/1/2026
Policy Control #: 1370/20.000444
Next Annual Review: January, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

DESCRIPTION

Non-covered technologies are experimental, investigational, or non-standard services that are not covered under an enrollee's benefit plan. CDPHP specifically excludes benefits for experimental and investigational services. Experimental and investigational means the technology is:

- Not of proven benefit for the particular diagnosis or treatment of a covered enrollee's particular condition; and/or
- Not generally recognized by the medical community, as reflected in the published evidence-based medical literature, as effective or appropriate for the particular diagnosis or treatment.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

- Technology Assessment & Policy Development, 1370/20.000407.
- Experimental, Investigational & Non-Standard Treatments/Clinical Trials, 1370/20.000152.
- Coverage with Evidence Development for Medicare Advantage, 1370/20.000517

POSITION STATEMENT

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

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POLICY NAME: NON-COVERED TECHNOLOGIES

In general, CDPHP does not administer benefits for any medical or behavioral health interventions that have been determined to be investigational, experimental, non-standard, or unproven. Benefits are limited to scientifically established procedures in accordance with the criteria outlined in the above referenced CDPHP resource coordination policies.

Services may also be non-covered due to the nature of the service, or if the service is specifically identified as a contract exclusion. The following list is not all-inclusive but contains examples of non-covered technologies as determined by the CDPHP technology assessment team. As such, they are not covered unless specifically addressed in a contract, or when a case-specific review justifies a medical exception as determined by a CDPHP medical director.

Investigational services are often so new that they do not have a procedure code assigned to them yet. Therefore, not all of the services listed below will have CPT or HCPCS codes listed.

A

Ablation, percutaneous, cryoablation of upper and lower extremity distal/peripheral nerve and nerve plexus or other truncal nerve
Air displacement/body plethymography (BOD-POD)
Allogeneic Hematopoietic Stem Cell Transplant for Multiple Myeloma
Anoscopy for fecal incontinence (Secca® procedure)
Antiprothrombin
Axial lumbar interbody fusion system, AxiaLIF
Artificial lumbar intervertebral disc (Charite artificial disc, Prodisc-L)
Autologous Serum Tears
Avise PG
AVISE Lupus

B

Balloon Septoplasty
Baroreflex stimulation implanted device
Bioimpedance spectroscopy (BIS) for assessment of lymphedema
Bronchial thermoplasty for treatment of asthma (e.g., Alair®)

C

Carbon monoxide, expired gas analysis
Cardiac contractility modulation system
Cerebral Embolic Protection Device (CEPD)
Contractility modulation generator
Chemical exfoliation or cryotherapy for treatment of facial wrinkling, pigmentation, or acne
Collagen meniscus implant (e.g., CMI, collagen scaffold, Menaflex™)
ColoSense
Combined electrochemical therapy (CET) for treatment of peripheral
Common carotid intima-media thickness (IMT)

POLICY NAME: NON-COVERED TECHNOLOGIES

Comprehensive computer-based motion analysis by videotaping and 3D kinematics
Computerized dynamic posturography
Coronary artery disease, mRNA, gene expression profiling
Cryoablation of the posterior nasal nerve (i.e., ClariFix).
Cryosurgery for plantar fasciitis

D

Digital Motion X-ray of the spine
Diverticular Peroral Endoscopic Myotomy (D-POEM) for treatment of esophageal diverticula
Drug Coated Balloons (e.g., Optilume)
Dynamic flexion devices (Dynasplint)

E

Electrical water-circulating cold pad with pump (Cryocuff)
Electron beam computed tomography (Ultrafast CT or Cine CT)
Electronic positional OSA treatment (e.g., NightBalance Lunoa System)
Electromagnetic navigation bronchoscopy (e.g., virtual bronchoscopy)
Electronic brachytherapy for the treatment of breast cancer (e.g., IORT, Intrabeam therapy)
EndoPAT to detect coronary artery endothelial dysfunction
Endoscopic or percutaneous spinal surgical techniques (Racz procedure)
Endovenous Ablation Therapy
Exsufflation belt
Extracorporeal shock wave therapy- high energy

F

Focused ultrasound ablation of uterine leiomyomata
Foot, adductus positioning device (e.g., Universal Neonatal Foot Orthotic/UNFO-S)

G

Gastric Peroral Endoscopic
Myotomy (G-POEM) for the treatment of gastroparesis
Gastric electrical stimulation (GES)/gastric pacing (Enterra™ Therapy)
Gastroenterology (Barrett's esophagus), whole slide-digital imaging

H

HART CADhs®
HART CVE®
High-dose-rate brachytherapy for prostate cancer

I

Implantable pulmonary artery pressure measurement system (e.g., CardioMEMS)
Infrared therapy for neuropathy, wound healing, or pain management

InPen Smart Insulin Pen
Insertion of Drug-Eluting Implant into Lacrimal Canaliculus
Interferential stimulation
Interspinous process decompression system (e.g., X-Stop®)
Intravaginal Device (i.e., Flyte)
Intranasal sphenopalatine ganglion (SPG) block
Intravascular Lithotripsy
Iontophoresis

K
KidneyIntelX

L
Latera Absorbable Nasal Implants
Leadless pacemaker (e.g., Micra Transcatheter Pacing System)
Low dose radiation therapy for treatment of osteoarthritis
Lower esophageal sphincter augmentation devices for GERD (LINX® Reflux System)
Low-level or high-level laser therapy
Lumbar pneumatic traction device (Saunders Lumbar HomeTrac)
Lung expansion airway clearance

M
Magnetic Controlled Growing Rods (e.g., MAGEC- Magnetic Expansion Control System)
Magnetic-resonance-guided focused ultrasound (MRgFUS) for essential tremor
Magnetic resonance imaging (MRI) low-field
Magnetic resonance imaging (MRI) cerebral perfusion analysis
Magnetic resonance neurography (MRN)
Magnetic source imaging (MSI)
Manipulation of spine requiring anesthesia (MUA)
Microvas vascular treatment system for peripheral neuropathy
Mobile Cardiovascular Telemetry
MyoPro Orthosis

N
Nerivio Migra for acute migraine episodes
Neurofeedback (Electroencephalograpy (EEG) Biofeedback)
Neuropsychological testing administered by a computer (e.g., ImPACT™, CogState Sport®)
Neutralizing antibody testing: beta interferon
Non-pneumatic compression controller w/o calibrated gradient pressure (e.g., Dayspring Lite)

O
Oncology (breast ductal carcinoma in situ), protein expression profiling
Oral brush biopsy (e.g., Oral CDx) for screening of mouth cancer

Oral Superabsorbent Hydrogel for Weight management (e.g., Plenity)
Oxinium knee implants
Oxygen therapy for headaches (e.g., migraine)

P

Pap Smears for members under 21 years of age
Percutaneous image-guided lumbar decompression for lumbar spinal stenosis
Periurethral transperineal adjustable balloon continence device (e.g., ProAct, ACT)
Platelet-rich plasma (PRP) therapy
PleximarkTM
Positron emission tomography (FDG) for infection/inflammation
Positron emission tomography (PET) imaging, any site not otherwise specified
PET for detection of breast cancer (e.g., Naviscan)
PET whole body imaging; melanoma for non-covered indications.
Positional magnetic resonance imaging (MRI) (e.g., upright MRI)
PrismRA Molecular Test
Prolotherapy for the treatment of musculoskeletal pain
Prometa® therapy for alcohol, cocaine, and methamphetamine dependence
Artery Embolization

Q-R

Qualitative electroencephalography (QEEG) for the treatment of ADHD
Radiofrequency ablation for the treatment of epicondylitis
Radiofrequency ablation of thyroid nodule(s)
Radiofrequency ablation for the treatment of prostate cancer
Radiofrequency ablation/cryotherapy ablation for clinically localized suspected renal malignancy
Radiofrequency generated water vapor thermotherapy for the prostate (i.e., Rezum)
Radiofrequency spectroscopy (e.g., MarginProbe®)
Radiofrequency Tissue Volume Reduction (i.e., Somnoplasty®)
Referenced electroencephalography (rEEG) for predicting pharmacotherapeutic outcomes
Remote Imaging Fundus Photography/Retinal telescreening (i.e., RetinaVue™, Optomap®)
RhinAer

S

Scintimammography (radioimmunoscintigraphy of the breast)
Serum Hepcidin Testing
Skin advanced glycogen end products (AGE) measurement
SNaP® Wound Care System/PICO™ Single Use Negative Pressure Wound Therapy
Static progressive (SP) stretch device (e.g., joint active systems (JAS) devices)
Subchondroplasty/Subchondral Calcium Phosphate (SCP) injections
Subtalar arthroereisis
Suit therapy (Theratogs, TheraSuit, PediaSuit)
Superior capsular reconstruction

Supervised exercise therapy (SET) for symptomatic peripheral artery disease
Sural nerve grafting during radical prostatectomy
Surface electromyography (EMG)

T

Temporary Implantable Nitinol Device (iTIND)
Thermal destruction of intraosseous basivertebral nerve (i.e., intracept system)
Thermography (e.g., BreastCare DTS™/BreastAlert®)
Tinnitus retraining therapy (e.g., Neuromonics Tinnitus Treatment/Oasis device)
Tocolytic infusion therapy; home setting
Tongue neuromuscular stimulation device for mild obstructive sleep apnea (e.g., eXciteOSA)
Transcatheter renal sympathetic nerve denervation
Transcervical uterine fibroid ablation (i.e., Sonata)
Transperineal Laser Ablation (TPLA)
Transurethral, radiofrequency micro-remodeling for stress incontinence (Renessa®)

U

Ultrafiltration system for acute decompensated CHF (e.g., Aquadex Flexflow®)
Ultrasound Therapy for wound healing (e.g., Sanuwave UltraMIST)
Uterine activity monitoring; home setting
Uterine Transplantation

V

Vectra DA Blood Test for Rheumatoid Arthritis
Vertebral body tethering
Vertebral fracture assessment (VFA)
Very–Long Chain Acyl–CoA Dehydrogenase (VLCAD) Enzyme Activity
Virtual bronchoscopy
Viscocanalostomy
ViVaer

W-Z

Whole body CT/MRI screening (Lifescan imaging)
Whole body integumentary photography for early detection of melanoma
Wireless abdominal aortic aneurysm pressure measurement system (e.g., CardioMems Endosure® System)
Zenker-Peroral Endoscopic Myotomy (Z-POEM) for the treatment of Zenker's diverticulum

Procedure Description	Codes	Comments
Ablation, percutaneous, cryoablation (includes imaging guidance) of upper and lower extremity distal/peripheral nerve and	0440T 0441T 0442T	Experimental, investigational, or unproven

Procedure Description	Codes	Comments
nerve plexus or other truncal nerve		
Air displacement/body plethymography for measurement of body composition (BOD-POD)	94726 99199	Experimental, investigational, or unproven
Allogeneic Hematopoietic Stem Cell Transplant for Multiple Myeloma	38205, 38240 when billed with ICD 10 codes: C90.00-C90.02	Experimental, investigational, or unproven For Medicare Advantage, please see Coverage with Evidence Development for Medicare Advantage, 1370/20.000517
Infrared therapy used for the treatment of diabetic and/or non-diabetic peripheral sensory neuropathy, wound healing, or pain management (e.g., Anodyne Therapy System)	97026 A4639, E0221	Experimental, investigational, or unproven *Exception*: Covered for Medicare Advantage members for the destruction of actinic keratoses without restrictions based on lesion or patient characteristics. Experimental, investigational, or unproven
Anoscopy, with delivery of thermal energy to the muscle of the anal canal for fecal incontinence • Secca® procedure	46999	Experimental, investigational, or unproven
Antiprothrombin (phospholipid cofactor) antibody, each Ig class	86849	Experimental, investigational, or unproven
Artificial lumbar intervertebral disc to include, but not limited to, the following: • Charite artificial disc, Prodisc-L	22860 0164T 0165T	Experimental, investigational, or unproven
Autologous Serum Tears		Experimental, investigational, or unproven
Avise PG to measure methotrexate metabolism in rheumatoid arthritis patients	84999	Experimental, investigational, or unproven
AVISE Lupus for the diagnosis of systemic lupus erythematosus (SLE)	0312U	Experimental, investigational, or unproven
Balloon Septoplasty	30999	Experimental, investigational, or

Procedure Description	Codes	Comments
		unproven
Baroreflex stimulation implanted device (i.e., Barostim Neo for resistant hypertension or heart failure)	64654	Experimental, investigational, or unproven
Bioimpedance spectroscopy (BIS) for assessment of lymphedema	93702	
Bronchial thermoplasty for treatment of asthma (e.g., Alair® Bronchial Thermoplasty System)	31660 31661	Experimental, investigational, or unproven
Carbon monoxide, expired gas analysis	84999	Experimental, investigational, or unproven
Cardiac contractility modulation system	0408T 0409T 0410T 0411T 0915T 0916T 0917T 0918T 0919T 0920T 0921T 0922T 0923T 0924T 0925T 0926T 0927T 0928T 0929T 0930T 0931T 0948T 0949T	Experimental, investigational, or unproven For Medicare Advantage, please see Coverage with Evidence Development for Medicare Advantage, 1370/20.000517
Cerebral Embolic Protection Device (CEPD) (i.e., Sentinel)	33370	Experimental, investigational, or unproven
Contractility modulation generator - external recharging system for battery (internal); replacement only	K1030	Experimental, investigational, or unproven
Chemical exfoliation or cryotherapy for treatment of facial wrinkling, pigmentation, or	17340 17360	Scientific evidence does not support the efficacy of peeling regimens for these

Procedure Description	Codes	Comments
acne		indications
Collagen meniscus implant (e.g., CMI, collagen scaffold, Menaflex™)	G0428	Experimental, investigational, or unproven
ColoSense (Oncology (colorectal) screening for colorectal cancer risk)	0421U	Experimental, investigational, or unproven
Combined electrochemical therapy (CET) for treatment of peripheral neuropathy (electronic signal therapy with local anesthetics)		Experimental, investigational, or unproven
Common carotid intima-media thickness (IMT) for evaluation of atherosclerotic burden or coronary heart disease risk-factor assessment	93998	Experimental, investigational, or unproven
Comprehensive computer-based motion analysis by videotaping and 3D kinematics; with dynamic plantar pressure measurements during walking	96000 96001 96002 96003 96004	Experimental, investigational, or unproven *Exception: Covered when performed as part of a preoperative assessment for an individual diagnosed with cerebral palsy, and the results will be used in surgical planning.*
Computerized dynamic posturography	92548	Experimental, investigational, or unproven
Coronary artery disease, mRNA, gene expression profiling by real-time RT-PCR of 23 genes, utilizing whole peripheral blood, algorithm reported as a risk score	81493	Experimental, investigational, or unproven
Cryoablation of the posterior nasal nerve (i.e., ClariFix).	C9771 31242 31243	Experimental, investigational, or unproven
Cryosurgery for plantar fasciitis		Experimental, investigational, or unproven
Digital Motion X-ray of the spine	76120 76125	Experimental, investigational, or unproven
Diverticular Peroral Endoscopic Myotomy (D-POEM) for treatment of esophageal diverticula Gastric Peroral Endoscopic Myotomy (G-	43497 43999	Experimental, investigational, or unproven **Note:** Peroral Endoscopic Myotomy (POEM) for the treatment of achalasia is covered.

Procedure Description	Codes	Comments
POEM) for the treatment of gastroparesis Zenker-Peroral Endoscopic Myotomy (Z-POEM) for the treatment of Zenker's diverticulum		
Dynamic flexion devices • Dynasplint	E1802 E1815, E1820, E1821, *E1822, E1823, E1828, E1829,* E1830 E1840	Experimental, investigational, or unproven for ankle, toe, shoulder, and forearm. *Exception: Dynasplint for fingers, elbow, wrist or knee only (E1800, E1803, E1804, E1805, E1807, E1808, E1810, E1812, E1813, E1814, E1825, E1826, and E1827) may be approved on an individual consideration for up to four months for either of the following:* *• As an adjunct to physical therapy in members with symptoms of significant joint motion stiffness/ loss unresponsive to other therapies in sub-acute injury or post-operative period (i.e., at least 3 weeks after injury or surgery but no more than 4 months after injury or surgery) OR* *• In the acute post-operative period for members who are undergoing additional surgery to improve motion of a previously affected joint.* *CDPHP considers the prophylactic use of dynamic splinting experimental and investigational in the management of chronic contractures (no significant change in motion for a 4-month period) and joint stiffness due to joint trauma, fractures, burns, head and spinal cord injuries, rheumatoid arthritis, multiple sclerosis, muscular dystrophy or cerebral palsy.*
Electrical water-circulating cold pad with pump (Cryocuff)	E0218	Experimental, investigational, or unproven; no significant proven benefit over standard cryotherapy with ice

Procedure Description	Codes	Comments
		bags/packs
Electron beam computed tomography • Ultrafast CT or Cine CT	S8092	Experimental, investigational, or unproven
Electronic positional OSA treatment, with sensor, includes all components and accessories (e.g., NightBalance Lunoa System)	E0530	Experimental, investigational, or unproven, as long-term compliance and effectiveness of these devices is unknown.
Electromagnetic navigation bronchoscopy (ENB) for peripheral lung lesions (e.g., virtual bronchoscopy) • superDimension® Bronchus System	31627, C7509, C7510, C7511, C7567	Experimental, investigational, or unproven *Exception: Covered for Medicare Advantage members or on a case-by-case review for members where there has been consultation with an interventional radiologist and pulmonologist and it is determined that ENB is the safest and most efficient procedure for the member.*
Electronic brachytherapy for the treatment of breast cancer (e.g., IORT, Intrabeam therapy)	77436, 77437, 77438,77439	Experimental, investigational, or unproven
EndoPAT to detect coronary artery endothelial dysfunction	93998	Experimental, investigational, or unproven
Endoscopic or percutaneous spinal surgical techniques (laminectomy/disc decompression, epidural, Racz procedure)	22899 64999 C2614	Experimental, investigational, or unproven
Endovenous ablation therapy for the treatment of vein disease (i.e., varicose veins) • mechanochemical ablation: (i.e., Clarivein) • Polidocanol microfoam: (i.e., Varithena) • Medical adhesive: (i.e., VenaSeal)	36473, 36474 36465, 36466 36482, 36483	Experimental, investigational, or unproven *Exception: Coverage of endovenous ablation therapy is limited to Medicare members who remain symptomatic after a six-week trial of conservative therapy and there is **reflux in a saphenous vein** with:* • *a maximum vein diameter of 12mm and* • *absence of thrombosis or vein tortuosity (except for polidocanol*

Procedure Description	Codes	Comments
		microfoam), which would impair catheter placement. *Coverage is only for devices with FDA approval or clearance consistent with saphenous ablation and used according to its approved instructions for use (IFU).*
Exsufflation belt	A4468	Experimental, investigational, or unproven
Extracorporeal shock wave therapy, high energy, involving the humeral epicondyle	0102T	Experimental, investigational, or unproven *Exception: Covered for Medicare Advantage members.*
Focused ultrasound ablation of uterine leiomyomata, including MR guidance	0071T 0072T	Scientific evidence does not demonstrate this technology improves health outcomes more than established standard therapies
Foot, adductus positioning device (e.g., Universal Neonatal Foot Orthotic/UNFO-S)	L3161	Experimental, investigational, or unproven
Gastroenterology (Barrett's esophagus), whole slide-digital imaging	0108U	Experimental, investigational, or unproven
HART CADhs®, risk score for obstructive coronary heart disease	0308U	Experimental, investigational, or unproven
HART CVE®, risk score for major adverse cardiac event	0309U	Experimental, investigational, or unproven
High-dose-rate brachytherapy for prostate cancer		Scientific evidence does not demonstrate that this technology improves health outcomes more than established standard therapies
Implantable pulmonary artery pressure measurement system for monitoring chronic heart failure (e.g., CardioMEMS)	G0555	Experimental, investigational, or unproven For Medicare Advantage, please see Coverage with Evidence Development for Medicare Advantage, 1370/20.000517
InPen Smart Insulin Pen		Experimental, investigational, or unproven *Exception: Covered for Medicare Advantage members with Part D*
Interferential stimulation	E1399	Experimental, investigational, or

Procedure Description	Codes	Comments
		unproven
Interspinous process decompression system (e.g., X-Stop®) for lumbar spinal stenosis	22868 22870 C1821	Experimental, investigational, or unproven
Intranasal sphenopalatine ganglion (SPG) block for the treatment of migraine headaches		Experimental, investigational, or unproven
Intravaginal device intended to strengthen pelvic floor muscles during Kegel exercises (i.e., Flyte System Controller/and or supplies)	E0715, E0716	Non-Covered as it is considered disposable.
Intravascular Lithotripsy (i.e., Shockwave Intravascular Lithotripsy System)	92972, C1761, C9764 C9765 C9766 C9767 C9772 C9773 C9774 C9775 37262 37279	Experimental, investigational, or unproven
Iontophoresis for primary focal hyperhidrosis	97033	Experimental, investigational, or unproven *Exception:* Covered for Medicare Advantage for primary focal hyperhidrosis when there has not been a response to recognized standard therapy. Good hygiene measures, extra-strength antiperspirants (for axillary hyperhidrosis), and topical aluminum chloride should initially be tried.
Iontophoresis device for home use for hyperhidrosis (i.e., Dermadry, miraDry)	E1399, A9900, A9999	Experimental, investigational or unproven *Exception:* Covered for Medicare Advantage for primary focal hyperhidrosis when there has not been a response to recognized standard therapy. Good hygiene measures, extra-strength antiperspirants (for axillary

Procedure Description	Codes	Comments
		hyperhidrosis), and topical aluminum chloride should initially be tried.
KidneyIntelX	0407U	Experimental, investigational, or unproven *Exception*: Covered for members with type 2 diabetes and Stage 1, 2, or Stage 3 chronic kidney disease (CKD).
Latera Absorbable Nasal Implants	30468	Experimental, investigational, or unproven
Leadless pacemaker (e.g., Micra Transcatheter Pacing System)	33274 C1605 0823T 0824T 0825T 0826T	Experimental, investigational, or unproven For Medicare Advantage, please see Coverage with Evidence Development for Medicare Advantage, 1370/20.000517
Low dose radiation therapy for treatment of osteoarthritis		Experimental, investigational, or unproven
Lower esophageal sphincter augmentation devices for the treatment of gastroesophageal reflux disease (LINX® Reflux System)	43284 43285	Experimental, investigational, or unproven
Low-level or high-level laser therapy performed by a qualified health care professional (i.e., MD, physical therapist)	S8948 97037 97039 0552T	Experimental, investigational, or unproven
Low temperature radiofrequency for treatment of chronic rhinitis (i.e., RhinAer)	30117	Experimental, investigational, or unproven
Lumbar pneumatic traction device • Saunders Lumbar HomeTrac	E1399	Experimental, investigational, or unproven
Lung expansion airway clearance, continuous High Frequency Oscillation and Nebulization Device (i.e., Volera system)	E0469, A7021	Experimental, investigational, or unproven
Magnetic Controlled Growing Rods (e.g., MAGEC- Magnetic Expansion Control System) for scoliosis treatment	22899	Experimental, investigational, or unproven
Magnetic-resonance-guided focused	61715, C9734	Experimental, investigational, or

Procedure Description	Codes	Comments
ultrasound (MRgFUS)		unproven *Exception: Covered for the treatment of idiopathic essential tremor (G25.0) for members with medication refractory tremors. PA is not required when billed with this diagnosis.*
Magnetic resonance imaging (MRI) cerebral perfusion analysis	76498	Experimental, investigational, or unproven
Magnetic resonance neurography (MRN)		Experimental, investigational, or unproven
Magnetic source imaging (MSI)	S8035	Experimental, investigational, or unproven
Manipulation of spine requiring anesthesia (MUA)	22505	Experimental, investigational, or unproven
Microvas vascular treatment system for peripheral neuropathy	97139	Experimental, investigational, or unproven
MyoPro Orthosis	L8701, L8702	Experimental, investigational, or unproven
Neurofeedback (Electroencephalograpy (EEG) Biofeedback) for mental health diagnoses Electroencephalograpy (EEG) for mental health diagnoses	90901 95812, 95816	Experimental, investigational, or unproven Experimental, investigational, or unproven
Nerivio Migra for acute migraine episodes	A4540	Experimental, investigational, or unproven
Neuropsychological testing administered by a computer (e.g., ImPACT™, CogState Sport®)	96146	Experimental, investigational, or unproven
Neutralizing antibody testing: beta interferon		Scientific evidence does not demonstrate this technology improves health outcomes.
Non-pneumatic compression controller without calibrated gradient pressure (e.g., Dayspring Lite) and compression garments	E0677, E0678, E0679, E0680, E0681, E0682	Experimental, investigational, or unproven
Oncology (breast ductal carcinoma in situ), protein expression profiling by immunohistochemistry of 7 proteins i.e.,	0295U	Experimental, investigational, or unproven

POLICY NAME: NON-COVERED TECHNOLOGIES

Procedure Description	Codes	Comments
DCISionRT, PreludeDX		
Oral brush biopsy (e.g., Oral CDx) for screening of mouth cancer	88104 D7288	The sensitivity and specificity of the office- based test compromise ability to reliably direct management of care
Oral Superabsorbent Hydrogel for Weight management (e.g., plenity)		Experimental, investigational, or unproven
Oxinium knee implants		Scientific evidence does not demonstrate that this technology improves health outcomes more than established standard therapies
Oxygen therapy for headaches (e.g., migraine)		Experimental, investigational, or unproven *Exception: covered for cluster headaches*
Pap Smears for members under 21 years of age	88141,88142 88143,88147 88148,88150 88152,88153, 88154, 88164,88165 88166,88167 88174,88175 G0123, G0124 G0141, G0143 G0144, G0145 G0147, G0148 P3000, P3001 Q0091	Considered not medically necessary except in the following circumstances: • HIV-infected women beginning in adolescence • Sexually active immunocompromised adolescent women, including those who have received an organ transplant or those with long-term steroid use • Women beginning in adolescence who have been diagnosed with cervical dysplasia or cervical cancer • Sexually active women beginning in adolescence who have been exposed in utero to diethylstilbestrol (DES)
Percutaneous image-guided lumbar decompression for lumbar spinal stenosis	0275T	Experimental, investigational, or unproven For Medicare Advantage, please see Coverage with Evidence Development for Medicare Advantage, 1370/20.000517
Periurethral transperineal adjustable balloon continence device (e.g., ProAct, ACT	53451 53452	Experimental, investigational, or unproven

Procedure Description	Codes	Comments
therapy systems)	53453 53454	
Platelet-rich plasma (PRP) therapy	0232T	Experimental, investigational, or unproven For Medicare Advantage, please see Coverage with Evidence Development for Medicare Advantage, 1370/20.000517
PleximarkTM®, risk for kidney transplant rejection	0018M	Experimental, investigational, or unproven
Positron emission tomography (FDG) for infection/inflammation (e.g., chronic osteo-myelitis, infection of hip arthroplasty and FUO)	78999	Experimental, investigational, or unproven
PET for detection of breast cancer (e.g., Naviscan)		Experimental, investigational, or unproven
PrismRA Molecular Test	81599	Experimental, investigational, or unproven
Prolotherapy for the treatment of musculoskeletal pain	M0076	Experimental, investigational, or unproven
Prometa® therapy for alcohol, cocaine, and methamphetamine dependence		Experimental, investigational, or unproven
Embolization of the following arteries: • Genicular artery for the treatment of osteoarthritis knee pain • Left gastric artery for the treatment of obesity	37242, 37243 billed with ICD 10 codes: E66.01-E66.9, M17.0-M17.9	Experimental, investigational, or unproven
Qualitative electroencephalography (QEEG) for the treatment of ADHD		Experimental, investigational, or unproven
Radiofrequency ablation for the treatment of epicondylitis		Experimental, investigational, or unproven
Radiofrequency ablation of thyroid nodule(s)	60660/60661	Experimental, investigational, or unproven
Radiofrequency ablation for the treatment of prostate cancer	53852 53854	Experimental, investigational, or unproven
Radiofrequency ablation/cryotherapy ablation for clinically localized suspected renal malignancy	50542 50592 50593	Experimental, investigational, or unproven except under the following condition:

Procedure Description	Codes	Comments
		When used to treat peripheral lesion(s) that are ≤ 4 cm in diameter and meets one or more of the following criteria: • Individual has a single kidney • Individual has renal insufficiency as defined by a glomerular filtration rate of ≤ 60ml/min/m2 • Individual is considered a high-risk surgical candidate
Radiofrequency generated water vapor thermotherapy for the treatment of prostate cancer (i.e., Rezum)	53854	Experimental, investigational, or unproven *Exception: covered for benign prostatic hyperplasia (BPH)
Radiofrequency spectroscopy for intraoperative assessment of surgical margins (e.g., MarginProbe®) following lumpectomy in patients diagnosed with breast cancer	19499	Experimental, investigational, or unproven
Radiofrequency Tissue Volume Reduction (RFTVR)	30801	Experimental, investigational, or unproven Exception: Covered for Hypertrophy of nasal turbinates (J34.3) **Please see Obstructive Sleep Apnea Diagnosis and Treatment/1370/20.000060 policy for additional exclusion.
Referenced electroencephalography (rEEG) for predicting pharmacotherapeutic outcomes		Experimental, investigational, or unproven
Remote Imaging Fundus Photography/Retinal telescreening (i.e., RetinaVue™, Optomap®)	92227 92228 92229	Experimental, investigational, or unproven *Exception: Coverage for retinal telescreening is available only to enrollees diagnosed with diabetes. Refer to CDPHP policy, Vision Care Services by Eye Care Specialists, 1370/20.000059.*
Scintimammography (radioimmunoscintigraphy of the breast)	S8080	Experimental, investigational, or unproven

POLICY NAME: NON-COVERED TECHNOLOGIES

Procedure Description	Codes	Comments
Serum hepcidin testing	0251U	Experimental, investigational, or unproven
Skin advanced glycogen end products (AGE) measurement by multi-wavelength fluorescent spectroscopy	88749	Experimental, investigational, or unproven
Single Use Negative Pressure Wound Therapy i.e., SNaP® Wound Care System/PICO™, Avelle	97607, 97608, A9272	Experimental, investigational, or unproven
Static progressive (SP) stretch device for the treatment of joint stiffness and contractures (e.g., joint active systems (JAS) devices)	E1801 E1806 E1811 E1816 E1818 E1821 E1831, E1832 E1841	Experimental, investigational, or unproven
Subchondroplasty/Subchondral Calcium Phosphate (SCP) injections for any indication	0707T	Experimental, investigational, or unproven
Subtalar arthroereisis for the treatment of any condition including, but not limited to, rigid or flexible pes planus (e.g., flatfoot) or posterior tibial tendon dysfunction	S2117 0335T 28899	Experimental, investigational, or unproven; there is insufficient evidence in the published medical literature to compare the safety, efficacy, and long-term outcomes of subtalar arthroereisis with results of conservative treatment or alternative surgical procedures.
Suit Therapy (i.e., Theratogs, TheraSuit, PediaSuit) for any indication	L1499	Experimental, investigational, or unproven
Superior capsular reconstruction for the treatment of rotator cuff tears	23929, 29999	Experimental, investigational, or unproven
Supervised exercise therapy (SET) for symptomatic peripheral artery disease	93668	Coverage for medical supervision of peripheral vascular rehabilitation programs is not provided, as the value of such supervision is not conclusively documented in the available peer- *Exception: Coverage is provided for Medicare Advantage members with intermittent claudication for the treatment of symptomatic peripheral artery disease in accordance with CMS national coverage determination: NCD for SET for Symptomatic Peripheral*

Procedure Description	Codes	Comments
		Artery Disease (20.35).
Sural nerve grafting during radical prostatectomy		Experimental, investigational, or unproven
Surface electromyography (EMG)	S3900	Experimental, investigational, or unproven
Thermal destruction of intraosseous basivertebral nerve (i.e., intracept system)	64628, 64629	Experimental, investigational, or unproven Covered for Medicare Advantage when criteria in LCD are met: Thermal Destruction of the Intraossious Basivertebal Nerve for Vertebrogenic Lower Back Pain Effective 9/1/2026, covered for Medicaid line of business when criteria is met: https://www.health.ny.gov/health_care/medicaid/program/update/2026/no06_2026-05.htm#BVNA
Thermography	93740	Experimental, investigational, or unproven
Tinnitus retraining therapy (e.g., Neuromonics Tinnitus Treatment/Oasis device)		Experimental, investigational, or unproven
Tocolytic infusion therapy; home setting	S9349	Experimental, investigational, or unproven
Tongue neuromuscular stimulation device for treatment of mild obstructive sleep apnea e.g., eXciteOSA Device	E0492, E0493	Experimental, investigational, or unproven
Transcatheter renal sympathetic nerve denervation	0338T, 0339T	Experimental, investigational, or unproven For Medicare Advantage, please see Coverage with Evidence Development for Medicare Advantage, 1370/20.000517
Transcervical uterine fibroid ablation (i.e., Sonata Sonography-Guided Transcervical Fibroid Ablation System)	58580	Experimental, investigational, or unproven
Transurethral, radiofrequency micro-	53860	Experimental, investigational, or

POLICY NAME: NON-COVERED TECHNOLOGIES

Procedure Description	Codes	Comments
remodeling of the female bladder neck and proximal urethra for the treatment of stress incontinence (Renessa®)		unproven
Ultrasound therapy (including high-frequency and non-contact low-frequency ultrasound devices) for wound healing (i.e., Mist Therapy System, Sanuwave UltraMIST)	97610	Experimental, investigational, or unproven
Ultrafiltration system for acute decompensated congestive heart failure (e.g., Aquadex Flexflow®)		Scientific evidence does not demonstrate use of this technology improves health outcomes
Uterine activity monitoring; home setting	S9001 S9208	Covered when performed during an inpatient hospitalization only
Uterine Transplantation	0664T, 0665T, 0666T, 0667T, 0668T, 0669T, 0670T	Experimental, investigational, or unproven
Vectra DA Blood Test for Rheumatoid Arthritis	81490	Experimental, investigational, or unproven
Vertebral body tethering	22836, 22837, 22838, 0656T, 0657T, 0790T	Experimental, investigational, or unproven
Vertebral fracture assessment (VFA)	77085 77086	Screening for vertebral fractures using dual X-ray absorptiometry (DXA) as a stand-alone procedure or in addition to standard bone mineral density studies is considered a non-covered service; current scientific evidence does not demonstrate that treatment decisions based on vertebral fracture assessment, in combination with bone mineral density, result in better patient outcomes than the standard method of utilizing clinical risk factors and measurement of bone mineral density. *Exception: Medicare provides coverage for vertebral fracture assessment when performed as part of bone mass measurement screening (77085). Code 77086 does not represent a bone density study and should not be billed for screening. This code may be billed only*

POLICY NAME: NON-COVERED TECHNOLOGIES

Procedure Description	Codes	Comments
		when a vertebral fracture assessment is medically necessary and it is anticipated the results of the test will be used in the medical management of the patient.
Very–Long Chain Acyl–CoA Dehydrogenase (VLCAD) Enzyme Activity to measure the levels of VLCAD enzyme activity in leukocytes to aid in diagnosis and treatment planning for VLCAD deficiency	0257U	Experimental, investigational, or unproven
Virtual bronchoscopy	76497	Experimental, investigational, or unproven
Viscocanalostomy	66999	Experimental, investigational, or unproven
Radiofrequency for the ablation of septal wall (e.g., VivAer) for treatment of nasal airway obstruction: • Ablation of the septal swell body • Nasal valve collapse remodeling	30117 30469	Experimental, investigational, or unproven
Whole body integumentary photography for early detection of melanoma	96904	Experimental, investigational, or unproven

POLICY CONSIDERATIONS

If CDPHP has identified a specific indication for a particular technology, or if the procedure is already addressed in a resource coordination policy, it will not appear in this document. Specific resource coordination/payment policies can be accessed through the CDPHP secure physician interface at www.cdphp.com. Examples include:

- Allergy Testing and Treatment, 2.01.10.
- Cosmetic & Reconstructive Surgery, 1370/20.000071.
- AssistedReproductiveTechnologies,4.01.05
- Obstructive Sleep Apnea: Diagnosis & Treatments, 1370/20.000060.

Pursuant to the applicable participating provider agreement, providers ordering or performing the non-covered service must inform the enrollee of the non-covered status before rendering the service. CDPHP requires a written waiver specific to the service being performed; a generic waiver is not considered an acceptable form of enrollee consent.

- If a provider informs the enrollee prior to performing a specific service that it is not covered, and the enrollee consents to accept liabilities for the services by signing a waiver specific to that service, the provider ***may bill*** the enrollee.
- If a provider performs a specific service without notifying the enrollee that the service is

not covered, or the enrollee does not consent to accept liability for the specific service, the provider ***may not bill*** the enrollee.

- If a provider sends the enrollee or enrollee's specimen to a participating outside provider or vendor, it is the responsibility of the servicing provider or vendor to obtain a copy of the signed waiver (indicating the services is non-covered) from the ordering provider before performing and billing the services. If the provider sends the enrollee or enrollee's specimen to a non-participating outside provider or vendor, it is the responsibility of the ordering physician to inform the enrollee that the provider or vendor does not participate with CDPHP.

Additions and deletions to the list of non-covered services will be made as new issues arise or the investigational status of a service changes.

Services and supplies related to a non-covered procedure are considered non-covered.

Services for personal convenience or considered not primarily medical in nature are non-covered.

CDPHP considers above services, including those represented by category III codes, as excluded from coverage since clinical safety and efficacy or applicability to clinical practice has not been established.

- Providers are encouraged to contact the resource coordination department prior to providing a service or technology that may not be covered under the enrollee's benefit plan.

Re-review of denied technologies will be considered by a CDPHP medical director pending submission of updated evidence-based medical literature by the requesting physician.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy unless specifically addressed by traditional Medicare as a covered benefit.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. CDPHP Technology Assessment Team
2. CDPHP Board Certified Consultants
3. Centers for Medicare and Medicaid Services national coverage determinations (NCD) &

local coverage determinations (LCD)
4. Centers for Medicare & Medicaid: Decision Memo for Positron Emission Tomography (FDG) for Infection and Inflammation (CAG-00382N), https://www.cms.hhs.gov.mcd/viewdecisionmemo.asp?id=207U
5. Other payers
6. U.S. Food & Drug Administration
7. Centers for Medicare & Medicaid Services (CMS). Decision Memo for Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (CAG-00433N). January 9, 2014. Available at http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=269
8. Centers for Medicare & Medicaid Services (CMS). Decision Memo for Screening for Colorectal Cancer - Stool DNA testing (CAG-00440N), effective October 9, 2014, http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=277
9. Hayes, Inc. Search and Summary Report: V-Go™ Disposable Insulin Delivery Device, July 1, 2013.
10. V-Go™ Disposable Insulin Delivery Device, Valeritas Inc., Shrewsbury, MA, https://www.valeritas.com/vgo
11. Hayes Inc., Brief Report: Solesta for Treatment of Fecal Incontinence, 12/29/13.
12. National Government Services Local Coverage Determination (LCD L31391): Posterier Tibial Nerve Stimulation for Voiding Dysfunction, http://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/home-lob/pages/medical-policy-center/mpc-search-detail/l31391/!ut/p/a1/xVNNU8IwEP0rvXDsZEsCqcdQsCAtBQShvTAhrRht0wod_Pj1psAM6Iyo4zjmlJe8vN19u0ERmqNI8a1c8VLmiqcVjpoLwnody3KgH7QtCqxPhtCdBOA2KJqhCEUbvk1Enj_IpEliTfj6CMcdtxcMdheqLMo7FKrVJktiKfhav1JlokqVPNXg5HiHizyV4qUGqYg3BlexsT8w-LqUOsbGMI2sEMZBQvOwhS-sKlAhZIxCAg2wY4FNjJvUJPTCNpccqCmAkjqJ-ZIvScX2ghYKh1rVaOl6Q10vfLIYfMuOdxQc2MDIZavdHg2x26ofCGdChDoHelSwnb4DzPGG_uDSARhRdP3DGs8LNslecOb4i9G0M9bsk35gdNpPDQ_91LtT436V0QcfPfrvGdmTsfao73s3056Nwf256VdfjYoetfrad_yVluXlnSnVbY7mhyHWI_L-8TFi-tdU8_1covnffpsiexi7Ns7MOdw3iu3rhLFuthj4jCVLG3Aj3XrsDSMFIGY!/dl5/d5/L2dBISEvZ0FBIS9nQSEh/?clearcookie=&savecookie=&REGION=&LOB=Part%20B
13. Centers for Medicare & Medicaid Services (CMS) Coverage with Evidence Development: Autologous
14. CMS Local Coverage Article: Billing and Coding: Category III CPT® Codes (A56195), https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=56195&ver=31&Cntrctr=297&ContrVer=1&CntrctrSelected=297*1&DocType=Active&bc=AAABAAIAAAAA&
    Platelet Rich Plasma (PRP): http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Autologous-Platelet-rich-Plasma-PRP.html
15. Hayes, Inc. Search and Summary Report: Image Guided Intranasal Sphenopalatine Ganglion

(SPG) Block for the Treatment of Migraine Headaches, April 17, 2015.
16. Medicare Benefit Manual Chapter 15, 80.5 Bone Mass Measurements (BMMs) at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf. (Accessed July 9, 2015,)
17. National Government Services Local Coverage Article: Bone Mass Measurement (A51974), http://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=51974&ver=19&ContrId=298&ContrVer=1&CntrctrSelected=298*1&Cntrctr=298&s=41&LCntrctr=180&bc=ABAAAAEAAAAAAA%3d%3d&
18. Medicare's National Coverage Determination: Percutaneous Left Atrial Appendage Closure (20.34): https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=367&ncdver=1&CoverageSelection=National&KeyWord=atrial&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAACAAAAAAAA%3d%3d&
19. Medicare Coverage with Evidence Registry & Clinical Study Approvals for Percutaneous Left Atrial Appendage Closure (LAAC): https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/LAAC.htm
20. Medicare Local Coverage Determination: Magnetic resonance image guided high intensity focused ultrasound (MRgFUS) for essential tremor (L37421), effective 4/1/18, https://www.cms.gov/medicare-coverage-database/indexes/lcd-list.aspx?Cntrctr=275&name=National%20Government%20Services,%20Inc.%20%2806302,%20MAC%20%20Part%20B%29&DocType=Active%7CFuture%7CAllProposed&LCDId=26375&ContrId=275&ver=58&ContrVer=1&CntrctrSelected=275*1&LCntrctr=275*1&bc=AgACAAIAAAAAAA==&#ResultsAnchor
21. CMS Decision Memo for Vagus Nerve Stimulation (VNS) for Treatment Resistant Depression (TRD) (CAG-00313R2), effective 2/15/19: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=292
22. Hayes Evolving Evidence Review: Subchondral Calcium Phosphate Injections for Knee Bone Marrow Lesions, November 15, 2021
23. Medicare National Coverage Determination: Treatment of Actinic Keratosis (250.4): https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=129&ncdver=1&keyword=actinic%20keratosis&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

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POLICY APPROVAL DATES

New: 09/07

POLICY NAME: NON-COVERED TECHNOLOGIES

10/07, 12/07, 01/08, 03/08, 05/08, 07/08, 09/08, 11/08, 01/09, 3/09, 05/09, 09/09, 01/10, 03/10, 5/10, 09/10, 11/10, 01/11, 03/11, 05/11, 07/11, 09/11, 11/11, 01/12, 03/12, 05/12, 07/12, 09/12, 11/12, 01/13, 03/13, 05/13, 07/13, 09/13, 11/13, 01/14, 03/14, 05/14, 07/14, 09/14, 01/15, 03/15, 05/15, 07/15, 09/15, 11/15, 01/16, 03/16, 05/16, 07/16, 09/16, 01/17, 03/17, 07/17, 09/17, 11/17, 01/18, 03/18, 05/18, 07/18, 11/18, 01/19, 05/19, 09/19, 11/19, 1/20, 3/20, 07/20, 11/20, 01/21, 3/21, 5/21, 7/21, 9/21, 11/21, 01/22, 3/22, 5/22, 7/22, 9/22, 1/23, 3/23, 7/23, 9/23, 11/23, 1/24, 3/24, 5/24, 7/24, 9/24, 11/24, 3/25, 5/25, 7/25, 9/25,
Revised: 11/25, 1/26, 3/26, 5/26, 7/26, 9/26

Reviewed: 12/25

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
9/1/2026	Removed laser therapy for acne treatment from policy as it is now housed in the Light and Laser Therapies for Dermatologic Conditions policy, 8.01.21. Removed diagnoses for which cpt code 64590 does not require a PA. Code will now require PA for all indications. Removed Injectable bulking agents for treatment of fecal incontinence (e.g., Solesta) as it is now housed in the Bulking Agents for Treatment of Urinary or Fecal Incontinence policy, 7.01.22. Removed Vagus Nerve Stimulation (VNS) from policy as it is now housed in Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy policy, 7.01.05. Removed Gastric electrical stimulation (GES)/gastric pacing (Enterra™ Therapy) as it is now housed in Gastric Electrical Stimulation policy, 7.01.64. Removed Endoscopic treatment for gastroesophageal reflux disease from policy as it is now housed in the Transendoscopic Therapies for Gastroesophageal Reflux Disease (GERD) policy,

	7.01.45.
8/1/2026 * No change to effective date of policy	Added link to BVN/code 64628, 64629 effective 7/15/2026 for Medicare due to a new LCD and Medicaid update effective 9/1/2026.
8/1/2026	Removed codes E0721, E0732, E0733 and E0735 as these are now addressed in new policy Cranial and Auricular Neuromodulation, 1.01.58
7/1/2026 *No change to policy effective date	Removed codes 90901, 95812, 95816 from policy.
7/1/2026	Removed lantrida info from this policy as it is now housed in the Pancreas Transplant, 07.02.01 policy
4/1/2026	Added laser therapy for acne treatment as experimental.
1/1/2026 No change needed to effective date for this update	Removed scalp cooling device. Removed embolization of the prostate artery for treatment of BPH. This will now be housed in the Minimally Invasive Treatments for Benign Prostatic Hyperplasia (BPH), 7.01.104 policy. Updated coverage for MRgFUS to include all LOBs for essential tremor. Under Electromagnetic navigation bronchoscopy added new code C7567. Removed the following codes from the policy as they will be reviewed by HealthHelp: 22586 22865 22857 22862 22865 0274T 0275T 33289 C2624 22867

	22869 33275 93264 Added Cerebral Embolic Protection Device (CEPD) to policy Removed deleted codes 0266T-0273T, 0394T, 0395T and replaced with new codes. Under intravascular lithotripsy added new codes 37262 and 37279. Removed MRI/TRUS for diagnosis of prostate cancer from policy. Removed codes 52284, 0714T, 0867T, 53865 and 53866 from policy as they are now in the Minimally Invasive Treatments for Benign Prostatic Hyperplasia (BPH), 7.01.104 policy
1/1/2026	Added transcatheter renal sympathetic nerve denervation to policy. Added PrismRA (81599) to policy as experimental/ investigational.
11/1/2025 Policy update did not require a date change	Added codes 0823T, 0824T, 0825T, 0826T to leadless pacemaker section. Removed Positional magnetic resonance imaging (MRI) (e.g., upright MRI) and Whole-body CT/MRI screening (76498) from policy.
11/1/2025	Added the following treatments for BPH as experimental/investigational: • Transperineal Laser Ablation (TPLA); • Temporary Implantable Nitinol Device (iTIND) • Drug coated balloons (e.g., Optilume) Added code 0108U as E/I.
9/1/2025	Under code 0407U added additional diagnosis of stage 1 kidney disease, effective 1/1/25.

POLICY NAME: NON-COVERED TECHNOLOGIES

7/1/2025	Added code 0295U as experimental/investigational Added new codes 0948T & 0949T to cardiac contractility modulation system.
5/1/2025* *No change to effective date for this update	Removed elastography from grid.
5/1/2025	Added exception under vagus nerve stimulators for treatment resistant depression for Medicare LOB. Removed code 68841 as this is now in the Vision Services By Eye Care Specialists, 1370/20.000059 policy Added Intravaginal device intended to strengthen pelvic floor muscles during Kegel exercises as non-covered. Added codes G0341, G0432, G0343 to islet cell transplant. Added Radiofrequency ablation of thyroid nodule(s) as experimental. Under Iontophoresis, added "for primary focal hyperhidrosis" and Iontophoresis device for home use as experimental and exception for Medicare Advantage members. Added new code E1832 to static progressive stretch devices effective 4/1/2025. Added exception coverage for Medicare Advantage for dx of actinic keratosis under infrared therapy.
3/1/2025	Added new codes that were effective 1/1/2025 Removed cervical traction devices as they are addressed in the Durable Medical Equipment, Prosthetics/Orthotics, & Medical Supplies policy.
3/1/2025	Added exception coverage criteria for MRI/TRUS fusion biopsy.
2/1/2025	Removed Iluvien from grid as this is no longer considered experimental.

POLICY NAME: NON-COVERED TECHNOLOGIES

1/1/2025 *No change to effective date of policy	Added new codes effective 10/1/24: E0469, E0721, A4543, A7021 Removed peripheral nerve stimulator (E0734) from grid as this is now located in the Durable Medical Equipment, Prosthetics/Prosthetics and Medical Supplies,1370/20.000509 policy.
1/1/2025	Added embolization of the prostate, left gastric and genicular arteries as experimental. Added Low dose radiation therapy for treatment of osteoarthritis.
10/1/2024	Added insertion of a drug-implant eluting into lacrimal canaliculus (68841). Added Allogeneic Hematopoietic Stem Cell Transplant for Multiple Myeloma. Added ColoSense (0421U) as experimental/investigational
9/1/2024 *No change to effective date of policy	Added Radiofrequency generated water vapor thermotherapy to policy. Removed codes S8042, G0219, and G0235 from policy since of 9/9/24, they will be managed by HealthHelp per Elective Outpatient High Tech Imagining Services policy 1370/20.000518.
9/1/2024	Removed Percutaneous and non-percutaneous left atrial appendage closure devices as these are now located in new policy, Procedures for Occlusion of The Left Atrial Appendage, 1370/20.000515 Removed Medicare exceptions for items that are now identified in Coverage with Evidence Development for Medicare Advantage, 1370/20.000517.
8/1/2024	Added additional information and removed code 0105U under KidneyIntelX
7/1/2024	Added new code C1605 to leadless pacemakers as experimental. Added testing for Covid 19.

	Added 0407U under KidneyIntelX
6/1/2024 * No change to effective date of policy for this update	Added Vertebral body tethering as experimental. Added Neurofeedback and EEG for mental health conditions as experimental. Removed V-Go from experimental category (see External Ambulatory Insulin Infusion Pump, 1370/20.000457 policy for coverage details) Removed Stomaphyx from grid as this information is also housed in the Bariatric Surgery policy. Removed A9586 from experimental services (please see Radiopharmaceutical policy 1550/20.000151 for coverage guidelines)
6/1/2024	Added superior capsular reconstruction as experimental.
3/1/2024* No change to effective date of policy for this update	Added intravascular lithotripsy as experimental. Removed Genicular Nerve Branch Injections/Radiofrequency Ablation as this is addressed in the RC policy Pain Management Services, 1370/20.000105.
3/1/2024* No change to effective date of policy for this update	Added allogeneic islet cell transplant as experimental. Removed termed code K1015 and replaced with new code L3161(effective 1/1/24). Removed termed codes K1028 and K1029 and replaced them with new codes E0492 and E0493 (effective 1/1/24). Removed termed code K1001 and replaced with new code E0530 (effective 1/1/24). Removed termed codes K1031, K1032, and K1033 and replaced them with new codes E0678-E0682 (effective 1/1/24).

	Removed termed code K1002 and replaced it with new code E0732 (effective 1/1/24). Removed termed code K1016 and replaced it with new code E0733 (effective 1/1/24). Removed termed code K1018 and replaced it with new code E0734 (effective 1/1/24). Removed termed code K1020 and replaced it with new code E0735 (effective 1/1/24). Removed termed code K1023 and replaced it with new code A4540 (effective 1/1/24). Removed termed code 0404T and replaced it with new code 58580 (effective 1/1/24). Added new code 97037 for low-level laser therapy (effective 1/1/24). Added new codes 31242 and 31243 to Cryoablation of the posterior nasal nerve (effective 1/1/24). Added new code A4468 (Exsufflation belt) to policy (effective 1/1/24)
3/1/2024	Added autologous serum tears as experimental/investigational Added PLA codes 0251U, 0257U, 0308U, 0309U, 0312U, 0316U, 0018M as experimental/investigational Added RFTVR as experimental with one exception
11/1/2023* No change to effective date of policy	Added Viscocanalostomy and Elastography ultrasound to policy. Removed canaloplasty from policy.
11/1/2023	Added Low temperature radiofrequency for treatment of chronic rhinitis (RhinAer) to grid. Added Suit Therapy to grid. Added ultrasound therapy for wound healing.

	Added VivAer (for specific conditions). Removed eustachian tube balloon dilation from policy.
7/1/2023* No change to effective date of policy	Added exception to electromagnetic navigation bronchoscopy. Added Vectra DA to grid as experimental. Added Medicaid coverage indications for VNS.
7/1/2023	Added Endovenous ablation therapy to grid. Removed Vagus Nerve Blocking Therapy (VBLOC) from grid as it is already addressed in the Bariatric Surgery policy.
4/1/2023	Added new HCPCS code E0677 to the Non-pneumatic compression section.
1/1/2023 *No change to effective date	Added new codes C7509, C7510, C7511 to navigational bronchoscopy.
1/1/2023 *No change to effective date	Clarified that CPT code 64590 requires PA for indications other than urinary/fecal incontinence, urinary retention, and overactive bladder. Added coverage criteria for vagus nerve stimulation for the treatment of epilepsy. Removed topical oxygen therapy as it is already addressed in RC policy Hyperbaric Oxygen Therapy 1370/20.000203. Removed Procel (Gore-Tex) cast liner as it is already addressed in the Cast Application, and Supplies and Fracture Care payment policy, 1550/20.000153. Removed termed code 0163T and replaced with new code 22860 under artificial lumbar intervertebral disc. Under Air displacement/body plethymography Removed termed code 94750.
1/1/2023	Added code 97039 and 0552T to low-level or high-level laser therapy. Added D-POEM, G-POEM, and Z-POEM as experimental/investigational.

	Removed E1700, E1701, and E1702 for jaw rehabilitation systems as these are already addressed in the *Temporomandibular Joint Disorders policy 1370/20.000062*. Removed the following items as they are already addressed as non-covered in the RC Policy *Obstructive Sleep Apnea 1370/20.000060:* • Injection snoreplasty (42299) • Laser-assisted uvulopalatoplasty (LAUP) (S2080) • Pillar® Palatal Implant System (C9727) • Radiofrequency tissue volume reduction of the tongue base (41530), uvula or soft palate, or for tonsillar hypertrophy (e.g., Somnoplasty®) • Tongue base suspension (AIRVance Tongue and Hyoid Suspension System, 41512) • Hyoid myotomy and suspension (21685)
11/1/2022	Added code 92229 to Retinal telescreening for diabetic retinopathy section. Removed Implantable interstitial glucose sensors as all information is in the Diabetic Services policy *1370/20.000047*.
10/1/2022	Added Baroreflex stimulation implanted device i.e., Barostim Neo as experimental/investigational. Added new HCPCS code A4596 (system supplies and accessories, per month) to cranial electrotherapy stimulation device.
7/1/2022 *No change to effective date	Relocated coronary artery calcium scoring to the Adjunct and Non-Standard Technology payment policy. Added exception coverage criteria for Dynasplint. Added oxygen therapy for headaches as experimental/investigational with an exception of cluster headaches. Added thermal destruction of intraosseous basivertebral nerve as experimental/investigational. Added MyoPro Orthosis as experimental/investigational.

POLICY NAME: NON-COVERED TECHNOLOGIES

	Added new codes effective 7/1/2022, G0309 & G0309, to Implantable interstitial glucose sensors and added Medicare as an exception.
7/1/2022 *No change to effective date	Added the below items as experimental, investigational/unproven. • Subchondroplasty/Subchondral Calcium Phosphate (SCP) injections • Cardiac contractility modulation system and generator • Oral Superabsorbent Hydrogel for Weight management Added new codes that were effective 4/1/22 (K1028, K1029-Tongue neuromuscular stimulation device, K1030, K1031, K1032, K1033) as experimental, investigational/unproven.
7/1/2022	Updated verbiage for Anodyne therapy (97026) to be consistent with language in Occupational and Physical Therapy policies. New Code, 43497, effective 1/1/2022 for Peroral endoscopic myotomy (POEM) for the treatment of achalasia. Removed Peroral endoscopic myotomy (POEM) for the treatment of achalasia from policy as this is no longer considered experimental. Latera Absorbable Nasal Implants (30468) added to policy as experimental/investigational.
5/1/2022	Added "Atriclip" to grid as experimental, investigational, or unproven. Added language for "watchman" device.
31/2022	Added balloon septoplasty to grid as considered experimental/investigational.
1/1/2022* No change to effective date	Added new CPT codes that are effective 1/1/22, 53451-53454, Periurethral transperineal adjustable balloon continence devices as experimental. Updated code for Clarifix from 30117 to C9771
1/1/2022* No change to effective date	SNaP® Wound Care System/PICO™ Single Use Negative Pressure Wound Therapy added as experimental. This was previously housed in Vacuum Assisted Wound Therapy policy. Removed SEPT9 (Septin9) (e.g., colorectal cancer) promoter

	methylation analysis as this is now in the DNA Based Testing for Colorectal Cancer policy.
1/1/2022	Removed A4305/A4306 (Drug delivery system) from grid as they have been moved to the Adjunct and Non-Standard payment policy. Added Nerivio Migra for acute migraine episodes.
11/1/21	Added magnetic controlled growing rods and genicular nerve branch injections to grid as these are considered experimental/investigational. Updated entry on grid for InPen Smart Insulin Pen to include exception that it is covered for Medicare Advantage members with Part D.
7/1/2021	Added new CPT codes that are effective 7/1/2021 as experimental/investigational: Scalp cooling device: 0662T & 0663T Uterine transplant: 0064T, 0065T, 0066T, 0067T, 0068T, 0069T, 06670T
6/1/21	Added Stage 2 CKD to the exceptions for coverage of 0105U (KidneyIntelX). Added InPen Smart Insulin Pen to grid as experimental/investigational. Added new HCPCS codes K1015, K1016, K1018, K1020 as experimental/investigational.
5/1/21* (No change to effective date)	Added codes 81493 and 81327 to grid as experimental/ investigational. Replaced miscellaneous code 69799 with new codes 69705 and 69706 for eustachian tube balloon dilation.
5/1/21	Coding updates: Removed termed codes and replaced with new codes where applicable throughout policy. Removed left atrial appendage closure devices (e.g., Watchman device, LARIAT® suture delivery system) from grid. Added entry for pap smears performed on members under 21 years of age with exceptions.

	Removed termed code 0126T and replaced with 93998.
11/11/20	Removed codes for the insertion of drug-eluting implant (0356T) into lacrimal canaliculus and the drug Dextenza (J1096).
11/1/20	Endobronchial valve system (e.g., Zephyr®) for treatment of severe emphysema removed from policy (coverage criteria now contained in Lung Volume Reduction Surgery policy). Transcervical uterine fibroid ablation (i.e., Sonata Sonography-Guided Transcervical Fibroid Ablation System) is added to policy. Cryoablation of the posterior nasal nerve (i.e., ClariFix) is added to policy.
7/1/2020	Added code J1096 for Dextenza insert to policy. Replaced unlisted code (E1399) for cranial electrotherapy stimulation with newly created CPT code K1002. Added electronic positional sleep apnea treatment (K1001) to policy as experimental/investigational.
5/1/2020	Removed 0042T as it has been transitioned to the Adjunct and Non-Standard Technology payment policy, 1550/20.000187. Removed reference to Transcranial Magnetic Stimulation as there is specific policy to address coverage criteria for this procedure. Revised entry for comprehensive computer-based motion analysis to add additional codes and exception for dx of cerebral palsy. Added drug-inducing ocular implants (i.e., Dextenza®, 0356T). Replaced deleted code 0233T with new code 88749. Added transoral incisionless fundoplication surgery (TIF) for treating gastroesophageal reflux disease (EsophyX® Device, EsophyX-Z® Device) (43210) as E/I except for Medicare Advantage members. Added supervised exercise therapy (SET) for symptomatic

	peripheral artery disease as non-covered **except** for Medicare Advantage members. Removed reference to obsolete payment policy Cervical Cytopathology, Computer-Assisted. Removed code 55874.
1/1/2020	• Removed Sinuva and Propel as new policy was created with coverage criteria, *Mometasone Furoate Sinus Implants, 1550/20.000501*. • Added KidneyIntelX (0105U). • Removed collagen cross linking of cornea as it has been moved to the Refractive Surgery-Keratoplasty, 1370/20.000257 policy with coverage criteria.

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MEDICAL POLICY

Medical Policy Title	**Non-Invasive Surface Electrical Stimulation for Pain and Rehabilitation**
Policy Number	**1.01.61**
Current Effective Date	**August 1, 2026**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Transcutaneous Electrical Nerve Stimulation (TENS)

I. TENS devices are considered **medically necessary** when **ALL** of the following criteria are met:
   A. The device is U.S. Food and Drug Administration (FDA) approved;
   B. The device is utilized for the treatment of pain;
   C. Symptoms persist for more than three (3) months;
   D. There has been a failure of physical therapy, osteopathic manipulative therapy, or chiropractic therapy;
   E. Failure of medications (e.g., simple analgesics, nonsteroidal anti-inflammatory drugs (NSAIDS), or opioids); **and**
   F. A 30-day trial period has demonstrated efficacy of the treatment.

II. Form-fitting TENS conductive conducting garments utilized for the delivery of TENS therapy are considered **medically necessary** when **ALL** of the following criteria are met:
   A. The criteria in policy statement I are met;
   B. The nerve supply to the stimulated area is intact; **and**
   C. At least **ONE** of the following criteria apply:
      1. Treatment includes a large stimulation area or considerable number of stimulation sites, and the member cannot reasonably manage the treatment without the use of the garment;
      2. The stimulation site is not accessible with standard electrodes, adhesive tape, or lead wires; **or**
      3. Skin or other medical conditions exist that would prevent the adherence of standard electrodes, tapes, or lead wires.

III. TENS is considered **not medically necessary** for the following indications:

A. The relief of pain in labor and vaginal delivery;
B. Treatment of headaches and/or migraines;
C. Visceral abdominal pain;
D. Temporomandibular joint (TMJ) disorder;
E. Cancer pain;
F. Essential tremor;
G. Low back pain;
H. Neck pain.

Neuromuscular Electrical Stimulation (NMES)

IV. NMES is considered **medically necessary** for disuse muscle atrophy when **BOTH** of the following criteria are met:
    A. Nerve supply to the muscle is intact (including brain, spinal cord, and peripheral nerves); **and**
    B. For non-neurological reasons (e.g., casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip or knee replacement surgery) (until orthotic training begins).

V. NMES is considered **not medically necessary** for **ALL** other indications.

Functional Electrical Stimulation (FES)

VI. FES is considered **not medically necessary** for **ANY** of the following indications, including but not limited to:
    A. For ambulation in patients with spinal cord injury;
    B. For stroke rehabilitation;
    C. Gait training.

Investigational

VII. The following forms of stimulation are considered **investigational**:
    A. Interferential Stimulation; (e.g., RS 4i Sequential Stimulator, Empi IF 3Wave);
    B. Transcutaneous Electrical Joint Stimulation (TEJSD) for the treatment of joint pain associated with arthritis;
    C. Multiple Modality Delivery Stimulation (e.g., RS-4i Plus).

Durable Medical Equipment (DME) Repair

VIII. Repair and/or replacement of medically necessary electrical stimulation devices or components not under warranty will be considered **medically appropriate** when the following criteria are

met:

A. Physician documentation includes **ALL** of the following:
   1. date of DME initiation;
   2. manufacturer warranty information, if applicable;
   3. attestation that the patient has been compliant with the use of the DME and will continue to benefit from the use of device;

B. The DME is no longer functioning adequately; and **BOTH** of the following criteria are met:
   1. inadequate function interferes with activities of daily living; **and**
   2. repair is expected to make the equipment fully functional (as defined by manufacturer).

IX. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

DME Replacement

X. Replacement of a medically necessary electrical stimulator or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:
   A. The DME is no longer functioning adequately and has been determined to be non-repairable, or the cost of the repair is in excess of the replacement cost;
   B. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

XI. The replacement of a properly functioning electrical stimulator, its components or accessories, is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or to make the DME more aesthetically pleasing;

XII. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

XIII. Accessories or components for electrical stimulation devices that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

1.01.58 Cranial and Auricular Neuromodulation

01.01 59 Electromagnetic and Pulsed Field Stimulation

1.01.60 Implantable and Invasive Neuromodulation Systems

1.01.62 Specialized Neuromodulation for Specific Conditions

7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

7.01.10 Sacral Nerve Stimulation

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. The use of TENS therapy is a relative contraindication in patients with a pacemaker or an implantable cardioverter defibrillator (ICD). Electrical interference from the TENS unit has been reported and may interfere with the proper functioning of these devices.

DESCRIPTION

Electrical stimulation (Estim) is a technique that uses low level electrical currents to stimulate muscles or nerves for therapeutic purposes. These devices and treatments are used in various medical and physical therapy applications. The FDA has approved many stimulation devices based on their substantial equivalence to predicate devices. There are devices for both home and clinic use. Altering the frequency, intensity, location, and pulse duration of the devices allows them to be marketed individually.

Transcutaneous Electrical Nerve Stimulation (TENS)

TENS is the application of an electrical current through the skin to stimulate the nervous system. The first device was patented by Medtronic Inc. and is utilized to relieve pain in a portable, non-invasive way. The device delivers mild pulsed electrical currents through electrode pads placed on the surface of the skin. Users can change the frequency, intensity, and pulse duration of the TENS based upon the patient's comfort and response. The intensity of the TENS device can be altered to a comfortable sensation without motor contraction, to the highest level of motor contractions (noxious). Traditional TENS is delivered utilizing high-frequency, low intensities and small pulse durations. Noxious level TENS have been investigated for patients with chronic pain.

TENS for the Treatment of Arthritis

The BioniCare Bio-1000 stimulator (VQ OrthoCare) delivers pulsed electrical stimulation for adjunctive treatment of osteoarthritis of the knee and was then later approved for rheumatoid arthritis of the hand. The FDA originally determined that this device was equivalent to TENS devices. In 2006, the FDA reclassified the device as a transcutaneous electrical stimulator for arthritis upon the manufacturer's request given that the target tissue is not nerve, but rather joint tissue.

The OrthoCor Active Knee System (OrthoCor Medical; acquired by Caerus Corp) uses pulsed electromagnetic field energy at a radiofrequency of 27.12 MHz to treat pain. The OrthoCor Knee System is classified as a short-wave diathermy device for use other than applying therapeutic deep heat. It is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue and for the treatment of muscle and joint aches and pain associated with overexertion, strains, sprains, and arthritis. the SofPulse (also called Torino II, 912-M10, and Roma;

Ivivi Health Sciences, renamed Amp Orthopedics) was cleared for marketing as a short-wave diathermy device that applies electromagnetic energy at a radiofrequency of 27.12 MHz. The device is indicated for adjunctive use in the palliative treatment of postoperative pain and edema in superficial soft tissue.

H-wave Stimulation is a form of electrical stimulation that differs from others given its waveform. It emits prolonged pulse width/duration and can produce effective anesthesia/analgesia without weakness or tetany with extended use such as that which is seen with neuromuscular electrical stimulation. H -wave devices are available for home use as durable medical equipment. H-wave stimulation has been used for pain control, treatment of diabetic neuropathy, muscle sprains, TMJ dysfunctions or reflex sympathetic dystrophy. It has also been used to accelerate healing of wounds (e.g., diabetic ulcers).

Neuromuscular Electrical Stimulation (NMES) /Functional Electrical Stimulation (FES)

NMES is a form of treatment that uses a device that transmits an electrical impulse to activate muscle groups by way of electrodes. NMES is proposed to promote neuromuscular re-education, improve motor unit recruitment, and prevent or diminish muscle atrophy. NMES is typically used as a component of a comprehensive rehabilitation program. Compared to TENS, NMES delivers a stronger current with a wider pulse width. The stimulator device is classified as durable medical equipment. NMES can be referred to as functional electrical stimulation (FES), functional neuromuscular stimulation (FNMS), or electromyography (EMG) triggered neuromuscular stimulation.

Functional electrical stimulation involves the use of an orthotic device or exercise equipment with microprocessor controlled electrical muscular stimulation. FES devices are being developed to restore function and improve health in individuals with damaged or destroyed nerve pathways (e.g., spinal cord injury [SCI], stroke, multiple sclerosis, cerebral palsy). It attempts to replace stimuli from destroyed nerve pathways with computer-controlled sequential electrical stimulation of muscles through surface or implanted electrodes. The goal is to enable patients with spinal cord injury (SCI) or stroke to function independently or at least maintain muscle tone and strength.

Surface or percutaneous devices for upper extremity FES (e.g., H200 Wireless Hand Rehabilitation System) combine a wrist/hand orthosis with integrated surface electrodes to activate muscles of the paralyzed forearm and hand. Upper extremity surface FES devices may be most effective when used soon after spinal cord injury, during the acute phase of rehabilitation.

Threshold electrical stimulation (TES) uses surface electrodes to stimulate the muscle when the patient is in a resting state. It is intended to increase muscle strength and joint mobility, leading to improved voluntary motor function.

Parastep I is a surface FES device intended to allow patients with lower extremity paralysis to stand and walk short distances.

The WalkAide system is a FES device that improves the walking ability of people suffering from foot drop. WalkAide uses sensor technology to analyze the movement of the leg and foot, sending electrical signals to the peroneal nerve which activates the muscles to raise the foot at the appropriate time during the step cycle.

Implanted FES devices (e.g., the Freehand System) incorporate surgically implanted stimulation electrodes, an implanted stimulator, and an external power supply. A shoulder position sensor mounted on the chest and shoulder translates small shoulder movements into a control signal. Use of these devices requires intensive and lengthy training by rehabilitation specialists.

MicroVas is a noninvasive electrical stimulator that causes muscles contraction and relaxation cycles. It is used to treat small vessel disease and neuropathy in the feet and ankles. The MicroVas stimulator is supposed to increase blood flow, tissue oxygenation, promote lymphatic drainage, and induce involuntary exercise. However, it has not been proven for this purpose. MicroVas therapy was developed originally by the U.S. Military to treat hypothermia in Navy Seals.

VitalStim Therapy is a type of neuromuscular electrical stimulation in which a small current is passed through external electrodes placed on the neck to stimulate inactive or atrophied swallowing muscles. With repeated therapy, throat muscles are reported to be re-trained, and the patient progresses to an optimum level of swallow function.

Interferential Stimulation (IFS)

IFS is an anti-inflammatory based treatment modality. The interferential stimulator crosses two medium frequency alternating currents, which penetrate deep into soft tissue. It is intended for use in the treatment of circulation disorders, range of motion issues, edema, and muscle spasms. It is reported to stimulate bone healing, inhibit pain and promote soft tissue healing. A number of interferential stimulator devices have received FDA approval including the Medstar 100 (Mednet Services and the RS-4V (RS Medical).

Multimodal Electrotherapy Stimulation Devices

Combination transcutaneous electrical nerve stimulation, interferential stimulation and neuromuscular electrical stimulation devices are TENS devices capable of delivering any of the three modalities depending on electrode arrangement on the body and programming options. This type of device is intended to treat a wide variety of symptoms especially for acute and chronic pain relief. TruWave Plus, NexWave, and Empi Continuum are examples of combination devices.

SUPPORTIVE LITERATURE

Transcutaneous Electrical Nerve Stimulation and H-Wave Stimulation

TENS and H-Wave Muscle Stimulators have a treatment effect beyond that of a credible placebo. Their use may be justified in those individuals with mild acute or chronic pain who wish to use a nonpharmacological form of analgesia. The FDA classified this device as a TENS unit; however, the manufacturer has indicated that it is a new category of device, as it uses a different array of proprietary electrical amplitudes than a TENS unit and does not function to stimulate nerves. Instead, the BioniCare device is purported to stimulate chondrogenesis. However, no studies have been performed to evaluate whether chondrogenesis occurs with use of this device.

Johnson et al (2022) conducted a systematic review and meta-analysis that evaluated the effectiveness and safety of TENS for pain relief in adults. Researchers analyzed data from 381 randomized controlled trials involving 24,532 participants. The findings showed that TENS

significantly reduced pain intensity during or immediately after treatment compared to placebo, with moderate-certainty evidence. It also showed benefits over standard pharmacological and non-pharmacological treatments, though with low-certainty evidence due to small sample sizes and imprecision. The type of pain and study methodology did not significantly affect outcomes. Adverse events were infrequently reported, generally mild, and similar to those in comparison groups. Overall, TENS appears to be a safe and moderately effective method for short-term pain relief.

Neuromuscular and Functional Electrical Stimulation

Sajiki-Ito et al (2024) conducted a retrospective study to investigate the effects of inpatient rehabilitation on muscle mass and physical performance in older adults following hip fracture surgery. Seventeen patients with a mean age of 85 years underwent a rehabilitation program that included exercises for joint mobility, muscle strengthening, gait training, early mobilization, and neuromuscular electrical stimulation. Over six weeks, lower limb muscle mass significantly increased, while upper limb muscle mass and body weight decreased. Total muscle and fat mass remained stable. Grip strength was maintained, and knee extension strength improved on both the healthy and affected sides. All patients showed better ability to perform daily activities, though only about half regained their pre-injury walking ability. The findings suggest that targeted rehabilitation can effectively enhance lower limb muscle mass and functional recovery after hip fracture surgery.

Conley et al (2021) conducted a systematic review aimed to evaluate how different neuromuscular electrical stimulation (NMES) parameters affect quadriceps strength recovery following knee surgery. Researchers searched four major databases and included eight randomized controlled trials (RCTs) that met strict criteria, such as reporting specific NMES parameters and quadriceps strength outcomes. The study consisted of 17 patients with a mean age of 84 years. Postoperative factors measured after one and six weeks were: muscle mass, body weight, fat mass, grip strength, bilateral knew extension strength, ability to walk and ability to perform activities of daily living (ADLs). Results showed lower limbs skeletal muscle mass increased (median 4.8 kg to 4.9 kg), while upper limbs skeletal muscle mass and body weight decreased (median 1.2 kg to 1.1 kg), (median 46.8 kg to 45.5 kg). Total skeletal muscle mass and fat mass remained unchanged. Grip strength was maintained, and knee extension muscle strength on the healthy and affected sides increased (healthy side median 10.7 kgf to 13.7 kgf; affected side median 5.5 kgf to 9.5 kgf). Ability to perform ADLs improved amongst all patients. Patients regained their pre-injury walking ability (52.9%). Optimal outcomes were associated with NMES applied within the first two weeks post-surgery, using a frequency of ≥ 50 Hz, maximum tolerable intensity, biphasic current, large electrodes, and a duty cycle ratio of 1:2 to 1:3 with a 2–3 second ramp time.

There is insufficient data to demonstrate that FES results in improved net health outcomes. Data is insufficient regarding whether patients remain compliant and committed with long-term use of the devices (Parastep I, the Neuro Control Freehand System, the Ness H200 Hand Rehabilitation System, the Ness L300 Foot Drop System, G. Estim FES, and the WalkAide System).

No published studies of the MicroVas device were identified. Micro Vas therapy has been around since the late 1980s. It was originally used to treat hypothermia in Navy Seals who experienced the negative effects of extreme temperatures. Over time, Micro Vas therapy evolved into a treatment for

neuropathy and other painful conditions, especially those that affect the extremities.

To date, there have been very few studies of surface electrical stimulation to the neck for swallowing that support the efficacy of VitalStim. These studies have small sample sizes and report mixed results. There is insufficient evidence in the peer reviewed literature to conclude that electrical stimulation is effective in the treatment of dysphagia. Stimulators have not been studied in pregnant women or patients with seizures and balance disorders.

Interferential Stimulation

Hussien et al (2022) conducted a meta-analysis including 19 trials, (N=1167) to analyze the efficacy of IFS in alleviating musculoskeletal pain. Two trials compared IFS with placebo and the pooled mean difference in pain was significantly reduced with IFS versus a placebo (-0.98; 95% confidence interval [CI], -1.42 to -0.54; p<.0001), but this was not demonstrated in the six (6) trials comparing IFS to other interventions (-0.04; 95% CI, -0.20 to 0.12; p<.65). When used as an adjunct to other pain interventions, IFS did not significantly improve pain compared with placebo in four (4) studies (-0.06; 95% CI, -0.6 to0.48; p=.82) or compared with active treatment in eight (8) studies (0.02; 95% CI, -0.88 to 0.92; p=not reported). The authors concluded that IFS reduced musculoskeletal pain when used as a single agent compared with placebo, but this is limited by the small number of trials (n=2) and patients enrolled.

PROFESSIONAL GUIDELINE(S)

According to the Agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness publication on Non-Invasive Treatments for Low Back Pain (2016), additional evidence demonstrates that TENS is not effective versus sham TENS. Effectiveness of TENS was previously classified as insufficient, and the strength of evidence remains low because of methodological limitations in the trials and imprecision. Evidence on harms associated with TENS was limited but suggests an increased risk of skin site irritation without an increased risk of serious adverse events (AHRQ 2016).

The American College of Physician's Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain Clinical Practice Guideline (2017), stated that evidence was insufficient to determine the effectiveness of transcutaneous electrical nerve stimulation (TENS).

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates electrical stimulation devices as medical devices. All electrical stimulation devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Mar 20]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Mar 20]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates)
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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HCPCS Codes

Code	Description
A4595	Electrical stimulation supplies, 2 lead, per month, (e.g., TENS, NMES)
A4630	Replacement batteries, medically necessary, transcutaneous electrical stimulator, owned by patient
E0720	TENS, two lead, localized stimulation
E0730	TENS, four or more leads, for multiple nerve stimulation
E0731	Form-fitting conductive garment for delivery of TENS or NMES (with conductive fibers separated from the patient's skin by layers of fabric).
E0744	Neuromuscular stimulator for scoliosis
E0745	Neuromuscular stimulator, electronic shock unit
E0762 (E/I)	Transcutaneous electrical joint stimulation device system, includes all accessories
E0764 (NMN)	Functional neuromuscular stimulation, transcutaneous stimulation of sequential muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program
E0770 (NMN)	Functional neuromuscular stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified
G0283 (NMN)	Electrical stimulation (unattended), to one or more areas for indication(s) other than wound care, as part of a therapy plan of care
S8130 (E/I)	Interferential current stimulator, 2 channel
S8131 (E/I)	Interferential current stimulator, 4 channel

ICD10 Codes

Code	Description
E08.40-E08.42	Diabetes mellitus due to underlying condition with diabetic neuropathy (code range)
E09.40-E09.42	Drug or chemical induced diabetes mellitus with neurological complications with diabetic neuropathy (code range)
E10.40-E10.42	Type 1 diabetes mellitus with diabetic neuropathy (code range)
E11.40-E11.42	Type 2 diabetes mellitus with diabetic neuropathy (code range)
E13.40-E13.42	Other specified diabetes mellitus with diabetic neuropathy (code range)
G43.101-G43.419	Polyneuropathy in diseases classified elsewhere
G43.701-G43.719	Sequelae of inflammatory polyneuropathy (code range)
G43.B0-G43.B1	Chronic pain, not elsewhere classified (code range)
G43.801-G43.919	Chronic pain syndrome
G44.1	Complex regional pain syndrome I (code range)
G44.201-G44.209	Polyosteoarthritis (code range)
G44.211-G44.219	Osteoarthritis of hip (code range)
G44.221-G44.229	Osteoarthritis of knee (code range)
G44.301-G44.309	Osteoarthritis of first carpometacarpal joint (code range)
G44.321-G44.329	Osteoarthritis, shoulder, arm and hand (code range)
G46.0-G46.8 (NMN)	Pain in joint (code range)
G50.0-G50.9	Systemic sclerosis with polyneuropathy

Code	Description
G51.2-G51.9	Fusion of spine, lumbosacral region
G56.00-G56.03	Fusion of spine, sacral and sacrococcygeal region
M15.0-M15.9	Polyosteoarthritis (code range)
M16.0-M16.9	Osteoarthritis of hip (code range)
M17.0-M17.9	Osteoarthritis of knee (code range)
M18.0-M18.9	Osteoarthritis of first carpometacarpal joint (code range)
M19.011-M19.079	Primary osteoarthritis (code range)
M19.111-M19.179	Post-traumatic osteoarthritis (code range)
M19.211-M19.279	Secondary osteoarthritis (code range)
M19.90-M19.93	Osteoarthritis, unspecified site (code range)
M25.50-M25.579	Pain in joint (code range)
M26.621-M26.629	Arthralgia of temporomandibular joint (code range)
M43.26-M43.28	Fusion of spine (code range)
M43.8x6-M43.8x9	Other specified deforming dorsopathies (code range)
M51.16-M51.17	Intervertebral disc disorders with radiculopathy (code range)
M53.1	Cervicobrachial syndrome
M53.2x7	Spinal instabilities, lumbosacral region
M53.2x8	Spinal instabilities, sacral and sacrococcygeal region

Code	Description
M53.3	Sacrococcygeal disorders, not elsewhere classified
M53.86-M53.88	Other specified dorsopathies (code range)
M53.9	Dorsopathy, unspecified
M54.06-M54.09	Panniculitis affecting regions of neck and back (code range)
M54.16-M54.18	Radiculopathy (code range)
M54.30-M54.32	Sciatica (code range)
M54.40-M54.42	Lumbago with sciatica (code range)
M54.5	Low back pain
M60.80-M60.9	Other myositis (code range)
M62.830	Muscle spasm of back
M77.10-M77.12	Lateral epicondylitis (code range)
M79.0	Rheumatism, unspecified
M79.10-M79.18	Myalgia (code range)
M79.2	Neuralgia and neuritis, unspecified
M79.601-M79.676	Pain in limb, hand, foot, fingers and toes (code range)
R10.0-R10.9	Abdominal and pelvic pain (code range)
R51.0-R51.9	Headache (code range)
R52	Pain, unspecified

REFERENCES

Allen CB, et al. Do electrical stimulation devices reduce pain and improve function? A comparative review. Pain Ther 2023;12:1339-1354.

Beltran-Alacreu H, et al. Percutaneous versus transcutaneous electrical nerve stimulation for the treatment of musculoskeletal pain. A systematic review and meta-analysis. Pain Med. 2022 Aug 01; 23(8):1387-1400.

Boldt I, et al. Non-pharmacological interventions for chronic pain in people with spinal cord injury. Cochrane Database Syst Rev. 2014;11:CD009177.

Brosseau L, et al. Transcutaneous electrical nerve stimulation (TENS) for the treatment of rheumatoid arthritis in the hand (Review). Cochrane Database Syst Rev. 2010;(7):CD004377.

Buchmuller A, et al. Value of TENS for relief of chronic low back pain with or without radicular pain. Eur J Pain. 2012 May;16(5):656-65.

Conley CEW, et al. A comparison of neuromuscular electrical stimulation parameters for postoperative quadriceps strength in patients after knee surgery: a systematic review. Sports Health. 2021 Mar;13(2):116-127.

Dantas et al. Gait training with functional electrical stimulation improves mobility in people post-stroke. International Journal of Environmental Research and Public Health. 2023 May; 20(9):5728.

Dowswell T, et al. Transcutaneous electrical nerve stimulation (TENS) for pain relief in labour. Cochrane Database Syst Rev. 2009;(2):CD007214.

Dubinsky RM, et al. Assessment: efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review). Report of the therapeutics and technology assessment subcommittee of the American Academy of Neurology. Neurology. 2010;74:173–6.

Gibson W, et al. Transcutaneous electrical nerve stimulation (TENS) for chronic pain. Cochrane Database Syst Rev. 2019;(4):CD011890.

Hurlow A, et al. Transcutaneous electrical nerve stimulation (TENS) for cancer pain in adults. Cochrane Database Syst Rev. 2012;(3):CD 006276.

Hussein HM, et al. A systematic review and meta-analysis investigating the pain-relieving effect of interferential current on musculoskeletal pain. Am J Phys Med Rehabil. 2022 July;101(7)624-633.

Johnson MI, et al. Efficacy and safety of transcutaneous electrical nerve stimulation (TENS) for acute and chronic pain in adults: a systematic review and meta-analysis of 381 studies (the meta-TENS study). BMJ Open. 2022 Feb 10;12(2):e051073.

Johnson MI, et al. Transcutaneous electrical nerve stimulation (TENS) for phantom pain and stump pain following amputation in adults. Cochrane Database Syst Rev. 2015 Aug 18;8:CD007264.

Khadilkar A, et al. Transcutaneous electrical nerve stimulation (TENS) versus placebo for chronic low-back pain. Cochrane Database Syst Rev. 2013;(2):CD003008.

Kreiner DS, et al. Guideline summary review: an evidence-based clinical guideline for the diagnosis

and treatment of low back pain. Spine J. 2020 Jul;20(7):998-1024.

Kroeling P, et al. Electrotherapy for neck pain. Cochrane Database Syst Rev. 2013;(8):CD004251.

Loh J, et al. The use of transcutaneous electrical nerve stimulation (TENS) in a major cancer center for the treatment of severe cancer-related pain and associated disability. Pain Med. 2015 Jun;16(6):1204-1210.

Martimbianco ALC, et al. Transcutaneous electrical nerve stimulation (TENS) for chronic neck pain. Cochrane Database Syst Rev. 2019 Dec 12;12(12):CD011927.

Pelland L, et al. Electrical stimulation for the treatment of rheumatoid arthritis (Review). Cochrane Database Syst Rev. 2010;(7):CD003687.

Rutjes AWS, et al. Transcutaneous electrostimulation for osteoarthritis of the knee. Cochrane Database Syst Rev. 2010;(1):CD002823.

Sajiki-Ito M, et al. Postoperative rehabilitation program for increasing muscle mass in patients with hip fracture: a retrospective study. Cureus. 2024 Jun 24;16(6):363053.

Simpson PM, et al. Transcutaneous electrical nerve stimulation for relieving acute pain in the prehospital setting: a systematic review and meta-analysis of randomized-controlled trials. Eur J Emerg Med. Feb 2014;21(1):10-17.

van Middlelkoop M, et al. A systematic review of the effectiveness of physical and rehabilitation interventions for chronic non-specific low back pain. Eur Spine. J 2011 Jan;(1):19-39.

Vance CG, et al. Effects of transcutaneous electrical nerve stimulation on pain, pain sensitivity and function in people with knee osteoarthritis: a randomized controlled trial. Phys Ther. 2012 Jul;92(7):898-910.

Walsh DM et al. Transcutaneous electrical nerve stimulation for acute pain. Cochrane Database Syst Rev. 2009;(2):CD006142.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Assessing Patient's Suitability for Electrical Nerve Stimulation Therapy (NCD 160.7.1) [accessed 2026 Mar 13]

Transcutaneous Electrical Nerve Stimulators (TENS) (LCD L33802) [accessed 2026 Mar 13]

Transcutaneous Electrical Nerve Stimulation (TENS) for Acute Post-Operative Pain (NCD 10.2) [accessed 2026 Mar 13]

Transcutaneous Electrical Nerve Stimulation (TENS) for Chronic Low Back Pain (CLBP) (NCD 160.27) [accessed 2026 Mar 13]

Supplies Used in the Delivery of Transcutaneous Electrical Nerve Stimulation (TENS) and

Neuromuscular Electrical Stimulation (NMES) (NCD 160.13) [accessed 2026 Mar 13]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New:7/26 **Revised**: **Reviewed**:	
Date	**Summary of Changes**
8/1/2026	New policy in conjunction with other new policies 1.01.58, 1.01.59, 1.01.60, & 1.01.62, which will replace Neuromuscular/Functional Electrical Stimulation policy 1370/20.000073 which is being made obsolete.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

MEDICAL POLICY

Medical Policy Title	**Non-Surgical Management of Sleep Disorders**
Policy Number	**1.01.63**
Current Effective Date	**February 15, 2027**
Next Review Date	**October 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Positive Airway Pressure Devices (Continuous [CPAP] and Auto-Adjusting [APAP])

Initial 90-day Trial

I. CPAP and APAP are considered **medically appropriate** for **ANY** of the following indications:
   A. Adults with obstructive sleep apnea (OSA) who meet **ONE** of the following indications:
      1. Polysomnography (PSG) or home sleep testing (HST) results documenting an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) of >5 (five), and <15 respiratory events per hour and ONE of the following associated symptoms:
         a. Symptoms of OSA (e.g., excessive daytime sleepiness, impaired cognition, insomnia); **or**
         b. Documented cardiovascular diseases, including hypertension, ischemic heart disease, or history of stroke; **or**
      2. PSG or HST results document an AHI or RDI of ≥15 respiratory events per hour;
   B. Children <18 years with OSA who meet **ALL** of the following indications: (90-day continuation review is **not** required for pediatric members.)
      1. **Any** of the following indications:
         a. Failure of adenotonsillectomy to relieve OSA symptoms;
         b. A contraindication to surgical intervention;
         c. Nonsurgical approach is strongly preferred; **and**
      2. PSG results document **Either** of the following:
         a. AHI or RDI of ≥5 and exhibits OSA symptoms;
         b. AHI or RDI within normal ranges and the individual exhibits OSA symptoms (e.g., excessive daytime sleepiness, impaired cognition, insomnia) and **any** of the following:
            i. Child exhibits episodes of hypercarbia based on end-tidal CO_2 measurements

>53 mm Hg;

ii. End-tidal CO_2 is >50 mmHg for 10 to 24% of the sleep time.

Continuation of Use (Past 90-day Trial)

II. Continuation of coverage after the 90-day trial is **medically appropriate** when **BOTH** of the following have been demonstrated. (See Policy Guidelines for Failure of Compliance)

A. Improved AHI and symptom resolution during trial;

B. Compliance has been demonstrated (e.g., defined by using the device for 70% of the nights, for four (4) or more hours per 24-hour period, during a consecutive 30-day period).

III. CPAP is **not medically necessary** for the treatment of snoring without accompanying OSA.

Oral Appliances (OAs)

IV. OAs are **medically appropriate** for the treatment of OSA when **ALL** of the following are met:

A. Individual meets **one** of the following:

1. The individual cannot tolerate or refuse CPAP therapy; **or**
2. The physician determines that the use of PAP therapy is contraindicated;

B. Individual meets **one** of the following indication severity specific criteria:

1. Mild OSA diagnosis documented with a AHI or RDI ≥ 5 and ≤ 14, confirmed by a sleep study (e.g., PSG or home sleep study) with at least **any** of the following indications:
   a. Hypertension;
   b. Heart disease;
   c. Stroke;
   d. Excessive daytime sleepiness;
   e. Impaired cognition;
   f. Mood disorders; **or**
   g. Insomnia;
2. Moderate OSA diagnosis documented with a AHI or RDI ≥ 15 and < 30 confirmed by a sleep study; **or**
3. Severe OSA diagnosis documented with a AHI or RDI ≥ 30, confirmed by a sleep study.

V. Oral Appliances (OAs) are considered **not medically necessary** for **ANY** of the following indications, including but are not limited to:

A. Upper Airway Resistance Syndrome (UARS) with or without snoring and without a diagnosis of OSA;

B. Primary snoring;

C. Temporomandibular joint disorders (TMJD);

D. Central sleep apnea;

E. Prefabricated or non-custom OAs

VI. Non-surgical management for sleep disorders are considered **investigational**, including but not limited to **EITHER** of the following:

A. Daytime neuromuscular electrical stimulation devices (e.g., eXciteOSA);

B. Sleep positioning trainer with or without vibration.

VII. Replacement of a medically necessary OA is **eligible for coverage** after five (5) years, unless there is documented evidence of device failure or a clinically significant change in the patient's condition that necessitates earlier replacement (e.g., tooth loss or major dental reconstruction).

Durable Medical Equipment (DME) Repair

VIII. Repair of a medically necessary non-surgical sleep disorder DME or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** the following:

1. date of DME initiation;
2. manufacturer warranty information, if applicable;
3. attestation that the patient has been compliant with the use of the DME and will continue to benefit from the use of the DME;

B. The DME is no longer functioning adequately; and **BOTH** of the following criteria are met:

1. inadequate function interferes with activities of daily living; and
2. repair is expected to make the equipment fully functional (as defined by manufacturer).

IX. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

DME Replacement

X. Replacement of a medically necessary non-surgical sleep disorder DME or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

A. The DME is no longer functioning adequately and has been determined to be non-repairable, or the cost of the repair is in excess of the replacement cost;

B. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

XI. The replacement of a properly functioning non-surgical sleep disorder DME, its components or accessories are considered **not medically necessary**. This includes, but is not limited to,

replacement desired due to advanced technology or to make the DME more aesthetically pleasing;

XII. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

XIII. Accessories or components for non-surgical sleep disorder DME that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

Device Repair

XIV. Repair of a medically necessary non-surgical sleep disorder device or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** of the following:

1. date of device implantation/initiation;
2. manufacturer warranty information, if applicable;
3. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device;

B. The device is no longer functioning adequately; and **BOTH** of the following criteria are met:

1. inadequate function interferes with activities of daily living; **and**
2. repair is expected to make the equipment fully functional (as defined by manufacturer).

XV. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

Device Replacement

XVI. Replacement of a medically necessary non-surgical sleep disorder device or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

A. The device is no longer functioning adequately and has been determined to be non-repairable, or the cost of the repair is in excess of the replacement cost;

B. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

XVII. The replacement of a properly functioning non-surgical sleep disorder device, its components or accessories are considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing;

XVIII. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when

another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

XIX. Accessories or components for non-surgical sleep disorder devices that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

1.01.00 Durable Medical Equipment (DME) and Devices, Standard and Non-Standard

7.01.41 Surgical Management of Sleep Disorders

11.01.03 Experimental or Investigational Services

11.01.17 Temporomandibular Joint Disorders (TMJD)

POLICY GUIDELINE(S)

CPAP

I. Individuals who do not meet the criteria for continuation of coverage during the initial 90 day trial are eligible to re-qualify for a CPAP device, but must have a clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to CPAP therapy (e.g., documentation of failure of symptoms to resolve or improper fit of device, and re-education of the individuals regarding proper use of the equipment or re-fitting of masks).

I. CPAP with expiratory relief or APAP are options for patients who cannot tolerate the high constant air pressure associated with CPAP but wish to continue treatment for OSA.

II. Supplemental oxygen or humidification can be added to positive pressure devices to increase oxygen saturation and decrease vasomotor rhinitis.

III. Coverage is allowed for a one-month rental when the CPAP device is malfunctioning and out of warranty, (and not associated with a manufacturer recall) while the device is being repaired.

IV. The monitoring feature/device, stand-alone or integrated, any type, including all accessories, components, and electronics, not otherwise classified (HCPCS: A9279) is considered inclusive to the positive airway pressure device.

V. Devices used to clean or sanitize CPAP devices are considered a convenience item and are ineligible for coverage (e.g., SoClean, SoClean 2 Go).

Oral Appliances

I. Attempts at behavioral modifications and lifestyle changes (e.g., good sleep hygiene, weight loss, avoidance of alcohol consumption in evening, smoking cessation, sleep position change, treatment of nasal congestion) for individuals with UARS and sleep apnea should be an integral part of the treatment regimen for sleep-disordered breathing.

II. The decision for the use and fabrication of an OA should be made by a sleep medicine physician (e.g., somnologist or sleep specialist; ear, nose, and throat [ENT] specialist) or by an experienced dentist/orthodontist in collaboration with a sleep specialist.

III. All impressions, try-ins, and adjustments and repairs are inclusive to the lifetime of the appliance after approval of the device.

DESCRIPTION

Sleep related breathing disorders are characterized by abnormal respiration during sleep, which may or may not also occur during wakefulness. These abnormalities can include pauses in breathing, shallow breathing, or reduced airflow, often leading to fragmented sleep and reduced oxygen levels. Other symptoms can include loud snoring, gasping, choking during sleep, morning headaches, dry mouth, daytime fatigue, sleepiness, mood changes, and cognitive issues.

Primary Snoring

Primary snoring (also called simple snoring or non-apneic snoring) is defined as habitual snoring in the absence of obstructive sleep apnea — specifically, an apnea-hypopnea index (AHI) <5 events per hour on polysomnography, without significant oxygen desaturation, frequent arousals, or gas exchange abnormalities.

Sleep Apnea

Sleep apnea is a common sleep disorder characterized by repeated interruptions in breathing during sleep. These interruptions called apnea can occur hundreds of times per night which can lead to fragmented sleep and decreased oxygen levels resulting in daytime fatigue, cardiovascular problems, and other health issues.

Obstructive Sleep Apnea (OSA)

Obstructive sleep apnea (OSA) is a sleep-related breathing disorder (the most common type) caused by upper-airway obstruction, most often from relaxed throat muscles during sleep. In adults, OSA involves recurrent episodes of complete or partial upper airway blockage lasting more than 10 seconds and is commonly linked to obesity, male sex, aging, and anatomical factors. Symptoms include loud snoring, witnessed apneas, gasping, excessive daytime sleepiness, and hypertension, and diagnosis requires polysomnography or home sleep testing with evidence of clinical impairment. Untreated adult OSA increases the risk of hypertension, heart failure, atrial fibrillation, other arrhythmias, and nonalcoholic fatty liver disease.

Pediatric OSA, typically caused by enlarged tonsils and adenoids, is defined by prolonged partial obstruction or intermittent complete obstruction lasting at least two respiratory cycles and may present with snoring, breathing pauses, restless sleep, behavioral issues, or poor growth. If left untreated, children may experience growth abnormalities, neurologic problems, or cor pulmonale. Polysomnography (PSG) is the preferred diagnostic tool, although normative AHI/RDI values for children are not well established. Adenotonsillectomy is first-line therapy for pediatric OSA, while persistent cases or those with contraindications may require CPAP, observation, medications, or additional airway surgery. Obstructive hypoventilation (OH), a related condition in children, may

present with normal AHI but episodes of hypercarbia indicated by elevated end-tidal CO_2.

Central Apneas

Central sleep apnea is defined as the cessation of airflow through the nose and mouth for at least 10 seconds with no respiratory effort noted. Central sleep apnea occurs when the brainstem, which regulates breathing, does not respond appropriately to changes in carbon dioxide levels in the blood. This results in reduced or absent respiratory effort, leading to pauses in breathing during sleep. Central apneas are often linked to heart failure or neurological conditions. The central apneas occur without any airway obstruction. Approximately 4% of individuals undergoing PSG in a sleep laboratory are diagnosed with central sleep apnea, making this an uncommon condition.

Mixed Apneas

Mixed sleep apnea is a combination of obstructive and central sleep apnea. Not only does the patient have an obstruction in the airway, but the patient may have a neurological dysfunction or cardiopulmonary as well that contributes to the central apnea component.

Continuous Positive Airway Pressure (CPAP)

CPAP is the gold standard treatment option for adults with documented OSA. The symptoms associated with OSA, such as excessive daytime sleepiness, impaired cognition, and mood disorders are reduced or eliminated with the consistent use of CPAP. CPAP is not indicated in individuals with simple snoring that is not associated with pauses in respirations. Treatment recommendations for OSA are based primarily on the RDI or the AHI, the severity of the presenting symptoms, and the existence and severity of co-morbid conditions.

CPAP provides constant pressure throughout the respiratory cycle by raising the intraluminal upper airway pressure above the positive critical transmural pressure of the pharynx or hypopharynx. The pressure is delivered by a flow generator through either nasal mask or modified nasal prongs to keep the upper airway patent resulting in adequate ventilation and arterial oxygenation. The pressure used is determined individually, with a range of 3 to 20 cm. water.

Auto- or Self-Titrating Positive Airway Pressure (APAP)

Auto- or self-titrating positive airway pressure, or APAP, systems utilize an algorithm that uses a pressure transducer and microprocessor to monitor the airway for vibration patterns and then makes air pressure adjustments based on the incidence of apnea or absence of vibration. APAP devices are also referred to as demand positive airway pressure devices (DPAP).

CPAP with expiratory relief (e.g., C- Flex technology Respironics, Inc., Murrysville, PA) is designed to provide pressure relief during expiration, while maintaining optimal pneumatic splinting for effective therapy. CPAP with expiratory relief technology monitors the patient's airflow during expiration and reduces expiratory pressure proportional to expiratory flow. CPAP with C-Flex technology can increase compliance in those patients who find it difficult or uncomfortable to breathe out against the continuous positive pressure. This technology can be applied to CPAP, BPAP and APAP devices.

Most PAP machines now contain a data card that can record and transmit daily use rates of the device. In addition, most PAP machines can also be equipped with a modem (either wired or

wireless) that is capable of transmitting data daily to a manufacturer-owned database. The ability to detect disturbances in a variety of measures, including air flow, amount of time used, and mask leak, is also included in most commercially available PAP machines.

Upper Airway Resistance Syndrome (UARS)

UARS is a milder form of obstructive sleep related breathing. The airway narrows but does not fully close. This can cause sleep fragmentation and fatigue.

Hypoventilation Disorders

Sleep related hypoventilation disorders causes inadequate breathing during sleep which can lead to high carbon dioxide levels. Hypoventilation disorders are common in obesity, neuromuscular disorders, or medication use.

Hypoxemia

Sleep related hypoxemia is sustained low oxygen levels during sleep without elevated carbon dioxide. Often due to lung diseases or other medical conditions.

Oral Appliances (OAs)

OAs can be prefabricated, ready-made, or custom fitted device worn in the mouth during sleep to treat OSA and snoring. They work by repositioning the jaw, tongue, or soft tissues to keep the airway open, allowing for uninterrupted breathing throughout the night. The most common type of oral appliance is the mandibular advancement device (MAD), which is custom made for each individual and adjustable to allow a dentist to modify the degree of jaw advancement as needed. The goal is to achieve the most comfortable and effective position for the individual. Examples of custom oral appliances include tongue-retaining devices, non-adjustable mandibular repositioning devices (MRDs), and adjustable MRDs. These appliances may be used as an alternative to other medical (e.g., CPAP and surgical (e.g., Uvulopalatopharyngoplasty) interventions.

AIO BREATHE (AIOMEGA LLC, Texas) is a lightweight MAD that increases airway size and repositions the jaw to keep the airway more open during sleep. It is recommended for mild to moderate sleep apnea and snoring.

ProSomnus EVO PH (ProSomnus Sleep Technologies), sleep and snore devices use medical grade polymers and hinge components to reposition and stabilize the jaw during sleep. The OA causes an increase in the pharyngeal space, reducing the risk of upper airway collapse. The device is recommended for snoring and to treat mild to moderate OSA.

iNAP (Somnics Health, Inc.) uses gentle suction to move the tongue forward. No mask or headgear is required.

Vivos (Vivos Therapeutics, Inc) OAs are noninvasive, custom-made devices designed to treat OSA and snoring. They function by repositioning the hard and soft tissues of the airway to enhance airflow and improve upper airway function. The Vivos System gradually remodels the upper airway and jaw structure over time to address the underlying anatomical causes of OSA. Recently, the United States Food and Drug Administration (FDA) approved Vivos OAs the treatment of severe OSA.

Neurostimulators

eXciteOSA is an FDA approved daytime therapy designed to treat snoring and mild OSA by strengthening tongue muscles through neuromuscular electrical stimulation (NMES). It is intended for adults aged 18 and older with an AHI less than 15. The device consists of a mouthpiece with four electrodes, two above and two below the tongue that are connected to a control unit via USB. It delivers electrical pulses to stimulate both intrinsic and extrinsic tongue muscles. This stimulation strengthens the muscles, helping to prevent the tongue from collapsing backward during sleep. As a result, it supports airway patency and contributes to the reduction of snoring and apnea events.

Positional Sleep Aids

Positional sleep aids encourage sleeping positions that may help with snoring, sleep apnea, back pain, and acid reflux. There are many different types of positional sleep aid devices such as pillows or noodles or devices that can be placed on the body that vibrate or inflate when in the supine sleep.

SUPPORTIVE LITERATURE

CPAP

Figard et al (2025) conducted an umbrella review of meta-analysis of randomized controlled trials that evaluated the effectiveness, adherence, and safety of treatments for OSA by synthesizing evidence from 34 meta-analyses of 230 randomized controlled trials involving 36,353 participants. The review found that CPAP remains the most effective treatment for reducing the AHI and improving daytime sleepiness. Other interventions, including glucagon-like peptide-1 (GLP-1) receptor agonists such as tirzepatide and MADs, also significantly reduced OSA severity, although to a lesser extent than CPAP. Daytime sleepiness improved with CPAP, hypoglossal nerve stimulation (HNS), wake-promoting medications, and myofunctional therapy. Physical activity produced the greatest improvements in quality of life, while CPAP provided more modest benefits. Overall, most of the evidence was of low to moderate certainty, with only one meta-analysis providing high-certainty evidence. The authors concluded that CPAP remains the most effective therapy for OSA, but alternative treatments may offer meaningful benefits for selected patients. However, limited data on long-term adherence, safety, and combination therapies highlight the need for further comparative and long-term research to support individualized treatment approaches. The findings should also be interpreted cautiously because of limitations related to the quality of the included meta-analyses and their selection criteria.

Sanchez-de la-Torre et al (2023) conducted a systematic review and meta-analysis of individual participant data (IPD) from three RCT, Sleep Apnea Cardiovascular Endpoints (SAVE), Impact of Sleep Apnea Syndrome in Acute Coronary Syndrome (ISAACC) and Randomized Intervention with CPAP in Coronary Artery Disease and Sleep Apnea (RICCADSAO) to assess whether adherence to CPAP therapy reduces the risk of major adverse cardiac and cerebrovascular events (MACCEs) in individuals with OSA and established cardiovascular disease. The study included 4186 adults with cardiovascular disease and OSA. The primary outcome was the first MACCEs. Statistical analysis included one stage and two stage IPD meta-analysis as well as on treatment analysis using marginal structural models to assess the effects of CPAP adherence. A total of 691 MACCEs (16.5%) were observed, the CPAP group had 349 and the no CPAP group 342. The main outcome intention- to-treat analysis did not show a significant difference in MACCEs between the CPAP and the no CPAP

group. The on-treatment analysis revealed good adherence to CPAP (≥4 hours per day) was associated with a reduced risk of MAACEs reoccurrence. Adherence to CPAP was associated with reduced MACCE recurrent risks suggesting that treatment adherence is a key factor in secondary cardiovascular prevention in individuals with OSA.

Patil et al (2019) conducted a systematic review and meta-analysis of 184 studies to evaluate the effectiveness of PAP therapy for adults with OSA. CPAP significantly reduced AHI by 23 events/hour versus no treatment—an 86% reduction from 32.7 to 4.1 events/hour. CPAP also improved daytime sleepiness by 2.4 points in symptomatic patients and showed clinically meaningful benefits for sleep-related quality of life, blood pressure, and motor vehicle crash risk. Observational evidence suggested reductions in cardiovascular events and mortality, though RCTs did not confirm these outcomes. No major differences were found among CPAP, APAP, and BiPAP for individual clinical outcomes, supporting CPAP as first-line therapy unless not tolerated. Home-based versus in-lab APAP initiation showed comparable results. Education, behavioral interventions, and telemonitoring improved adherence. Nasal masks enhanced adherence and reduced AHI more effectively than oronasal masks. Humidification reduced side effects without improving adherence or outcomes. Overall, CPAP reliably reduces OSA severity, improves sleepiness, and lowers blood pressure, particularly in symptomatic or hypertensive adults. Benefits for asymptomatic individuals and long-term cardiovascular outcomes remain uncertain.

Wang et al (2019) conducted a systematic review to assess the effectiveness of home noninvasive NIPPV (home mechanical ventilation (HMV), BiPAP, or CPAP devices) in adults with chronic respiratory failure. 68 studies evaluating 53,733 patients were included. In patients with COPD, home BiPAP (compared to no device) was associated with lower mortality, decreased need for intubations and hospital admissions, but no change in quality of life. In patients with COPD, HMV (compared individually with BiPAP, CPAP, or no device) was associated with fewer hospital admissions. In patients with thoracic restrictive diseases, HMV (compared to no device) was associated with lower mortality. In patients with neuromuscular diseases, home BiPAP (compared to no device) was associated with lower mortality and better quality of life. In patients with obesity hypoventilation syndrome, home HMV/BiPAP (compared to no device) was associated with lower mortality. Current evidence was not available to assess the comparative effectiveness of many device capabilities on patient outcomes. Criteria to initiate home NIPPV and home respiratory services varied and were not validated in comparative studies.

Oral Appliances (OAs)

Gupta et al (2026) conducted a systematic review and meta-analysis evaluating the effectiveness of mandibular advancement devices (MADs) compared with continuous positive airway pressure (CPAP) and sham/control interventions in adults with obstructive sleep apnea (OSA). Eight randomized controlled trials involving 642 participants were included. The analysis found that CPAP was significantly more effective than MAD therapy in reducing the AHI, with patients using MADs demonstrating higher residual AHI values (mean difference [MD] = 11.83 events/hour; 95% CI: 6.61-17.04). In comparison with sham or control devices, MAD therapy significantly improved AHI (MD = 15.78 events/hour; 95% CI: 8.43-23.13), although heterogeneity remained high (I^2 = 86.47%). Secondary outcomes were variable but generally favored MAD treatment. Overall, the

findings indicate that CPAP remains the most effective treatment for reducing respiratory events in OSA, while MADs provide a beneficial alternative for patients who are unable to tolerate or consistently adhere to CPAP therapy. The results should be interpreted with caution due to the considerable heterogeneity among studies and the limited amount of sham-controlled evidence available.

Hamoda et al (2025) conducted a multicenter, double-randomized trial comparing CPAP and mandibular advancement splints (MAS) in treatment-naïve adults with mild-to-severe OSA to evaluate adherence, effectiveness, and long-term treatment patterns. A total of 81 participants were enrolled, with 73 completing the crossover phase and included in the intention-to-treat analysis. During the crossover phase, objective adherence was significantly higher with MAS than with CPAP, averaging 6.0 versus 5.3 hours per night, respectively, a difference of 0.7 hours per night. However, CPAP demonstrated superior efficacy in reducing respiratory events, with a mean difference in AHI reduction of 10.4 events per hour favoring CPAP. Both therapies produced substantial improvements in patient-centered outcomes, including symptoms and quality of life measures, resulting in comparable overall clinical effectiveness. During the six-month observational phase, more than half of participants (55%) chose to alternate between CPAP and MAS therapy, suggesting that access to both treatment options may enhance long-term disease management. The findings indicate that while CPAP remains the most efficacious treatment for reducing OSA severity, the higher adherence observed with MAS may offset some of this advantage, making both therapies similarly effective from a patient-centered perspective and supporting the use of combined treatment strategies to improve long-term OSA management.

Beri et al (2023) evaluated the effectiveness of OA therapy in treating OSA, focusing on the use of MADs and tongue retaining devices (TRDs). The study used the AHI as the primary outcome measure. The inclusion criteria focused on adults with an AHI greater than 5, treated with MAD or TRD, and compared it to CPAP therapy. The analysis was based on a systematic review and meta-analysis of six randomized controlled trials conducted between 1998 and 2021. OA significantly improves AHI compared to baseline (Mean Difference = 13.40; 95% CI). CPAP outperformed OA in reducing AHI (Mean Difference = 8.40; 95% CI). TRDs showed comparable results to MADs in some studies. Researchers concluded that MADs are effective alternatives for patients with mild to moderate OSA, especially those that are intolerant to CPAP.

Rossi et al (2021) conducted a systematic review of 17 randomized controlled trials (RCTs) to assess the clinical effectiveness of OAs in treating OSA. The review included RCTs with at least 50 participants, comparing OAs to CPAP, placebo, surgery, or other interventions. Findings showed that OAs significantly reduced both the AHI and the Oxygen Desaturation Index (ODI), including some individuals with severe OSA. Custom-fitted, titratable devices were found to be more effective than non-custom or non-titratable alternatives. While CPAP generally achieved greater reductions in AHI, OAs were associated with higher patient compliance and better tolerability. In cases of mild to moderate OSA, some studies showed that OAs were non-inferior to CPAP. Additionally, improvements in daytime sleepiness (Epworth Sleepiness Scale), snoring, and quality of life were observed, although these outcomes varied across studies.

<u>Electrical Stimulation Appliances</u>

The current body of evidence supporting non-surgical neuromuscular electrical stimulation for OSA remains limited. High-quality data demonstrating its safety and clinical efficacy are lacking. Well-designed, controlled studies are needed to evaluate its therapeutic effectiveness, safety profile, and long-term outcomes. Two cohort studies (Kotecha et al (2021) and Baptista et al (2021)) studied habitual snorers who were treated with eXciteOSA. Both studies reported a reduction in snoring time measured by the Watch-PAT device and bed-partner-reported snorting was also decreased. A reduction in AHI was noted in those participants with mild OSA in the Kotecha study but there was no clinically significant reduction in AHI reported in the Baptista study. Both the Epworth Sleepiness Scale (ESS) and Pittsburgh Sleep Quality Index (PSQI) test showed improvements as reported by the participants as well as the bed partners. These studies suggest that daytime tongue stimulation may improve snoring, but the effect on OSA is uncertain.

PROFESSIONAL GUIDELINE(S)

The 2015 clinical practice guidelines jointly issued by the American Academy of Sleep Medicine (AASM) and the American Academy of Dental Sleep Medicine (AADSM) (Ramar et al) reported new guidelines to update and replace previous recommendations for the use of OAs in the treatment of OSA and snoring. The recommendations are as follows:

- "Sleep physicians should prescribe oral appliances instead of offering no treatment for adults seeking help for primary snoring without obstructive sleep apnea."
- "When treating adults with OSA sleep physicians should recommend that a qualified dentist provide a custom, adjustable OAs rather than a non-custom device."
- "For adults with obstructive sleep apnea who cannot tolerate CPAP or prefer another option, sleep physicians should consider prescribing OA instead of leaving the condition untreated."
- "Qualified dentists should monitor patients using OAs for OSA to detect and minimize dental side effects or bite changes, rather than providing no follow-up."
- "Sleep physicians should conduct follow-up sleep studies to confirm or improve the effectiveness of OA therapy, rather than relying on follow-up without testing."

The American Academy of Dental Sleep Medicine (AADSM) released an updated position statement in October 2022, on the use of OAT for the treatment of OSA. Some of the recommendations include:

- "OAT is an effective treatment for both OSA and snoring, and should be considered a first-line therapy, particularly for patients who are intolerant of CPAP therapy."
- "Patient evaluation and appliance fitting should be conducted by qualified dentists trained in dental sleep medicine."
- "Patients should be offered a trial of OA or PAP therapy prior to considering surgical interventions for OSA."

The 2021 National Institute for Health and Care Excellence (NICE) Clinical Guidelines for Diagnosis and Management of Obstructive Sleep Apnea/Hypopnea Syndrome (OASAHS), Obesity Hypoventilation Syndrome (OHS) and Chronic Obstructive Pulmonary Disease with OSAHS (COPD-

OSAHS overlap syndrome) in people over 16 years of age recommends:

- "Offering fixed-level CPAP in those with mild OSA when symptoms affect quality of life (QOL) and usual daytime activities if lifestyle changes alone have been unsuccessful or are considered inappropriate."
- "APAP as an alternative to fixed-level CPAP in those unable to tolerate CPAP."
- "In individuals who cannot tolerate or refuse CPAP, they recommend offering a customized mandibular advancement device."
- "In individuals with moderate to severe OSA, CPAP is recommended as a treatment option, with APAP offered as an alternative in those unable to tolerate CPAP."
- "A customized mandibular advancement device may be used if an individual refuses PAP or is unable to tolerate PAP."
- "A positional modifier may be considered for those with mild to moderate positional OSA if other treatments are unsuitable or not tolerated, but this should not be a first-line treatment option."

The 2015 clinical practice guidelines that was jointly issued by the American Academy of Sleep Medicine (AASM) and the American Academy of Dental Sleep Medicine (AADSM) (Ramar et al), aimed to update and replace previous recommendations for the use of oral appliance therapy for adults with OSA. Recommendations are as follows:

- "Sleep physicians should prescribe oral appliances instead of offering no treatment for adults seeking help for primary snoring without obstructive sleep apnea."
- "When treating adults with OSA sleep physicians should recommend that a qualified dentist provide a custom, adjustable OAs rather than a non-custom device."
- "For adults with obstructive sleep apnea who cannot tolerate CPAP or prefer another option, sleep physicians should consider prescribing OA instead of leaving the condition untreated."
- "Qualified dentists should monitor patients using OAs for OSA to detect and minimize dental side effects or bite changes, rather than providing no follow-up."
- "Sleep physicians should conduct follow-up sleep studies to confirm or improve the effectiveness of OA therapy, rather than relying on follow-up without testing."

The 2012 American Academy of Pediatrics Clinical Guidelines (Marcus et al) for the Diagnosis and Management of Childhood Obstructive Sleep Apnea Syndrome (OSAS), focusing on uncomplicated OSAS (OSAS associated with adenotonsillar hypertrophy and/or obesity in otherwise healthy children). The recommendations are as follows:

- "All children/adolescents should be screened for snoring."
- "Polysomnography should be performed in children/adolescents with snoring and symptoms/signs of OSAS; if polysomnography is not available, then alternative diagnostic tests or referral to a specialist for more extensive evaluation may be considered. "
- "Adenotonsillectomy is recommended as the first-line treatment of patients with adenotonsillar

hypertrophy.

- High-risk patients should be monitored as inpatients postoperatively.
- Patients should be reevaluated postoperatively to determine whether further treatment is required. Objective testing should be performed in patients who are high risk or have persistent symptoms/signs of OSAS after therapy.
- Continuous positive airway pressure is recommended as treatment if adenotonsillectomy is not performed or if OSAS persists postoperatively."

- "Weight loss is recommended in addition to other therapy in patients who are overweight or obese. "
- "Intranasal corticosteroids are an option for children with mild OSAS in whom adenotonsillectomy is contraindicated or for mild postoperative OSAS."

The 2019 AASM clinical practice guidelines for the Treatment of Adult OSA with PAP (Patil et al) state the following recommendations:

- "Clinicians use PAP, compared to no therapy, to treat OSA in adults with excessive sleepiness. (strong)"
- "Clinicians use PAP, compared to no therapy, to treat OSA in adults with impaired sleep-related quality of life. (conditional)"
- Clinicians use PAP, compared to no therapy, to treat OSA in adults with comorbid hypertension. (conditional)
- "PAP therapy be initiated using either APAP at home or in-laboratory PAP titration in adults with OSA and no significant comorbidities. (strong)"
- "Clinicians use either CPAP or APAP for ongoing treatment of OSA in adults. (strong)"
- "Clinicians use CPAP or APAP over BPAP in the routine treatment of OSA in adults. (conditional)"
- "Educational interventions be given with initiation of PAP therapy in adults with OSA. (strong)"
- "Suggest that behavioral and/or troubleshooting interventions be given during the initial period of PAP therapy in adults with OSA. (conditional)"
- "Clinicians use telemonitoring-guided interventions during the initial period of PAP therapy in adults with OSA. (conditional)"

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates oral appliances as medical devices. All oral appliances including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Jul 17]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most

serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Jul 17]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
94660	Continuous positive airway pressure ventilation (CPAP), initiation and management

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CDT Codes

Code	Description
D9947	Custom sleep apnea appliance fabrication and placement
D9948	Adjustment of custom sleep apnea appliance
D9949	Repair of custom sleep appliance

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HCPCS Codes

Code	Description
A7027-A7039	Accessories/supplies, code range for positive pressure airway devices (code range)
A7044-A7046	Accessories/supplies, code range for positive pressure airway devices (code range)
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified
E0485	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, prefabricated, includes fitting and adjustment
E0486	Oral device/appliance used to reduce upper airway collapsibility, adjustable or non-adjustable, custom fabricated, includes fitting and adjustment
E0490 (E/I)	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by hardware

Code	Description
	remote
E0491 (E/I)	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by hardware remote, 90-day supply
E0492 (E/I)	Power source and control electronics unit for oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, controlled by phone application
E0493 (E/I)	Oral device/appliance for neuromuscular electrical stimulation of the tongue muscle, used in conjunction with the power source and control electronics unit, controlled by phone application, 90-day supply
E0530 (E/I)	Electronic positional obstructive sleep apnea treatment, with sensor, includes all components and accessories, any type
E0561	Humidifier, nonheated, used with positive airway pressure device
E0562	Humidifier, heated, used with positive airway pressure device
E0601	Continuous airway pressure (CPAP) device
K1027	Oral device/appliance used to reduce upper airway collapsibility, without fixed mechanical hinge, custom fabricated, includes fitting and adjustment
K1037	Docking station for use with oral device/appliance used to reduce upper airway collapsibility

ICD10 Codes

Code	Description
E66.2	Morbid (severe) obesity with alveolar hypoventilation
F51.8	Other sleep disorders not due to a substance or known physiological condition
G47.00-G47.09	Insomnia (code range)
G47.10-G47.19	Hypersomnia (code range)

Code	Description
E66.2	Morbid (severe) obesity with alveolar hypoventilation
G47.20-G47.29	Circadian rhythm sleep disorder (code range)
G47.30-G47.39	Sleep apnea (code range)
G47.69	Other sleep related movement disorders
G47.8-G47.9	Other and unspecified sleep disorder (code range)
I50.9	Heart failure, unspecified
J39.8	Other specified diseases of upper respiratory tract
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.9	Chronic obstructive pulmonary disease, unspecified
J95.2	Acute pulmonary insufficiency following nonthoracic surgery
J96.00-J96.02	Acute respiratory failure (code range)
J96.10-J96.12	Chronic respiratory failure (code range)
J96.20-J96.22	Acute and chronic respiratory failure (code range)
J96.90-J96.92	Respiratory failure, unspecified, unspecified whether with hypoxia or hypercapnia (code range)
J98.4	Other disorders of lung
J98.8	Other specified respiratory disorders

REFERENCES

Alajmi M, et al. Impact of continuous positive airway pressure therapy on blood pressure in patients with obstructive sleep apnea hypopnea: a meta-analysis of randomized controlled trials. Lung 2007 Mar-Apr;185(2):67-72.

American Academy of Dental Sleep Medicine (AADSM) [Internet]. Dental sleep medicine standards for screening, treatment, and management of sleep-related breathing disorders in adults using oral

appliance therapy. [updated 2022; accessed 2026 Jul 17]. Available from: https://www.aadsm.org/docs/jdsm.10.10.2022.sa1.pdf

American Academy of Otolaryngology—Head and Neck Surgery (AAO-HNS) [Internet]. Position statement: Use of oral appliances for the treatment of obstructive sleep apnea (OSA). [revised 2019 Nov 11; accessed 2026 Jul 17]. Available from: https://www.entnet.org/resource/position-statement-use-of-oral-appliances-for-the-treatment-of-obstructive-sleep-apnea-osa/

American Academy of Pediatrics [Internet]. Clinical practice guideline: diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics 2002;109(4):704-712. [accessed 2026 Feb 13]. Available from: https://publications.aap.org/pediatrics/article/130/3/576/30284/Diagnosis-and-Management-of-Childhood-Obstructive?autologincheck=redirected

American Academy of Sleep Medicine. Practice parameters for the use of auto-titrating continuous positive airway pressure devices for titrating pressures and treating adult patients with obstructive sleep apnea. Sleep 2002;25(2):143-147.

Baptista PM, et al. Daytime neuromuscular electrical therapy of tongue muscles in improving snoring in individuals with primary snoring and mild obstructive sleep apnea. J Clin Med. 2021 Apr 27;10(9):1883

Benjafield Adam V, et al. Estimation of the global prevalence and burden of obstructive sleep apnoea: a literature-based analysis. The Lancet Respiratory Medicine 2019 Aug;7(8): 687–698.

Beri A, et al. Appliances therapy in obstructive sleep apnoea: a systematic review and meta-analysis. Cureus. 2023 Nov 4;15(11):e48280.

Chang H-P, et al. Obstructive sleep apnea treatment in adults. The Kaohsiung Journal of Medical Sciences 2019 Sept: 7-12.

Cistulli P, et al. Short-term CPAP adherence in obstructive sleep apnea: a big data analysis using real world data. Sleep Medicine 2019 Jul;59:114-116.

Downey R, et al. Nasal continuous positive airway pressure use in children with obstructive sleep apnea younger than 2 years of age. Chest 2000 Jun;117(6):1608-1612.

Figard C, et al. Effect of sleep apnoea interventions on multiple health outcomes: an umbrella review of meta-analyses of randomised controlled trials. EClinicalMedicine. 2025 Oct 8;89:103529.

Gupta AK, et al. Comparative effectiveness of mandibular advancement devices and continuous positive airway pressure in adults with obstructive sleep apnea: a systematic review and meta-analysis. Sleep Med. 2026 Oct;146:109083.

Hady KK, et al. Positive airway pressure therapy for pediatric obstructive sleep apnea. Children 2021 Nov;8(11):979.

Hamoda MM, et al. Continuous positive airway pressure and mandibular advancement splints: the CHOICE multicentre, open-label randomised clinical trial. Eur Respir J. 2025 Apr 3;65(4):2401100.

Ioerger P, et al. Mandibular advancement vs combined airway and positional therapy for snoring: a randomized clinical trial. JAMA Otolaryngol Head Neck Surg. 2024 Jul 1;150(7):572-579.

Jacobowitz O, et al; on behalf Governing Council of the World Sleep Society. Endorsement of "European Respiratory Society guideline on non-CPAP therapies for obstructive sleep apnoea" by World Sleep Society. Sleep Med. 2024 Jan;113:293-298.

Javaheri S, et al. Treatment of OSA and its impact on cardiovascular disease, Part 2: JACC state-of-the-art review. J Am Coll Cardiol. 2024 Sep 24;84(13):1224-1240.

Johal A, et al. The role of oral appliance therapy in obstructive sleep apnoea. Eur Respir Rev. 2023 Jun 21;32(168):220257.

Johnson K, Johnson D. In reference to positive airway pressure titration task force of the American Academy of Sleep Medicine. Clinical guidelines for the manual titration of positive airway pressure in patients with obstructive sleep apnea. Journal of Clinical Sleep Medicine 2008;4:157-171. J Clin Sleep Med. 2008 Dec 15;4(6):610.

Kotecha B, et al. A novel intraoral neuromuscular stimulation device for treating sleep-disordered breathing. Sleep Breath. 2021 Dec;25(4):2083-2090.Kushida CA, et al. Positive Airway Pressure Titration Task Force; American Academy of Sleep Medicine. Clinical guidelines for the manual titration of positive airway pressure in patients with obstructive sleep apnea. J Clin Sleep Med. 2008 Apr 15;4(2):157-71.

Macrea M, et al. Long-term noninvasive ventilation in chronic stable hypercapnic chronic obstructive pulmonary disease: an official American Thoracic Society clinical practice guideline. Am J Respir Crit Care Med 2020 Aug 15;202(4):e74-e87.

Marcus CL, et al. Diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics. 2012 Sep;130(3):576-84.

National Institute for Health and Care Excellence [Internet]. Obstructive sleep apnea/hypopnea syndrome and obesity hypoventilation syndrome in over 16s. Published Aug 2021. [accessed 2026 Aug 06]. Available from: https://www.nice.org.uk/guidance/NG202

Ng JH and Yow M. Oral appliances in the management of obstructive sleep apnea. Sleep Med Clin. 2019;14(1):109-118.

Ou YH, et al. Mandibular advancement vs CPAP for blood pressure reduction in patients with obstructive sleep apnea. J Am Coll Cardiol. 2024 May 7;83(18):1760-1772.

Patil SP, et al. Treatment of adult obstructive sleep apnea with positive airway pressure: an American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med 2019 Feb 15;15(2):335-343.

Qaseem A, et al; Clinical Guidelines Committee of the American College of Physicians. Management of obstructive sleep apnea in adults: A clinical practice guideline from the American College of Physicians. Ann Intern Med. 2013 Oct 1;159(7):471-83.

Ramar K, et al. Clinical practice guideline for the treatment of obstructive sleep apnea and snoring with oral appliance therapy: an update for 2015. J Clin Sleep Med. 2015 Jul 15;11(7):773-827.

Rossi A, et al. Clinical evidence in the treatment of obstructive sleep apnoea with oral appliances: a systematic review. Int J Dent. 2021 May 8;2021:6676158.

Sánchez-de-la-Torre M, et al. Adherence to CPAP treatment and the risk of recurrent cardiovascular events: a meta-analysis. JAMA. 2023 Oct 3;330(13):1255-1265.

Strohl, Kingman. Obstructive sleep apnea. Merck Manual 2020 Sept.

Uniken Venema JAM, Doff MHJ, Joffe-Sokolova D et al., Long-term obstructive sleep apnea therapy: a 10-year follow-up of mandibular advancement device and continuous positive airway pressure: J Clin Sleep. Med 2020 March 15;16(3) 353-359.

Veasey SC, Rosen IM. Obstructive sleep apnea in adults. N Engl J Med. 2019 Apr 11;380(15):1442-1449.

Wang Z, et al. Noninvasive positive pressure ventilation in the home. Rockville (MD): Agency for Healthcare Research and Quality (US); 2019 Mar 14. PMID: 32101390.

Weiss MR, et al. Defining the patterns of pap adherence in pediatric obstructive sleep apnea: a clustering analysis using real world data. Journal of Clinical Sleep Medicine 2020 May;17 (5):1005-1013.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Durable Medical Equipment Reference List (NCD 280.1) [accessed 2026 Aug 06]

Oral Appliances for Obstructive Sleep Apnea (LCD L33611) [accessed 2026 Aug 06]

Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (LCD L33718) [accessed 2026 Aug 06]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates
01/01/27

Date	Summary of Changes
02/15/27	• Original effective date

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: NUTRITIONAL THERAPY: ORAL/ ENTERAL/ PARENTERAL & MODIFIED SOLID FOOD PRODUCTS

POLICY EFFECTIVE DATE:	10/1/2026
Policy Control #:	1370/20.000480
Next Annual Review:	September, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

Various National Drug Codes and HCPCS B-codes.

DESCRIPTIONS

Specialized nutritional support is often required for patients who have chronic disease or for those undergoing long-term rehabilitation who are at risk for malnutrition. Nutritional support can be provided orally, enterally (through a tube into the stomach or small intestine), and intravenously. Malnutrition is commonly defined in the medical literature as a non-edematous or post-dialysis weight loss of at least 10 percent of ideal body weight over a three-month period or a serum albumin of less than 3.4 grams/dL. Malnutrition can occur in otherwise healthy individuals when they are deprived of adequate nutrients for an extended period of time.

Oral and Enteral Nutrition: Nutritional support provided via the gastrointestinal tract can be taken by mouth or provided enterally. Oral nutrition refers to nutrition taken through the mouth. Enteral nutrition is commonly defined as the provision of nutritional requirements through a tube in the stomach or small intestine. Enteral feeding provides nutritional support for patients who lack the ability for the body to properly digest essential nutrients contained in everyday foods. Examples of feeding tubes are:

- Nasogastric (NG): nose to stomach
- Gastrostomy (G-tube): surgically placed into the stomach through the abdominal wall
- Jejunostomy (J-tube): surgically placed into the small bowel through the abdominal wall

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Modified solid food products are everyday solid foods with essential nutrients removed in order to avoid allergic or other adverse reactions the foods might otherwise cause.

Parenteral nutrition refers to the intravenous provision of micro- or macro-nutrients through catheters in central and peripheral veins to prevent or correct nutritional deficiency. It is typically reserved for situations when there is inadequate or insufficient absorption of nutrients through the gastrointestinal tract.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policy:

Durable Medical Equipment, Prosthetics, Orthotics and Medical Supplies, 1370/20.000509

POSITION STATEMENT

CDPHP administers benefits for home use of oral/enteral/parenteral nutrition, and modified solid food products when medically necessary and proven effective as a disease-specific regimen as follows:

The following general requirements will apply:

- The enrollee must have a prescription drug benefit for products obtained at a participating pharmacy for products taken by oral route of administration. Products obtained from a home care agency that are administered via nasogastric feeding tube (a prosthetic device), gastrostomy/jejunostomy or needle catheter (a prosthetic device) jejunostomy will be covered under the medical benefit and no prescription drug benefit is necessary.

- Enteral formulas for home use are covered when a physician issues a written order stating the formula is medically necessary and has been proven effective as a disease-specific treatment regimen.

Oral and Enteral Nutrition

Enteral nutritional support provided via the gastrointestinal tract can be taken by mouth or provided enterally via a tube in the stomach or small intestine. The enteral formula diet consists of amino acids, simple carbohydrates, and/or complex protein and carbohydrate sources. Enteral formula diets are considered medically necessary when used in the treatment of objectively diagnosed conditions where caloric and dietary nutrients from food cannot be absorbed or metabolized.

CDPHP considers oral and enteral formula medically necessary when the following criteria are met:

POLICY NAME: NUTRITIONAL THERAPY: ORAL/ ENTERAL/ PARENTERAL & MODIFIED SOLID FOOD PRODUCTS

1. Ordered by a physician or other licensed health care provider
2. The enteral formula is clearly medically necessary and has been proven effective as a disease-specific treatment regiment.

Modified Solid Food Products

CDPHP considers modified solid food products medically necessary for certain inherited diseases of amino acids or organic acid metabolism, as well as severe protein allergic conditions. Modified solid food products are only those products that are low protein or which contain modified protein, or are amino acid based.

Parenteral/Total Parenteral Nutrition (TPN)

Also known as parenteral hyperalimentation, involves the delivery of micronutrients and macronutrients through catheters in central or peripheral veins. In most instances, the central venous route is utilized; for long-term total parenteral nutrition, a central catheter (e.g., Hickman, Broviac, PIC) is burrowed through a subcutaneous tunnel on the anterior chest.
CDPHP considers TPN therapy medically necessary only if adequate nutritional intake is not possible via the oral or tube-feeding route and any of the following criteria is met:

- Documentation of a failure of enteral (i.e., oral or tube feeding) nutrition, as defined by *either* of the following:
  - A non-edematous or post-dialysis documented loss of greater than 10 percent of body weight over a three-month period; *or*
  - Total protein less than 6 g/dL or serum albumin less than 3.4 g/dL
  - A condition in which it is necessary for the gastrointestinal tract to be totally non-functioning for a period of time.
  - Evidence of structural or functional bowel disease that makes oral and tube feedings inappropriate.
  - Hyperemesis gravidarum (only in cases of failed medical management or when used in a step-therapy program).

Parenteral nutrition is not considered medically necessary for members with a functioning gastrointestinal tract whose need for parenteral nutrition is only due to:

- A physical disorder impairing food intake such as the dyspnea of severe pulmonary or cardiac disease;
- A psychological disorder impairing food intake such as depression
- A side effect of a medication
- A swallowing disorder
- A temporary defect in gastric emptying such as a metabolic or electrolyte disorder
- Disorders inducing anorexia such as cancer

POLICY NAME: NUTRITIONAL THERAPY: ORAL/ ENTERAL/ PARENTERAL & MODIFIED SOLID FOOD PRODUCTS

- Renal failure and/or dialysis
- Patient preference (refusal for feeding tube placement)

Intra-dialytic parenteral nutrition (IDPN)

IDPN is the infusion of an intravenous nutritional formula of hyperalimentation, such as amino acids, glucose, and lipids during dialysis, to treat protein calorie malnutrition in an effort to decrease the associated morbidity and mortality experienced in patients with renal failure.

CDPHP administers benefits for IDPN for members who are currently receiving dialysis and meet the criteria for total parenteral nutrition as stated above.

POLICY CONSIDERATIONS

New York State Law mandates coverage for enteral formulas for all contracts that cover prescription drugs. The mandate requires coverage for home use of enteral formulas pursuant to a written order by the patient's physician or other licensed health care provider stating the enteral formula is medically necessary and proven effective as a disease-specific treatment regimen. The mandate also requires coverage of modified solid food products to treat inherited diseases of amino acid and organic acid metabolism and severe protein allergic conditions.

CDPHP covers the outpatient use of pasteurized donor human milk, which may include fortifiers, for an infant who is medically or physically unable to receive maternal breast milk, participate in breast feeding, or whose mother is medically or physically unable to produce maternal breast milk at all or in sufficient quantities or participate in breast feeding despite optimal lactation support. Such infant must have a documented birth weight of less than one thousand five hundred grams, or a congenital or acquired condition that places the infant at a high risk for development of necrotizing enterocolitis. This benefit is contract dependent. Please refer to member-specific contracts to determine benefit availability.

EXCLUSIONS

The following exclusions will apply regarding nutritional support:

- Enteral nutrition therapy for supplementation of daily protein-caloric intake where there is not documented medical necessity by a physician's order as defined in this policy.
- In patients with a stable nutritional status, in whom only short-term parenteral nutrition might be required (e.g., less than two weeks).
- Coverage is not intended for patients requiring specialized diets (e.g., gluten free foods, lactose
- Lactose free products or products to aid in lactose digestion.
- Supplemental enteral formulas/modified solid food products associated with weight-loss programs.
- Specialized infant formulas that are not disease-specific treatment.
- Enteral therapy used as a convenient food source.

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- Baby food, or other regular shelf food products (e.g., Ensure®, Similac®) that can be blenderized for use with an enteral feeding system
- Dietary or food supplements
- For routine pre- and/or postoperative care
- Food thickeners (B4100)
- Standard infant milk or soy products
- Intra-peritoneal nutrition therapy (for members on peritoneal dialysis)
- Nutritional therapy as a side effect of a medication

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in the above application. However, a prescription drug rider is not required. Prescription drugs are part of the benefit plan. These products are covered only when ordered by a practitioner.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in the above application with the following exceptions:

- This benefit is covered under the medical portion of the contract as a supply necessary to use a prosthetic device. A prescription drug benefit is not necessary.
- Medicare Advantage provides coverage only for enteral products that are administered via nasogastric feeding tube (a prosthetic device) gastrostomy/jejunostomy; or via needle catheter (a prosthetic device) jejunostomy, when the condition is deemed permanent (at least three months).
- The Medicare Advantage benefit plan does not cover enteral feeding products that are not delivered through a feeding tube.

For Parenteral/TPN Nutrition coverage guidelines, please click on below link:
Parenteral Nutrition

SELECT PLAN/HARP: CDPHP utilizes the New York State Medicaid Management Information System (MMIS) Durable Medical Equipment Manual (section 4.2- Enteral Therapy) for coverage guidance:

Medical Supplies Procedure Codes

All enteral products in section 4.2 are billed to Medicaid Fee for Service.

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S9435 & S9436: Coverage for certain inherited diseases of amino acid and organic acid metabolism includes modified solid food products that are low-protein or which contain modified protein or are amino acid based will be billed to CDPHP.

SOURCES

1. CDPHP Drug Rider, 2011
2. New York State Department of Health letter of June 20, 2011 regarding recommendations from the Medicaid Redesign Team.
3. Facts and Comparison, reviewed 10/2010.
4. NY State Enteral Formula Mandate, Chapter 177, December 1997.
5. NY Insurance Law 4303 (y), reviewed 10/13.
6. NYS enacts Hannah's Law, Bill A490, effective 1/1/14, http://open.nysenate.gov/legislation/bill/A490-2013
7. Office of Medicaid Management DOH Medicaid Update December 2002 Vol. 17, No. 13.
8. Office of Medicaid Management DOH Medicaid Update October 2003.
9. Centers for Medicare & Medicaid Services, Medicare Coverage Database, NCD for Enteral and Parenteral Nutritional Therapy (180.2), publication number 100-3, reviewed 10/2010.
10. Medicare Modernization Act 2003
11. NYS Codes, Rules and Regulations, Title 18, Section 505.5, effective 6/7/2013.
12. New York State Medicaid Management Information System (MMIS) Durable Medical Equipment Manual for coverage guidance: https://www.emedny.org/ProviderManuals/DME/PDFS/DME_Procedure_Codes.pdf
13. Medicare (NYS) Local Coverage Determination: Enteral Nutrition (L33783), Effective 1/1/17: https://med.noridianmedicare.com/documents/2230703/7218263/Enteral+Nutrition+LCD/8f3c8910-15b1-4b6b-bf0f-81dee9a1862c
14. NYS Law revising the Enteral Formula Mandate, effective 1/1/19. Insurance Law, Article 32, §3216, http://public.leginfo.state.ny.us/lawssrch.cgi?NVLWO:

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POLICY APPROVAL DATES

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: NUTRITIONAL THERAPY: ORAL/ ENTERAL/ PARENTERAL & MODIFIED SOLID FOOD PRODUCTS

New: 01/98

Revised: 12/98, 11/99, 11/00, 01/02, 11/02, 04/04, 04/05,10/05, 03/06, 02/07, 02/08, 02/09, 02/10, 08/11, 02/12, 06/12, 09/13 (regulatory requirement effective 6/13), 11/13, 01/14, 09/17, 09/18, 11/18, 03/19 (regulatory requirement effective 1/1/19), 9/21, 1/22, 9/22, 5/23, 9/24, 11/24, 3/25, 9/26

Reviewed: 02/11, 09/14, 09/15, 09/16, 9/19, 09/20, 9/23, 9/25

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
1/1/2026	Added information regarding pasteurized breast milk
10/1/2024 *No change to effective date of policy	Under the Medicare section, added link for parenteral nutrition guidelines.
10/1/24	Under Medicaid updated link for enteral therapy.
8/1/2024	Under Medicaid, removed B4105 as being billed to CDPHP as this is now covered under FFS.
4/1/2023	Medicaid section updated to reflect the changes for the Medicaid RX/DME Carveout.
10/1/2022	Removed examples of conditions for when considered medically necessary.
* 1/1/2022 *No change in effective date	Added statement to Medicaid regarding Women, Infants and Children (WIC) benefit: **Members with WIC eligibility, that meet the below criteria, may obtain oral formulas/nutrition through the WIC program.
1/1/2022	Added to exclusions: • Nutritional therapy as a side effect of a medication

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
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(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: OBSTRUCTIVE SLEEP APNEA: DIAGNOSIS & TREATMENT

POLICY EFFECTIVE DATE:	10/1/2025
Policy Control #:	1370/20.000060
Next Annual Review:	September, 2027

DISCLAIMER

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PROCEDURE CODES

- Attended (facility-based) polysomnography: 95782, 95783, 95807, 95808, 95810, 95811
- Unattended (home-based) sleep testing: 95800, 95801, 95806, G0398, G0399, G0400
- CPAP/BiPAP/APAP equipment: E0561, E0562, E0601, E0470, E0471, E0472
- Multiple Sleep Latency Test (MSLT): 95805
- Oral Appliances: E0485, E0486, K1027, D9947, D9948, D9949
- Surgical treatments: 42145, 64582-64584

DESCRIPTIONS

Sleep studies and polysomnography refer to the continuous and simultaneous monitoring and recording of various physiological parameters of sleep for six or more hours with physician review, interpretation, and report. The studies are performed to diagnose a variety of sleep disorders, including obstructive sleep apnea, and to evaluate a patient's response to therapies such as continuous positive airway pressure (CPAP).

Obstructive sleep apnea (OSA) is defined as repeated periods of complete airway obstruction (apnea) lasting at least 10 seconds, which occur only during sleep. **Apneas** are characterized as obstructive if the respiratory effort is present throughout the entire event, central if respiratory effort is absent throughout the entire event, or mixed if respiratory effort is initially absent but resumes during the latter portion of the event. **Hypopnea**, a respiratory event characterized by partial airway obstruction with at least 30-percent reduction in airflow for 10 seconds or more

and fall of oxygen saturation of at least three to four percent, may also be present. Respiratory-effort-related arousals are identified when there is a sequence of breaths lasting at least 10 seconds, characterized by increasing respiratory effort or flattening of the nasal pressure waveform, leading to an arousal from sleep; and the sequence of breaths does not meet criteria for apnea or hypopnea.

Polysomnography (PSG) utilizes the continuous and simultaneous monitoring and recording of physiological phenomena, including at least electroencephalography, electrooculography, electromyography, oximetry, electrocardiography, respiratory effort, and airflow. These are monitored during sleep for six or more hours with review, interpretation, and report by a physician. PSG (in contradistinction from home [portable] sleep tests) permits identification of: duration of sleep; duration of each of the stages of sleep; presence of respiratory-effort-related arousals (RERAs) as well as apneas and hypopneas; and frequency of respiratory events per hour of measured sleep across the entire period of sleep and in each of the sleep stages.

Home/Portable Sleep Studies (HST): Tests that utilize the continuous and simultaneous monitoring and recording of various physiological and pathophysiological parameters of sleep. They are performed with a portable machine that usually has four leads to measure chest and abdominal wall movement, oxygen saturation (oximetry), and cardiac activity (EKG). HSTs do not permit objective identification of sleep duration, identification of presence and duration of all sleep stages, frequency of arousals per hour of objectively measured sleep, or frequency of apneas, hypopneas, and RERAs per hour of objectively measured sleep.

RELATED POLICIES/DOCUMENTS

Payment Policies:

- APAP, BiPAP, and CPAP Rental and Purchase, 1550/20.000142

Resource Coordination Policies:

- Durable Medical Equipment, Prosthetics/Orthotics, and Medical Supplies, 1370/20.000509

POSITION STATEMENT

CDPHP provides coverage of sleep studies for the diagnosis and treatment of obstructive sleep apnea only when such services are performed by a participating CDPHP provider meeting the following credentialing standards in accordance with credentialing policy, *Credentialing & Recredentialing: Sleep Disorder Centers/Laboratories, 1315/20.000039* as follows:

- Physicians who conduct sleep studies must be board-certified in sleep medicine by the American Board of Medical Specialties (ABMS), American Board of Sleep Specialists (pertains to providers previously credentialed by CDPHP to practice sleep medicine under this board certification), or the American Osteopathic Association

(AOA), and must be affiliated with a credentialed sleep medicine program.
- Sleep medicine entities (office or facility) providing attended sleep studies must be accredited by the American Academy of Sleep Medicine (AASM).
- An out-of-center sleep testing supplier (e.g., drop and ship) must be accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

Diagnostic Testing - Medical Necessity Criteria

CDPHP considers diagnostic sleep studies medically necessary for the diagnosis of suspected obstructive sleep apnea in an adult (age 18 or older) when *both* of the following criteria are met:

- Comprehensive clinical evaluation is performed by, or under the direction of, a board-certified sleep medicine specialist or subspecialist in neurology, otolaryngology, or pulmonary medicine
- Documentation must include counseling regarding potential treatment options.

And

- Patient demonstrates three or more of the following symptoms or risk factors:
  - Documented excessive daytime sleepiness as evidenced by an Epworth sleepiness scale > 10.
  - Witnessed apneas
  - Gasping or choking at night
  - Disruptive loud snoring
  - Hypertension that is uncontrolled despite three-drug regimen that includes a diuretic
  - Obesity (i.e., body mass index ≥ 35)
  - Increased neck circumference (i.e., > 17 inches in men, > 16 inches in women).

CDPHP considers diagnostic sleep study medically necessary for the diagnosis of suspected obstructive sleep apnea in a pediatric patient (age 17 and under) when the following criteria are met:

Patient demonstrates any of the following symptoms or risk factors in association with habitual snoring/disturbed breathing:

- Restless or disturbed sleep
- Behavior disturbances, or learning disorders including deterioration in academic performance, hyperactivity, or attention deficit disorder
- Unexplained enuresis
- Frequent awakenings
- Failure to thrive, or growth impairment
- Witnessed apnea

- Excessive daytime somnolence, or altered mental status unexplained by other conditions or etiologies
- Polycythemia unexplained by other conditions or etiologies
- Cor pulmonale unexplained by other conditions or etiologies
- Hypertrophy of tonsils and adenoids associated with noisy daytime respirations where surgical removal poses a significant risk and would be avoided in the absence of sleep-disordered breathing.

Types of Sleep Studies

Diagnostic tests for obstructive sleep apnea (OSA) are classified into four types based on the number of physiologic signals measured. Type I is a full-channel polysomnography (PSG) with minimum of 12 monitored parameters performed, attended, in a sleep laboratory facility. Three categories of portable monitors (Type II, III, IV) are utilized in both attended and unattended settings and measure less than 12 physiologic parameters.

CDPHP utilizes the criteria outlined below to determine whether attended facility or office-based PSG or unattended home sleep testing is indicated. Prior authorization is required for attended (facility or office-based) sleep studies only.

Attended Polysomnography – Adults (95807, 95808, 95810, 95811)

CDPHP considers diagnostic, attended PSG medically necessary to confirm a diagnosis of sleep-related breathing disorder in an adult (age 18 and older) when the following criteria are met:

1. Medically necessary criteria for a diagnostic sleep study for suspected obstructive sleep outlined above have been met and when there is presence of any of the following conditions:
    - Significant comorbid conditions that would be expected to degrade the accuracy of a home/portable study, including, but not limited to:
        - Moderate to severe pulmonary disease (e.g., COPD).
        - Moderate to severe neuromuscular or neurodegenerative disorder causing restrictive lung diseases (examples include, but are not limited to: kyphoscoliosis, myasthenia gravis, amyotropic lateral sclerosis (ALS), polio, polymyositis, Guillian Barre syndrome)
        - Moderate to severe congestive heart failure classified by New York Heart Association as level III or IV
        - Moderate to severe pulmonary hypertension (> 40 mmHg)
        - Awake or obesity hypoventilation syndrome or suspicion of sleep-related hypoventilation
        - Chronic opioid medication use
        - History of stroke

- Severe insomnia

Or

2. In patients without suspected OSA, having one or more of the following indications corroborated by the clinical documentation:
   - Severe chronic periodic limb movement disorder (PLMD) (not leg movements associated with another disorder such as sleep-disordered breathing).
   - Parasomnia with documented disruptive, violent, or potentially injurious sleep behavior, suggesting rapid eye movement (REM) sleep-behavior disorder (RBD), not otherwise explained by concurrent medical therapy (sleep-inducing agents) with known side effects.
   - Narcolepsy, once other causes of excessive sleepiness have been ruled out.
   - History of central sleep apnea related to a significant comorbid condition to include, but not limited to, severe congestive heart failure, chronic kidney disease (Stage 3 or greater), advanced neurological disorder (e.g., Parkinson's disease, ALS), damage to brain stem (e.g., encephalitis).

Or

3. Recent home/portable testing proved to be technically inadequate or failed to establish the diagnosis of OSA in an individual with high pretest likelihood of OSA (i.e., meets medical necessity criteria for diagnostic testing as stated above in policy).

Or

4. Patient and/or caregiver are incapable of operating home testing equipment.

Or

5. For initial titration of a hypoglossal nerve stimulator (home sleep study can be used for subsequent adjustments and monitoring)

Repeat Attended Polysomnography (PSG) or Home Sleep Test (HST)– Adult

Repeat testing is considered medically necessary when any of the following conditions are present*:

*Note: A repeat attended PSG will be allowed only if the member met the criteria initially for an attended PSG.

6. Follow-up PSG or HST is recommended to assess response to treatment with non-PAP interventions.
7. Follow-up PSG or HST may be used if clinically significant weight gain or loss has occurred since diagnosis of OSA or initiation of its treatment.
8. Follow-up PSG may be used for reassessment of sleep-related hypoxemia and/or sleep-related hypoventilation following initiation of treatment for OSA.
9. Follow-up PSG or HST may be used in patients being treated for OSA who develop or have a change in cardiovascular disease.
10. Follow-up PSG may be used in patients with unexplained PAP device-generated data.

Split-Night Study/Attended PSG for PAP Titration (95811)

CDPHP considers a split-night study, in which the initial diagnostic portion of the PSG is followed by positive airway pressure (PAP) titration, medically necessary for patients who have met criteria for an attended PSG study and meet the following:

- An Apnea Hypopnea Index (AHI) of at least 40 is documented during a minimum of two hours of diagnostic PSG. Split-night studies should be considered at an AHI of 20-40, if supported by clinical factors (e.g., if there are also repetitive long obstructions and major desaturations).
- CPAP titration is carried out for more than three hours.
- PSG documents that CPAP eliminates or nearly eliminates the respiratory events during REM and non-REM sleep.

CDPHP expects a split-night study be performed as first-line testing for individuals who meet clinical criteria above and have a high pre-test probability of moderate to severe OSA. When authorizing initial in lab sleep studies, authorizations will be put up for 95811. If a titration was not needed, 95810 should be billed. If titration was required but not able to be completed, a new authorization request should be submitted indicating reason for incompletion and if medically necessary a new authorization will be entered with code 95811-52.

CDPHP considers an attended full-night study with positive airway pressure (PAP) titration medically necessary in patients who have met criteria for an attended PSG study and for whom diagnosis of OSA has been confirmed but did not meet criteria for a split-night study, or the split-night study was unsuccessful.

Multiple Sleep Latency Test (MSLT) (95805)

A MSLT may be indicated in the evaluation of patients with suspected narcolepsy (often characterized by cataplexy, sleep paralysis, and hypnagogic/hypnopomic hallucinations) to confirm the diagnosis or to differentiate between suspected idiopathic hypersomnia and

narcolepsy.

CDPHP considers MSLT's medically necessary for either of the following two indications:

1. For evaluation of symptoms of narcolepsy, to confirm the diagnosis; *or*
2. For evaluation of persons with suspected idiopathic hypersomnia to help differentiate idiopathic hypersomnia from narcolepsy.

Narcolepsy and OSA can co-occur. As it is not possible to differentiate between the excessive sleepiness caused by OSA and by narcolepsy, if symptoms of OSA are present, OSA should be ruled out and, if positive, treated before confirming a diagnosis of narcolepsy with the MSLT.

Unattended Home Sleep Test (HST) (95800, 95801, 95806, G0398, G0399, G0400)

CDPHP considers unattended home sleep studies using a minimum of three recording channels, including oxygen saturation, respiratory effort, and airflow medically necessary for the diagnosis of obstructive sleep apnea in an adult (age 18 and older) when *all* of the following criteria are met:

- Medical necessity criteria for a sleep study for suspected obstructive sleep apnea (OSA) as outlined above have been met.
- A high pre-test probability of moderate to severe OSA as determined by the comprehensive sleep evaluation.
- No sleep disorder other than OSA is suspected (e.g., central sleep apnea, insomnia, parasomnias, circadian rhythm disorders, narcolepsy, periodic limb movement disorder).
- Patient and/or caregiver are capable of operating home testing equipment and undergo a face-to-face demonstration of how to properly apply a portable sleep monitoring device before having the test. This education must be provided by the entity performing the home sleep test.

<u>Other Considerations for HST:</u>

- Unattended sleep-testing devices that use less than three channels are considered experimental/investigational when used in screening, diagnosing, or treating OSA and other respiratory conditions.

- CDPHP does not cover home/portable sleep study for the diagnosis of OSA in a child age 17 years and younger, as it is considered experimental, investigational, or unproven.

Attended Polysomnography – Pediatric (95782, 95783, 95808, 95810, 95811)

CDPHP considers diagnostic, attended PSG medically necessary to confirm a diagnosis of sleep-related breathing disorder in a pediatric patient (age 17 and under) when both of the following criteria are met:

- Medically necessary criteria for an attended sleep study for suspected obstructive sleep outlined above have been met; AND

Any of the following conditions:

- Suspected sleep apnea, including obstructive sleep apnea (OSA) and upper-airway resistance syndrome based on clinical assessment.
- Congenital central alveolar hypoventilation syndrome or sleep-related hypoventilation due to neuromuscular disorders or chest wall deformities:
- Nocturnal seizure disorder
- REM behavior disorder (rare in childhood)
- Repeat PSG following adenotonsillectomy if there are residual symptoms of OSA or to assess for residual OSA.
- Polysomnography of primary sleep apnea of infancy (when other medical disorders have been ruled out)
- Primary sleep apnea of infancy when other medical disorders have been ruled out.
- Clinical evidence of a sleep-related breathing disorder in infant who has experienced an apparent life-threatening event (ALTE).

Repeat Attended Polysomnography (PSG) – Pediatric

A repeat attended PSG is considered medically necessary in any of the following circumstances:

- Initial polysomnography is inadequate or non-diagnostic and the accompanying caregiver reports that the child's sleep and breathing patterns during the testing were not representative of the child's sleep at home.
- A child with previously diagnosed and treated obstructive sleep apnea continues to exhibit persistent snoring or other symptoms of sleep-disordered breathing.
- Following adenotonsillectomy, if there are residual symptoms of OSA or to assess for residual OSA.
    - To reevaluate the appropriateness of continuous positive airway pressure (CPAP) setting based on the child's growth pattern or the presence of recurrent symptoms while on CPAP
    - If obesity was a major contributing factor, and significant weight loss has been achieved, repeat testing may be indicated to determine the need for continued therapy.

Medical Management for Obstructive Sleep Apnea

Non-Surgical Treatments

Continuous positive airway pressure (CPAP) is a non-invasive technique for providing single levels of air pressure from a flow generator, via a nose or facial mask, through the nares. The purpose is to prevent the collapse of the oropharyngeal walls and the obstruction of airflow during sleep.

POLICY NAME: OBSTRUCTIVE SLEEP APNEA: DIAGNOSIS & TREATMENT

Bi-level positive airway pressure (BiPAP) devices are used in the treatment of OSA for an individual with coexisting central hypoventilation or for an individual who requires, but proves intolerant to, high pressures of CPAP or APAP.

Auto-titrating continuous positive airway pressure (APAP) *devices* are used to maintain a patent oropharynx to treat patients with obstructive sleep apnea. In contrast to CPAP, which maintains a fixed pressure titrated manually in a sleep center by a sleep technician, APAP devices titrate effective airway pressure throughout the night using an algorithm that responds to physiologic signals. AutoPap may be used as an alternative therapy for patients who are intolerant of pressures in conventional CPAP therapy, may be used for an unattended in-home CPAP titration after a positive sleep study or when follow-up indicates a need for CPAP pressure changes.

CDPHP administers benefits for Positive Airway Pressure (PAP) therapy, under the durable medical equipment benefit, in the treatment of symptomatic obstructive sleep apnea as confirmed by supervised polysomnography or an unattended home portable sleep study as follows:

CPAP (E0601):

Member has a sleep test that meets either of the following criteria (1 or 2):

1. The apnea-hypopnea index (AHI) or Respiratory Disturbance Index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; or,
2. The AHI or RDI is greater than or equal to five events and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
    a. Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; or,
    b. Hypertension, ischemic heart disease, or history of stroke.

BiPAP (E0470)

Member meets the criteria above, in addition to the below:

1. A CPAP device has been tried and proven ineffective based on a therapeutic trial conducted in either a facility or in a home setting. (Exception: BiPAP therapy is available as a first-line treatment for individuals with appropriate associated medical conditions i.e., obesity hypoventilation or neuromuscular disease).

An initial three-month rental of CPAP/BiPAP/APAP equipment will be allowed for home use.

- If CPAP titration is medically necessary, it is expected that APAP be used for in-home titration following a positive unattended home sleep study.

POLICY NAME: OBSTRUCTIVE SLEEP APNEA: DIAGNOSIS & TREATMENT

Patients must undergo objective CPAP/BiPAP/APAP monitoring and demonstrate compliance and effectiveness prior to purchasing the equipment. Compliance is defined as use of PAP ≥ four hours per night on 70 percent of nights during a consecutive 30-day period anytime during the first three months of initial usage.

- Requests for the initial purchase of CPAP/BiPAP/APAP equipment will be allowed only after the enrollee has completed two months of rental and compliance is well-documented.

Prior authorization is not required for non-heated (E0561) or heated humidifiers (E0562) when dispensed for use with covered positive airway pressure devices.

- Humidifiers are to be rented during the initial three-month period for use with CPAP/BiPAP devices. CDPHP will not provide reimbursement for the purchase of a humidifier while the equipment is being rented. If the rental period for the CPAP/BiPAP is extended, the humidifier rental may be extended as well.

Oral Appliances (E0485, E0486, K1027, D9947, D9948, D9949)

Oral appliances for the treatment of sleep-disordered breathing are devices worn in the mouth during sleep to maintain a patient's airway by raising the uvula, depressing the tongue, and/or advancing the mandible.

CDPHP considers a custom-fabricated mandibular-advancement oral appliance (E0486) used to treat obstructive sleep apnea (OSA) medically necessary when all of the following criteria are met:

- A face-to-face clinical evaluation is performed by, or under the direction of, a board-certified sleep medicine specialist or subspecialist in neurology, otolaryngology, or pulmonary medicine prior to the sleep test to assess the beneficiary for obstructive sleep apnea testing.
    - Documentation must include counseling regarding potential treatment options.
- The enrollee has a covered sleep test that meets *one* of the following three criteria:
    - The apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) is greater than or equal to 15 events per hour with a minimum of 30 events; **or**
    - The AHI or RDI is greater than or equal to five and less than or equal to 14 events per hour with a minimum of 10 events and documentation of:
        - Excessive daytime sleepiness, impaired cognition, mood disorders, or insomnia; **or**
        - Hypertension, ischemic heart disease, or history of stroke
    - If the AHI > 30 or the RDI > 30 and meets either of the following:
        - The beneficiary is not able to tolerate a positive airway pressure (PAP) device; **or**
        - The treating physician determines that the use of a PAP device is contraindicated.

- The device is ordered by the treating physician following a review of the report of the sleep test. (The physician who provides the order for the oral appliance could be different from the one who performed the clinical evaluation).
- The device is provided and billed for by a licensed dentist (DDS or DMD).

Benefit is limited to one appliance every five years (reasonable useful lifetime).

All follow-up care, including fitting, adjustments, modifications, and professional services required during the first 90 days after the provision of the oral appliance are considered to be included in the payment for the device.

Benefit is limited to either an oral appliance or CPAP. Coverage for both would require documentation from a physician stating the medical necessity for both types of treatment to be administered at the same time.

Casts and study molds for an oral appliance or device are considered global to the device.

Benefits for oral appliances are not available under the following conditions:

- Oral appliances that are available over the counter without a prescription.
- Oral appliances used to treat snoring without a diagnosis of obstructive sleep apnea.
- Oral appliances used to treat temporomandibular joint (TMJ) disorders that are dental in nature.

Surgical Treatments

Uvulopalatopharyngoplasty (UPPP) (42145)

Uvulopalatopharyngoplasty is used to treat OSA by the removal of excess tissue in the upper airway, including tonsils and uvula, to widen the area to increase airflow. It is considered medically necessary for individuals who do not respond to CPAP, are not appropriate candidates for CPAP, or who fail treatment attempts with CPAP or treatment with behavioral measures such as weight loss or sleep-position change.

Hypoglossal Nerve Stimulation (64582-64584, 64568, 64569, 64570)

Hypoglossal nerve stimulation, also known as upper airway stimulation, is an alternative treatment for the correction of moderate to severe obstructive sleep apnea for individuals who have failed or are intolerant to positive airway pressure. The treatment works by stimulating the hypoglossal nerve to restore the tone to (or stiffen) the key tongue muscles that, when relaxed, can block the airway, causing an obstruction that reduces or stops breathing during the night. The Inspire Upper Airway Stimulator is a fully implanted system consisting of three components: a small generator, a sensing lead, and a stimulation lead. The single external component is a small handheld sleep remote used to turn the therapy on before bed and off upon waking. The pacemaker-like implant in the chest sends a mild electrical jolt down a lead to the hypoglossal nerve at the base of the tongue, moving the tongue to clear the airway. A lead in the chest

senses when to send the pulse in the breathing cycle. When activated, Inspire therapy senses breathing patterns and delivers mild stimulation to key airway muscles, which keeps the airway open during sleep.

CDPHP administers benefits for hypoglossal nerve stimulation for the treatment of moderate to severe obstructive sleep apnea when *all* of the following criteria are met:

- Member is 22 years of age or older.
- Body mass index (BMI) is less than or equal to 35.
- Apnea-hypopnea index (AHI) is 15 to 65 events per hour, and they are predominantly obstructive events (defined as central and mixed apneas less than 25 percent of the total AHI).
- Member has a minimum of one month of CPAP monitoring documentation that demonstrates CPAP failure (defined as AHI greater than 20 despite CPAP usage) or intolerance (defined as less than four hours per night, five nights per week).
- Absence of complete concentric collapse at the soft palate level as evidenced on a drug-induced sleep endoscopy procedure.
- No other anatomical finding that would compromise the performance of upper airway stimulation (e.g., tonsillar hypertrophy, tumors, polyps, or nasal obstruction) or intrinsic neuromuscular disease or other neurologic deficits.
- Procedure is performed with a Food and Drug Administration (FDA) approved hypoglossal nerve neurostimulator.

OR

For pediatric patients (aged 13-18 years) with Down Syndrome and all of the following criteria:

- AHI greater than 10 and less than 50;
- Less than 25% central apneas after prior adenotonsillectomy;
- Absence of a complete concentric collapse at the soft palate level on drug induced sleep endoscopy;
- Body mass index ≤ 95th percentile for age;
- Have either a tracheotomy or have been confirmed to fail, or cannot tolerate, PAP therapy despite attempts to improve compliance;
- Have followed standard of care in considering all other alternative/adjunct therapies.

Additional Procedures/Services

CDPHP considers the following procedures experimental/investigational for the treatment of obstructive sleep apnea, as efficacy has not been established in published scientific literature.

- Injection snoreplasty (42299)
- Laser-assisted uvulopalatoplasty (LAUP) (S2080)
- Pillar® Palatal Implant System (C9727)
- Radiofrequency tissue volume reduction of the tongue base (41530), uvula or soft

palate, or for tonsillar hypertrophy (e.g., Somnoplasty®)
- Tongue base suspension (AIRVance Tongue and Hyoid Suspension System, 41512)
- Hyoid myotomy and suspension (21685)

EXCLUSIONS

Prefabricated oral appliance (E0485) as there is insufficient evidence to show that these items are effective therapy for OSA.

Expiratory positive airway pressure intranasal resistance valve; (i.e., the ULTepap system-A7049)

Polysomnography and home sleep tests to evaluate OSA are not covered in any of the following situations:

- For the evaluation of snoring, in the absence of criteria for obstructive sleep apnea.
- When performed as a screening tool or as part of a preoperative evaluation in asymptomatic patients.

CDPHP considers actigraphy testing (95803) experimental/investigational. This technique, when used alone (single-channel study), has not been validated as a method of diagnosing OSA or other sleep disorders.

CDPHP does not cover an abbreviated cardiorespiratory sleep study to acclimate an individual to PAP (e.g., PAP-Nap study, CPT code 95807-52) because it is considered experimental, investigational, or unproven.

NightOwl Home Sleep Test

Impression And Custom Preparation of Jaw Expansion Oral Prosthesis (0964T, 0965T,0966T).

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy. CPAP based on clinical diagnosis alone or using a diagnostic procedure other than polysomnography or Type II, III, or IV portable/home test measuring at least three channels is covered only when provided in the context of a clinical trial.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy with

	the below exception: Hypoglossal Nerve Stimulators are available for: • Individuals 13 years of age through 17 years of age with Down Syndrome and a diagnosis of moderate to severe OSA with inability to tolerate PAP therapy or has failed PAP therapy. • Individuals 18 years of age and over with a diagnosis of moderate to severe OSA and inability to tolerate PAP therapy or has failed PAP therapy.

SOURCES

1. Systematic Review of the Literature Regarding the Diagnosis of Sleep Apnea; AHCPR Evidence Report/Technology Assessment 2/99
2. Other payers
3. Board Certified Consultants
4. Practice Parameters for the Indications for Polysomnography and Related Procedures. An American Sleep Disorders Association Report 3/97.
5. Centers for Medicare & Medicaid, Empire Local Medical Review Policy: Surgical Treatment of Obstructive Sleep Apnea, effective 12/14/03, accessed 1/9/06, http://www.empiremedicare.com/combinedpolicies/policy/s145_su026w_final.htm
6. Radiofrequency Ablation for Sleep-Disordered Breathing Chest. Volume 113, No. 5, May 1998, pp.1151-1152.
7. Objective Evaluations of the Results of Treatment for Snoring and Sleep Apnea. Chest. Volume 115, No. 1, January 1999, pp. 305-306.
8. Fischer, Y.; Hafner, B.; Mann, W.J.: Radiofrequency Ablation of the Soft Palate (Somnoplasty). A New Method in the Treatment of Habitual and Obstructive Snoring. HNO. January, 2000. 48 (1). pp33-40. Abstract.
9. Exar, E.; Collop, N.: The Upper Airway Resistance Syndrome. Chest. Volume 115 Number 4. April 1999, pp1127-1139.
10. Loube, D.; Global Theme Issue: Emerging Technology in Clinical Medicine. Chest. Volume 116, Number 5. November 1999, pp1426-1433.
11. Radiofrequency Ablation for Sleep-Disordered Breathing Chest. Volume 113, No. 5, May 1998, pp.1151-1152.
12. Objective Evaluations of the Results of Treatment for Snoring and Sleep Apnea. Chest. Volume 115, No. 1, January 1999, pp. 305-306.
13. Fischer, Y.; Hafner, B.; Mann, W.J.: Radiofrequency Ablation of the Soft Palate (Somnoplasty). A New Method in the Treatment of Habitual and Obstructive Snoring. HNO. January, 2000. 48 (1). pp33-40. Abstract.
14. Exar, E.; Collop, N.: The Upper Airway Resistance Syndrome. Chest. Volume 115 Number 4. April 1999, pp1127-1139.
15. Loube, D.; Global Theme Issue: Emerging Technology in Clinical Medicine. Chest. Volume 116, Number 5. November 1999, pp1426-1433.

16. Li, K.K., et al, Radiofrequency volumetric tissue reduction for treatment of turbinate hypertrophy: A pilot study Otolargngology – Head and Neck Surgery, 119:6:569-573, 1998.
17. Rhee, C.S., et al, Changes of nasal function after temperature-controlled radiofrequency tissue volume reduction for the turbinate, Laryngoscope, 111, 153-158, 2001.
18. Smith, T.L., et al, Radiofrequency tissue ablation of the inferior turbinates using a thermocouple feedback electrode, Laryngoscope, 109, 683-686, 1999.
19. Utley, D.S., et al, Radiofrequency Energy tissue ablation for the treatment of nasal obstruction secondary to turbinate hypertrophy, Laryngoscope, 109: 683-686, 1999.
20. Blue Cross/ Blue Shield Tech Assessment, Radiofrequency volumetric tissue reduction for the treatment of simple snoring, upper airway resistance syndrome, and obstructive sleep apnea, September 2000.
21. Winifred S. Hayes, Inc, Radiofrequency Volumetric Tissue Reduction for the Treatment of Upper Airway Obstruction, November, 2000. Revised 11/02
22. Empire Medicare Services LMRP, Radiofrequency Ablation in the Upper Respiratory Tract, http://www.empiremedicare.com/combinedpolicies/policy/s142_su027w_final.htm
23. Nelson B. Powell, MD;Robert W. Riley, DDS; Robert J. Troell, MD; Kasey Li, DDS, MD; Marc B. Blumen, MD; and Christine Guilleminault, MD; "Clinical Investigations, Radiofrequency Volumetric Tissue reduction of the palate in Subjects With Sleep-Disordered Breathing," *Chest*, Vol. 113, No. 5, May 1998, pp 1163-1174.
24. Volumetric Tissue reduction of the palate in Subjects With Sleep-Disordered Breathing," *Chest*, Vol. 113, N
25. Marc B. Blumen, MD; Serge Dahan, MD; Isabelle Wagner, MD; Thibault De Dieuleveult, MD; and Frederic Chabolle, MD; "Radiofrequency versus LAUP for the treatment of snoring*," Otolaryngology-Head and Neck Surgery,* January 2002.
26. Daniel Loube, MD, "Radiofrequency Ablation for Sleep-Disordered Breathing," *Chest,* Vol. 113, No.5, May 1998, pp 1151-1152.
27. Byron J. Bailey, MD; Karen Calhoun, MD, FACS; Gerald B. Healy, MD; Harold C. Pillsbury III, MD; Jonas T. Johnson, MD; M. Eugene Tardy, Jr., MD; Robert K. Jackler, MD; *Head and neck Surgery-Otolaryngology,* Lippincott Williams & Wilkins, 2001, Third Edition, Volume One, pp 293, 303-304, 588-597, 694-699.
28. American Academy of Sleep Medicine, International Classification of Sleep Disorders, Third Edition: Diagnostic and Coding Manual, Westchester, Ill: American Academy of Sleep Medicine; 2014.
29. American Academy of Sleep Medicine, Clinical Guidelines for the Use of Unattended Portable Monitors in the Diagnosis of Obstructive Sleep Apnea in Adult Patients. Journal of Clinical Sleep Medicine, Vol. 3, No. 7, 2007.
30. American Academy of Sleep Medicine Practice Parameters for the Indications for Polysomnography and Related Procedures: An Update for 2005. *SLEEP,* Vol. 28, No. 4, 2005.
31. Adult OSA Task Force of the American Academy of Sleep Medicine Clinical Guidelines for the Evaluation, Management and Long-term Care of Obstructive Sleep Apnea in Adults, Journal of Clinical Sleep Medicine, Vol. 5, No. 3, 2009.
32. American Academy of Sleep Medicine Clinical Guidelines for the Evaluation and Management of Chronic Insomnia in Adults, Journal of Clinical Sleep Medicine, Vol. 4, No.

5, 2008.
33. Centers for Medicare and Medicaid Local Coverage Determination: Polysomnography and Sleep Studies, http://www.empiremedicare.com/newypolicy/policy/L26428_final_lcd_ngs.htm
34. Hayes, Inc., Repose® Tongue and Hyoid Suspension System for Obstructive Sleep Apnea, January 2012.
35. International Classification of Sleep Disorders, 3rd ed, American Academy of Sleep Medicine, Darien, IL 2014. http://www.esst.org/adds/ICSD.pdf
36. Black JE, Brooks SN, Nishino S. Conditions of primary excessive daytime sleepiness. Neurol Clin 2005; 23:1025.
37. Pépin JL, Guillot M, Tamisier R, Lévy P. The upper airway resistance syndrome. Respiration 2012; 83:559.
38. Calhoun DA, Jones D, Textor S, et al. Resistant hypertension: diagnosis, evaluation, and treatment. A scientific statement from the American Heart Association Professional Education Committee of the Council for High Blood Pressure Research. Hypertension 2008; 51:1403.
39. Mancia G, Fagard R, Narkiewicz K, et al. 2013 ESH/ESC Guidelines for the management of arterial hypertension: the Task Force for the management of arterial hypertension of the European Society of Hypertension (ESH) and of the European Society of Cardiology (ESC). J Hypertens 2013; 31:1281.
40. Wolters Kluwer, UpToDate Report: Definition, risk factors, and evaluation of resistant hypertension
41. U.S. Food and Drug Administration Premarket Approval: Inspire II Upper Airway Stimulator, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P130008
42. Strollo, PJ, Soose, RJ, Maurer, JT. Upper-airway stimulation for obstructive sleep apnea. N Engl J Med. 2014;370:139-149. **https://www.nejm.org/doi/pdf/10.1056/NEJMoa1308659**
43. Tucker Woodson, B., Strohl, K. P., Soose, R. J., Boyd Gillespie, M., Maurer, J. T., Vries, N. de, … Strollo, P. J. (2018). Upper Airway Stimulation for Obstructive Sleep Apnea: 5-Year Outcomes. *Otolaryngology–Head and Neck Surgery*, *159*(1), 194–202. https://journals.sagepub.com/doi/pdf/10.1177/0194599818762383
44. Post-Approval Upper Airway Stimulation Predictors of Treatment Efficacy in the Adhere Registry Clemens Heiser, Armin Steffen, Maurits Boon, Benedikt Hofauer, Karl Doghramji, Joachim T. Maurer, J. Ulrich Sommer, Ryan Soose, Patrick J. Strollo, Richard Schwab, Erica Thaler, Kirk Withrow, Alan Kominsky, Christopher Larsen, Eric J. Kezirian, Jennifer Hsia, Stanley Chia, John Harwick, Kingman Strohl, Reena Mehra ,European Respiratory Journal Jan 2018. https://erj.ersjournals.com/content/erj/early/2018/10/25/13993003.01405-2018.full.pdf
45. Noridian Healthcare Solutions, DME Jurisdiction A Local Coverage Determination for Oral Appliances for OSA (L33611), effective 1/1/19: https://med.noridianmedicare.com/documents/2230703/7218263/Oral+Appliances+for+Obstructive+Sleep+Apnea+LCD+and+PA/dc994aa8-c706-438b-9e31-db18a6be1358
46. American Academy of Sleep Medicine and American Academy of Dental Sleep medicine Clinical Practice Guideline for the Treatment of Obstructive Sleep Apnea and Snoring with oral Appliance Therapy: An Update for 2015,

http://jcsm.aasm.org/ViewAbstract.aspx?pid=30098
47. 2017 American Academy of Sleep Medicine Clinical Practice Guideline: https://jcsm.aasm.org/doi/full/10.5664/jcsm.6506
48. 2021 American Academy of Sleep Medicine Clinical Guidance Statement: https://jcsm.aasm.org/doi/10.5664/jcsm.9240
49. Medicare LCD Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718) https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33718
50. Medicare LCD Oral Appliances for Obstructive Sleep Apnea (L33611) https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33611&ContrId=389

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POLICY APPROVAL DATES

New:	12/91
Revised:	02/93, 08/95, 08/96, 07/97, 07/98, 08/99, 11/02, 09/03, 10/03, 09/04, 03/05, 02/06,04/06, 07/08, 05/09, 07/09, 01/10, 09/10, 11/10, 09/11, 11/11, 07/12, 09/13, 09/14, 03/15, 09/15, 03/16, 011/16, 09/17, 09/18, 03/19, 09/19, 01/19, 01/20, 3/20, 11/21, 01/22, 1/23, 5/23, 9/23, 11/23, 7/24, 11/24, 1/25, 3/25, 5/25, 7/25, 9/25
Reviewed:	09/93, 08/94, 08/94, 03/08, 09/12, 9/20, 9/21, 9/22, 9/24, 9/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
10/1/2025	Added allowance/criteria for hypoglossal nerve stimulator for pediatric members with down syndrome.
7/1/2025	Added codes 64568-64570 to hypoglossal nerve stimulation section

POLICY NAME: OBSTRUCTIVE SLEEP APNEA: DIAGNOSIS & TREATMENT

	Added new codes 0964T-0966T to exclusions.
3/1/2025 *No change to effective date of policy	Clarification added for split night studies.
3/1/2025	Under Medicaid section, added hypoglossal nerve stimulators guidelines.
2/1/2025	Added another indication for a in lab sleep study.
11/1/2024	Added NightOwl Home Sleep Test to the exclusion section.
8/1/2024	Under Diagnostic testing, updated criteria to state that only a person that is board certified in sleep medicine can perform an OSA evaluation.
3/1/2024	Removed section on Radiofrequency Tissue Volume Reduction for hypertrophy of nasal turbinates and moved to the Non-Covered Technology policy.
4/1/2023 *No change to effective date of policy	Removed below statement as replacement of DME source is identified in the Durable Medical Equipment, 1370/20.000509 policy: CDPHP will allow for the purchase of CPAP, BiPAP, APAP equipment (one unit), per enrollee, every five years, when the above criteria are met.
4/1/2023	Added new HCPCS code A7049 to the exclusions section.
5/1/2022* No change to effective date of policy	Updated verbiage under the Medical Management of OSA section as current verbiage implies that prior authorization is required for CPAP, BiPAP, or APAP machines.
5/1/2022	Updated criteria in the following sections: • Attended Polysomnography- Adults • Repeat PSG or HST- Adults • Medical Management for Obstructive Sleep Apnea Added Prefabricated Oral Appliance (E0485) to exclusions. Effective 01/01/2022: Removed deleted codes 0466T-04668T and updated with replacement codes 64582-64584. Also removed code 64568.
10/01/21	Added new codes for oral sleep appliances: K1027 (effective 10/1/21) and D9947, D9948, D9949 (effective 1/1/2022).

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POLICY NAME: OBSTRUCTIVE SLEEP APNEA: DIAGNOSIS & TREATMENT

7/1/2020	Updated criteria for oral appliances to include a face-to-face clinical evaluation is performed by, or under the direction of, a board-certified sleep medicine specialist or subspecialist in neurology, otolaryngology, or pulmonary medicine prior to the sleep test to assess the beneficiary for obstructive sleep apnea testing and that documentation must include counseling regarding potential treatment options.
5/1/2020	Updated criteria for oral appliances in the Application section in accordance with Medicare coverage criteria. Added additional sources of information (45 and 46)
1/1/2020	Added information and criteria for Multiple Sleep Latency Test (MSLT) to the Application section.

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: OCCUPATIONAL THERAPY

POLICY EFFECTIVE DATE:	3/1/2025
Policy Control #:	1370/20.000104
Next Annual Review:	March 2027

DISCLAIMER

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PROCEDURE CODES

Evaluation: 97165, 97166, 97167, 97168
Modalities: 97010-97039, G0281, G0283, G0329
Therapeutic Procedures: 97110-97546
Tests & Measurements: 97750, 97755
Orthotic & Prosthetic Management: 97760-97763

DESCRIPTIONS

The primary purpose of occupational therapy is to increase the strength of muscles and the range of motion in joints with special attention to fine motor activity.

Occupational therapy services must be specific, effective, and reasonable treatment for the patient's diagnosis and condition relative to the information gathered on the care plan/progress note. Services must be performed to achieve a specific diagnosis related goal for a patient who has reasonable expectation of achieving measurable improvement in a reasonable time.

Occupational therapy services must be performed by a qualified occupational therapist who is licensed where required and who is performing within the scope of the license. These services must require the judgment, knowledge, and skills of a qualified provider because of the

complexity and sophistication of the therapy and/or the physical condition of the patient.

Occupational therapy services may be habilitative or rehabilitative in nature.

- **Rehabilitation services** are health care services that help a person keep, get back, or improve skills and functioning for daily living that have been lost or impaired because a person was sick, hurt, or disabled.
- **Habilitation Services** are health care services that help a person keep, learn, or improve skills and functioning for daily living. They include the management of limitations and disabilities, including services or program that help maintain or prevent deterioration in physical, cognitive, or behavioral function.
  - *Refer to specific member contracts for availability of benefits, if any, relating to habilitative services*.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

- Chiropractic Care, 10.01.02
- Durable Medical Equipment, Prosthetics/Orthotics & Medical Supplies, 1370/20.000509
- Home Care Services: Home Health Care/Telehomecare/Personal Care/Personal Emergency Response System, 1370/20.000048
- Neuromuscular/Functional Electrical Stimulation, 1370/20.000073.
- Physical Therapy, 1370/20.000057.
- Speech Language/Pathology Services, 1370/20.000056

Payment Policies:

- Chiropractic Services, 1550/20.000167

POSITION STATEMENT

CDPHP administers benefits for medically necessary occupational therapy as outlined below.

Outpatient Occupational Therapy

CDPHP administers benefits for medically necessary occupational therapy that can result in clinical improvement in the enrollee's condition when all the following conditions are met:

1. Occupational therapy services are medically necessary, are recommended by the ordering practitioner, and are related to the treatment or diagnosis of a physical illness or injury (includes medically diagnosed congenital defect of a covered child).

2. Services are ordered by a primary care physician, neurologist, pediatric neurologist, neurosurgeon**,** orthopedic surgeon, physiatrist, rheumatologist, hand surgeon, vascular surgeon, or pulmonologist.

3. A plan to ensure the successful transition to a home exercise program will be initiated early in the course of therapy.

4. Services must be performed by a qualified occupational therapist who is performing within the scope of their license.

5. Occupational therapy services are subject to all applicable contract limitations.

Autism Spectrum Disorder

Benefits are provided for covered therapeutic services, to include those for habilitative services, necessary to develop, maintain, or restore, to the greatest extent practicable, functioning of an individual when such services are provided by a licensed occupational therapist for the treatment of autism spectrum disorder. Such benefits will apply only to those plans to which the mandate applies.

Vestibular Rehabilitation Therapy

Benefits may be provided for vestibular rehabilitation therapy for enrollees who meet the following criteria:

- Documentation of vestibular hypofunction with continuous presenting symptoms for at least two months and;
- Unresponsive to conventional therapy.

POLICY CONSIDERATIONS

Benefits for occupational therapy services are subject to all contract limitations and appropriate visit cost share as stated in the enrollee's contract.

CDPHP will reimburse occupational therapy services as a global payment based upon first service billed, per date of service, per practitioner, per contractual agreement.

A treatment plan will be developed in conjunction with the physician, enrollee, and other consultation as necessary.

All patients participating in occupational therapy are expected to actively participate in a daily home exercise program, outlined by the occupational therapist, to meet expected goals.

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POLICY NAME: OCCUPATIONAL THERAPY

A session is defined as a treatment, and/or evaluation provided on any given day.

The patient must exhibit significant and progressive improvements and compliance with home exercise programs.

Benefits are provided for medically necessary occupational therapy services in the home setting as follows:

- Services are rendered by a participating home health agency and;

- Required criteria for home health care services are met in accordance with resource coordination policy, *Home Care Services: Home Health Care/Telehomecare/Personal Care/Personal Emergency Response System.*

Coverage will be provided for establishment/re-evaluation of a home maintenance program, up to a maximum of six visits per calendar year. However, no coverage will be provided for the continuation of maintenance programs (i.e., activities which preserve the patient's present level of function or when no additional functional progress is apparent or expected to occur).

CDPHP does not provide benefits for massage therapy as a stand-alone treatment. Massage therapy (97124) is considered an acceptable treatment when it is part of a comprehensive treatment plan consisting of a combination of other covered procedures and modalities and performed by a practitioner who is licensed and is performing within the scope of the license**.**

Medically necessary occupational therapy conducted on two non-adjacent body parts (e.g., shoulder and wrist) will be reimbursed at one and a half times standard therapy when billed using modifier 59.

Medically necessary occupational therapy conducted on two or more co-linear and adjacent body parts (e.g., cervical and thoracic spine or a shoulder, elbow, and wrist) will be reimbursed as a single standard therapy.

Benefits will be provided for covered durable medical equipment required as part of a home program when in compliance with the requirements outlined in the CDPHP resource coordination policy: *Durable Medical Equipment, Prosthetics/Orthotics & Medical Supplies 1370/20.000509.*

When a service or procedure that may be either habilitative or rehabilitative in nature is provided for **habilitative purposes**, the use of modifier 96 is required to indicate that the service or procedure provided was a habilitative service.

Services or procedures provided for rehabilitative purposes do not require the use of a modifier.

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All occupational therapy services are subject to retrospective review for medical appropriateness as defined by this policy and for compliance with the enrollee's contract.

Coverage will no longer be provided once the allowable maximum benefit is exhausted, even if the medical necessity criteria stated above is met.

EXCLUSIONS

Occupational therapy that duplicates services already being provided as part of another therapy program through another therapy discipline (i.e., physical therapy). When multiple therapies are used, each must have separate written treatment plans and must provide significantly different treatments.

Occupational therapy that duplicates services being provided by a federal or state governmental agency (i.e., Early Intervention Program), by a school district (Individualized Educational Program) or by a developmental learning center that are sufficient in meeting the needs of an individual.

Chronic conditions which will require maintenance therapy (S8990) to prevent regression.

Iontophoresis (97033), used for administration of non-steroidal anti-inflammatory drugs or corticosteroids for treating musculoskeletal disorders, as scientific evidence does not support the use of this procedure as an effective therapy modality.

Infrared therapy (97026) used for the treatment of diabetic and/or non-diabetic peripheral sensory neuropathy, wound healing, or pain management (e.g., Anodyne Therapy System) as scientific evidence does not support the use of this procedure as an effective therapy modality.

Prolotherapy (M0076), for the treatment of joint or ligament instability, as scientific evidence does not support the use of this procedure as an effective physical therapy modality.

Hippotherapy (S8940), as scientific evidence is insufficient to determine the effects of this technology on health outcomes for any indication, including autism spectrum disorder, cerebral palsy, or other motor dysfunctions.

Music therapy/therapeutic listening.

Orthotic and prosthetic training, fitting, and checkout (97760, 97761, 97763) are considered global to the dispensing of the device.

Services for the purpose of athletic training evaluation (97169, 97170, 97171, 97172),

enhancing athletic performance or for recreation.

Sensory integrative techniques (97533), as currently the scientific evidence does not support the use of these services as an occupational therapy modality.

Self-care/home management training, community/work reintegration training, physical performance test or measurement and assistive technology assessment (97535, 97537, 97750, 97755).

Work hardening programs (97545, 97546), as such programs are not considered a medical necessity but rather a requirement of employment.

Benefits are not provided when a session consists of modalities alone, i.e., hot packs, whirlpool, paraffin baths, Hubbard tank, cold packs/ice packs and contrast baths. These alone are not considered a skilled level of treatment.

No coverage will be provided when maximum physical benefit has been achieved (i.e., the goals of achieving functional improvement have been met and the patient no longer requires skilled occupational therapy intervention).

Concurrent treatment for the same condition by both a chiropractor and occupational therapist will not be allowed.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy. Benefits are provided for a condition amenable to significant clinical improvement within a period of 60 days or less from the date of the initial treatment.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy Benefit coverage to include unlimited medically necessary occupational therapy visits. Includes therapy that would otherwise be covered as an inpatient and is provided under the care of a physician pursuant to a written plan of treatment. The following occupational therapy codes are covered: • Evaluation: 97165, 97166, 97167, 97168 • Modalities: 97010-97032, 97033-97039, G0281, G0283, G0329 (97026 is non-covered). G0281 and G0329 are only

	covered for chronic stage III and stage IV pressure ulcers, arterial ulcers, diabetic ulcers, and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care. • Therapeutic procedures: 97110-97130, 97139-97542, 97750-97755, 97760-97763 (97545, 97546 are non-covered).
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy. Benefit coverage includes unlimited medically necessary occupational therapy visits.
SMALL GROUP/ COMMERCIAL INDIVIDUAL	Covered rehabilitative occupational therapy services must begin within six months of the later to occur: • The date of the injury or illness that caused the need for the therapy; • The date of discharged from the hospital where the surgical treatment was rendered; or • The date outpatient surgical care is rendered. Habilitation services consisting of occupational therapy are covered in the outpatient department of a facility or in a health care professional's office.

SOURCES

1. American Society of Hand Therapists Treatment Guidelines (Multiple Editions).
2. Black, Angel; Pesznecker, Gianna, "Outcome Analysis of Individualized Vestibular Rehabilitation Protocols," "The American Journal of Otology," 21:543:551, 2000.
3. Blondis, T.; Attention-Deficit/Hyperactivity Disorder: Motor Disorders and Attention-Deficit/Hyperactivity Disorders. Pediatric Clinics of North America, Vol. 46 No. 5, October 1999.
4. CDPHP consultants.
5. Member contract language.
6. Helen Cohen, EdD, "Vestibular Rehabilitation Reduces Functional Disability," Otolaryngol Head Neck Therapy, 107:638, 1992.
7. Linderman, T.M.; Stewart, K.B.: Sensory Integrative-based Occupational Therapy and Functional Outcomes in Young Children with Pervasive Development Disorders: a single-

subject study. American Journal of Occupational Therapy – 1999 March-April; 53(2): 207-213.
8. Neil Shepard, Ph.D./Steven Telian, M.D., "Programmatic Vestibular Rehabilitation," Otolarngol Head Neck Surgery," 112: 173-82, 1995.
9. National Government Services, Inc. Local Coverage Determination: Outpatient Physical and Occupational Therapy Services (L33631), effective 10/1/18: https://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/home-lob/pages/medical-policy-center/mpc-search-detail/lcd%20for%20outpatient%20physical%20and%20occupational%20therapy%20services%20(l33631)/!ut/p/z1/pVJdb4IwFP0r2w8gt3xJfaygyJcgU5G-mA4KkgkYNJjt168uy0x0m1nWl-benp5zenqBwhpow_qqZMeqbdhO1CkdbDTijGXZRF5oyQYinhah6SJEtm7AClIHUuW0thoCyT00Fcfoh0UQuPcAwo7SBWZQAt2z41aqmqKFdVMeap5XGeu4sEA_SC4m1BAjok1GljWPVHukfAJ-UUnFM4wLAzY9ExHTj4LZxERobkDSV_wEy6btapHR05lxn1U5pIWuaFjjTOK5kktagbCEDZxJQx1nWoFZritDmN4oXAXlf6uQmMFmvhzH4u6B9Txr25eKn5myHWfdpfTDEaQR644PYo_HthPORPtvFg8TWMQiAS_wV0sHq8j-bwLu1RfdzEnifs0UlWFfN68SfR7E-LQotmVNSDSTUrd_88jjO7ebTAk!/dz/d5/L2dBISEvZ0FBIS9nQSEh/?clearcookie=&savecookie=&LOB=Part%20B&REGION=
10. New York State Medicaid Redesign Team: Medicaid Managed Care Benefit Changes, 2011-2012, www.health.ny.gov
11. Other payers.
12. Rene Shubert Balkany, "Visual-Vestibular Habituation and Balance Training for Motion Sickness," Physical Therapy, Vol. 79, #10, Oct. 1999.
13. Steven Telian, MD, "Habituation Therapy for Chronic Vestibular Dysfunction: Preliminary Results," Otolaryngology Head Neck Surgery, 103:89,1990.
14. Susan Whitney, PhD.,PT, Maureen Rossi, PhD, PT, "Practical issues in the Management of the Dizzy and Balanced Disorder Patient. Efficiency of Vestibular Rehabilitation," Otolaryngologic Clinics of North America, Vol. 33, #3, June 2000.
15. Vargas, S.; Camilli, G. A Meta-analysis of Research on Sensory Integration Treatment. American Journal of Occupational Therapy 1999 March-April; 53(2): 189-198.

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POLICY APPROVAL DATES

New: 07/93

POLICY NAME: OCCUPATIONAL THERAPY

Revised:	05/94, 05/95, 04/96, 03/97, 06/98, 03/00, 01/00, 01/01, 08/01, 05/02, 09/02, 03/03, 02/04, 08/04, 10/04, 05/05, 02/06, 05/06, 03/08, 03/09, 11/09, 03/10, 03/11, 09/11, 11/11, 3/12, 09/12, 03/13, 11/13, 03/16, 09/16, 01/17, 01/18, 03/18, 07/18, 11/18, 03/19, 11/20, 3/22, 3/23, 5/23, 3/24, 3/25
Reviewed:	04/07, 03/14, 03/15, 03/17, 3/20, 3/21,3/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
3/1/2025 *No change to effective date of policy	Under Medicare section, removed information on iontophoresis for hyperhidrosis as this listed in the Non-Covered Technologies policy with an exception for Medicare Advantage.
3/1/2025	Removed Pneumatic cervical traction devices (E0856) from Exclusions as it is addressed in the Durable Medical Equipment, Orthotics/Prosthetics and Medical Supplies policy.
6/1/2023 *No change to effective date of policy	Removed verbiage under the Small Group Commercial/Individual section to mirror contract language.
6/1/2023	Removed specific diagnoses from the exclusion section.
4/1/2022 *No change to policy effective date	Clarified coverage in Medicare section and removed deleted codes 97005 and 97006. Removed visit limitations under product variations as contracts are the best source for identifying limits.
4/1/2022	Updated Medicare section to include coverage of iontophoresis for treatment of intractable, disabling primary focal hyperhidrosis per LCD L33631
1/1/2021	Updated the Select Plan/Harp section as coverage now includes unlimited medically necessary occupational therapy visits.

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Background

Omisirge (omidubicel-onlv) is an ex-vivo expanded cell therapy derived from umbilical cord blood, engineered to enhance hematopoietic recovery following stem cell transplantation. Omisirge is manufactured using proprietary nicotinamide (NAM) technology, which modifies the stem cells to improve their functionality and speed up recovery. Ex-vivo expansion of cord blood derived hematopoietic progenitor cells (HPCs) in the presence of NAM leads to preservation of their stemness, supports bone marrow (BM) engraftment, and enables rapid neutrophil and multilineage immune recovery as demonstrated in clinical trials. Omisirge is FDA-approved for:

- Adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection.
- Adults and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning.

Umbilical cord blood (UCB) is a well-established alternative graft source for patients requiring hematopoietic cell transplantation (HCT) who lack a suitable human leukocyte antigen (HLA)-matched related or unrelated donor.[2] Unfortunately, the relatively low number of hematopoietic progenitor cells and mature T cells in a single UCB unit often results in inadequate or delayed engraftment. To address this limitation, transplantation with two UCB units has become standard practice in adults. Despite this, hematopoietic recovery remains slower compared to HCT from related or unrelated donors and is associated with higher treatment-related morbidity and mortality.[3] Consequently, UCB transplantation typically leads to longer hospital stays, increased resource utilization—such as blood product transfusions—and higher overall costs, particularly during the early post-transplant period.[4,5,6]

On April 17, 2023, the FDA approved Omisirge for adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection. This approval was supported by data from an open-label, Phase III, multicenter, randomized trial (Study P0501 [NCT02730299]) involving 125 patients eligible for allogenic transplant without a suitable human leukocyte antigen (HLA)-matched related or unrelated donor. In the trial, 62 patients were randomized to receive Omisirge and 63 patients were scheduled to undergo standard umbilical cord blood transplantation. Omisirge (omiduvicel-onlv) met its primary endpoint of faster neutrophil recovery compared to UCB. In addition, the Omisirge treatment arm demonstrated faster platelet recovery, a reduced rate of infections, and shorter hospital length of stay compared with UCB.[7]

Severe aplastic anemia is a rare, life-threatening hematologic disease characterized by bone marrow failure and low circulating blood cells. Although long term survival for SAA patients can be achieved with immunosuppressive therapy (IST), one quarter to one third will fail to respond and about half of responders will relapse. Hematopoietic stem cell transplant may be curative for SAA, but many refractory SAA pts lack an HLA matched donor for salvage allogeneic stem cell transplantation. Although umbilical cord blood transplantation (UCBT) offers an alternative treatment option for patients with severe aplastic anemia (SAA), it is associated with delayed engraftment and elevated rejection rates. Additionally, many UCB units contain insufficient total nucleated cells (TNCs) and CD34+ cells to achieve optimal transplant outcomes.[8]

On December 5, 2025, the FDA expanded the approval of Omisirge to include the treatment of severe aplastic anemia (SAA) in adults and pediatric patients 6 years and older following reduced intensity conditioning. The efficacy of Omisirge in patients with SAA was evaluated in an open-label, single-center study (17-H-0091 [NCT03173937]) consisting of patients with SAA who had intolerance or failure to respond to immunosuppressive therapy and the availability of at least one ≥ 4/8 human leukocyte antigen (HLA)-matched (HLA-A, B, C, and DR loci) cord blood unit. A total of 14 patients were treated with Omisirge, with 86% of patients experiencing early and sustained neutrophil recovery at 100 days, red blood cell transfusion independence, and platelet recovery ≥ 20,000/μL within a year. In addition, 79% of patients demonstrated platelet transfusion independence.

Summary	
Effective Date of Policy:	4/17/2026
Indications	• Adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infections • Adults and pediatric patients 6 years and older with severe aplastic anemia (SAA) following reduced intensity conditioning
HCPCS Code	J3590 (unclassified)
Availability	Two cryopreserved cell fractions and two infusion solutions
Duration	6 months to allow sufficient time for administration

Required Criteria for Approval

1. Must be prescribed by a hematologist, oncologist, or physician experienced in the treatment of hematologic malignancies and/or severe aplastic anemia AND
2. The patient must be eligible for an allogeneic hematopoietic (stem) cell transplant AND
3. The prescriber must attest that the patient does not have a readily available, matched related donor, matched unrelated donor, mismatched unrelated donor, or a haploidentical related donor
    a. If a more appropriately matched umbilical cord blood unit is available, a mismatched unrelated donor or haploidentical related donor would not be required AND
4. The patient must receive therapy at an authorized treatment center AND
5. The patient must meet ONE of the following (a or b):
    a. The patient must have a hematologic malignancy AND
        i. The patient must be 12 years of age or older AND
        ii. The prescriber must attest that the umbilical cord unit used will be HLA-matched at a minimum of 4 loci (including HLA-A, B at the antigen-level, and DRB1 at the allele level) AND
        iii. The requested treatment must be used to reduce the time to neutrophil recovery and the incidence of infection AND
        iv. The requested treatment must be used following myeloablative conditioning
    b. The patient must have severe aplastic anemia (SAA) as documented by the following:
        i. Bone marrow aspiration (BMA) cellularity of < 30% AND at least two of the following:
            1. Absolute neutrophil count (ANC) < 500 cells/mm^3
            2. Platelet count < 20,000/mm^3
            3. Reticulocyte count < 60,000/mm^3
        ii. The patient must be 6 years of age or older AND
        iii. The patient has tried and failed to respond to or had an intolerance to standard immunosuppressive therapy AND
        iv. The prescriber must attest that the umbilical cord unit used will be HLA-matched at a minimum of ≥ 4/8 loci (HLA-A, B, C and DR loci) AND
        v. The requested treatment must be used following reduced intensity conditioning AND
6. Omisirge is indicated for one-time intravenous administration only and therefore will not be authorized for retreatment. Retreatment will be considered experimental/investigational when any FDA approved gene or cellular therapy, or any other gene or cellular therapy under investigation, has been previously administered.
7. Please refer to the Omisirge FDA-approved prescribing information for complete dosage and administration instructions.
8. Omisirge (omidubicel-onlv) is considered investigational for all other non-FDA approved indications.
9. Authorization will be for 6 months to allow sufficient time for administration.

Considerations

- Patient must have medical drug coverage administered by CDPHP.
- Prior authorization is obtained through the CDPHP pharmacy department.
- Doses and frequency should be in accordance with the FDA label or recognized compendia (for off label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity

Administration, Retreatment, and Treatment with Additional or Other Gene/Cellular Therapies

a. One-Time Administration
    i. Most gene and cellular therapies, whether autologous, allogeneic ("off-the-shelf"), or in vivo gene-transfer therapies, are designed and studied as one-time treatments.
    ii. Repeat dosing, reinfusion, or sequential therapy with other gene or cellular products has not been established as safe, effective, or clinically appropriate.

b. Retreatment/Repeat Administration
    i. Retreatment with the same gene or cellular therapy product is considered experimental and investigational because:
        1. Clinical trials evaluated these therapies as single-administration interventions
        2. Safety, efficacy, and durability of a second administration have not been established
        3. Risks of immune activation, insertional mutagenesis, or vector immunity may be increased with repeat dosing

c. Treatment with an Additional or Other Gene/Cellular Therapy
    i. Treatment with an additional or different gene or cellular therapy after prior exposure to any gene or cellular therapy is also considered experimental and investigational, unless supported by evidence demonstrating (1-4):
        1. Anticipated clinical benefit beyond available standard therapies
        2. Safety of sequential administration
        3. Justification for selecting a second gene/cellular intervention after a prior one
        4. Meets the criteria established in the Off-Label Use of FDA Approved Pharmacy Management Drug Policy (Pharmacy-32)
    ii. This includes, but is not limited to:
        1. Switching between CAR-T products (e.g., CD19 → CD19 or CD19 → BCMA)
        2. Switching between autologous and allogeneic cellular therapies
        3. Sequential use of CAR-T, TCR-T, NK-cell therapies, or other genetically engineered cell therapies
        4. Receiving a gene therapy after previous gene or cellular therapy exposure
        5. Receiving an in vivo gene therapy following any prior vector-based therapy

d. Prior Gene/Cell Therapy Exposure
    i. An individual is generally not eligible for additional gene or cellular therapy if they have previously received:
        1. Any autologous cellular therapy (e.g., CAR-T, TCR-T, TIL),
        2. Any allogeneic genetically modified cellular therapy,
        3. Any in vivo gene therapy (e.g., AAV, lentiviral vector)
        4. Any ex vivo gene-modified cell product
        5. Are being considered for any other gene or cellular therapy without documented evidence supporting safety and anticipated benefit.

e. Coverage Determination
    i. Absent peer-reviewed evidence demonstrating safety and benefit, retreatment or sequential therapy is considered investigational and will not be covered.

References

		Updated	Accessed
1	Omisirge [package insert]. Naples, Fl: Gamida Cell Inc	12/2025	3/2026
2	Majhail NS, Miller b, Dean R, et al. Hospitalization and Healthcare Resource Utilization of Omidubicel-Onlv versus Umbilical Cord Blood Transplantation for Hematologic Malignancies: Secondary Analysis from a Pivotal Phase 3 Clinical Trial. Transplantation and Cellular Therapy. 2023;29(12): 749.e1-749.e5.	2/2023	3/2026
3	Majhail NS, Brunstein CG, Wagner JE Double Umbilical cord Blood transplantation. Curr Opin Immunol. 2006;18:571-575	10/2006	3/2026
4	Majhail NS, Mothukuri JM, Brunstein CG, et al. Costs of hematopoietic cell transplantation: comparison of umbilical cord blood and matched related donor transplantation and the impact of posttransplant complications. Biol Blood Marrow Transplant. 2009; 15: 564-573	5/2009	3/2026
5	Preussler JM, Denzen EM, Majhail NS Costs and cost-effectiveness of hematopoietic cell transplantation. Biol Blood Marrow Transplant. 2012: 18: 1620-1628	4/2012	3/2026
6	Rangarajan HG, Stanel JR, Abu-Arja R Costs of cord blood transplantation are higher than other graft sources in patients with acute leukemia and myelodysplastic syndrome treated at pediatric centers. Biol Blood Marrow Transplant. 2020: 26: e313-e315	9/2020	3/2026

7	Horwitz ME, Stiff PJ, Cutler C, et al. Omidubicel vs standard myeloablative umbilical cord blood transplantation: results of a phase 3 randomized study. Blood. 2021; 138: 1429-1440	10/2021	3/2026
8	Samour M, Aue G, Clara J, et al. Rapid Engraftment, Immune Recovery, and Resolution of Transfusion Dependence in Treatment-Refractory Severe Aplastic Anemia Following Transplantation with Ex Vivo Expanded Umbilical Cord Blood (Omidubicel). Blood. 2020; 136 (Supplement 1): 37-38	11/2018	3/2026
9	Kulasekararah A, Cavenagh J, Dokal I, et al. Guidelines for the diagnosis and management of adult aplastic anaemia: A British Society for Haematology Guideline. British Journla of Haematology. 2024; 204(3):784-804	3/2024	3/2026

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 4/17/2026

New: 4/2026

Revised	Reviewed

Revision Date	Changes Made

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Disclaimer Notice

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Background

Bispecific antibodies (BsAbs) have two distinct binding domains that can bind to two antigens or two epitopes (an antigen part) of the same antigen simultaneously. Most bsAbs are bispecific T-cell-engagers (BiTEs), designed to redirect and/or activate CD3-expressing cytotoxic T cells (CTLs) against a specific tumor target on malignant cells. Other bsAb classes include therapies that target immune checkpoints, oncogenic signaling pathways and cytokines. Bifunctional fusion proteins are a subset of bsAbs that are typically devoid of an Fc region.

Because the FDA has been encouraging drug development in this area, there are now over 100 BsAbs in clinical development, most of which are in the early stages. In 2021, the FDA finalized guidance on BsAb development programs, which discusses aspects for chemistry, manufacturing, and controls (CMCs) as well as nonclinical and clinical development programs. It also describes the challenges, such as immunogenicity related to the novel structures. In addition, the guidance recommends types of data to support BsAb approvals.

The majority of BsAbs to-date target different types of cancer these agents are often reserved for relapsed or refractory stages of cancer. Other BsAbs are focused on chronic inflammatory, autoimmune, and neurodegenerative diseases; vascular ocular, and hematologic disorders; and infections. There have been many FDA-approved bispecific antibodies over the years, most of which approved under the accelerated approval based on response rate and durability of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

FDA-approved bispecific antibodies for oncology indications include:

Trade name	Year Approved	Mechanism	Indication(s)
Blincyto® (blinatumomab)	2014	CD19-directed CD3 T-cell engager	CD19-positive B-cell precursor acute lymphoblastic leukemia (ALL) in first or second complete remission with minimal residual disease Or Relapsed or refractory CD19-positive B-cell precursor ALL Or CD19-positive Philadelphia chromosome-negative B-cell precursor ALL in the consolidation phase of multiphase chemotherapy
Columvi™ (glofitamab-gxbm)	2023	CD20-directed CD3 T-cell engager	Relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy
Epkinly™ (epcoritamab-bysp)	2023	CD20-directed CD3 T-cell engager	Relapsed or refractory DLBCL, not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy Or Relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy
Lunsumio™ (mosunetuzumab-axgb)	2022	CD20-directed CD3 T-cell engager	Relapsed or refractory follicular lymphoma after two or more lines of systemic therapy
Lynozyfic™ (linvoseltamab-gcpt)	2025	B-cell maturation antigen (BCMA)-directed CD3 T-cell engager	Relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody
Rybrevant® (amivantamab-vmjw)	2021	EGF receptor-directed and MET receptor-directed antibody	Locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations in combination with lazertinib Or Locally advanced or metastatic NSCLC with EGFR exon 19 deletions

			or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor, in combination with carboplatin and pemetrexed Or Locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, in combination with carboplatin and pemetrexed Or Locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, whose disease has progressed on or after platinum-based chemotherapy
Imdelltra™ (tarlatamab-dlle)	2024	Delta-like ligand 3 (DLL3)-directed CD3 T-cell engager	Extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy
Talvey™ (talquetamab-tgvs)	2023	GPRC5D-directed CD3 T-cell engager	Relapsed or refractory multiple myeloma who have received at least four prior lines of therapy
Tecvayli® (teclistamab-cqyv)	2022	BCMA-directed CD3 T-cell engager	Relapsed or refractory multiple myeloma who have received at least four prior lines of therapy
Elrexfio™ (elranatamab-bcmm)	2023	B-cell maturation antigen (BCMA)-directed CD3 T-cell engager	Relapsed or refractory multiple myeloma who have received at least four prior lines of therapy
Ziihera® (zanidatamab-hrii)	2024	Bispecific HER2-directed antibody	Previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC), as detected by an FDA-approved test

Due to the possibility of cytokine release syndrome and immune effector cell-associated neurotoxicity syndrome (ICANS), most BsAbs have specific step-up dosing protocols where patients should be hospitalized and monitored for potential reactions. Due to the risk of CRS and neurologic toxicity, including ICANS, some BsAbs have REMS programs where prescribers, pharmacies, healthcare settings, and wholesalers and distributers must be certified. Additionally, all BsAbs have a warning for embryo-fetal toxicity, and most have warnings for infections and other toxicities.

Summary	
Effective Date of Policy:	9/10/2025
Applicable Agents	Blincyto® (blinatumomab), Columvi™ (glofitamab-gxbm), Epkinly™ (epcoritamab-bysp), Lunsumio™ (mosunetuzumab-axgb), Rybrevant® (amivantamab-vmjw), Imdelltra™ (tarlatamab-dlle), Talvey™ (talquetamab-tgvs), Tecvayli® (teclistamab-cqyv), Elrexfio™ (elranatamab-bcmm), Lynozyfic™ (linvoseltamab-gcpt)
Duration	Initial: three months Continuation: three months

This policy applies to all bispecific antibodies for oncologic indications, including new to market agents not listed above.

Required Criteria for Initial Approval		
All of the following conditions for the requested indication must be met in order to approve therapy:		
Indication	**Inclusion Criteria**	**Recommended Dosing Regimen**
Refer to specific product for indication	1. Documented FDA approved indication per prescribing information or supported evidence per NCCN guidelines 2. Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 3. For enrollees of childbearing age: a. If female, documentation of negative pregnancy test	• Refer to FDA prescribing information

	b. If male, documentation enrollee has been counseled on reproductive risk and need for appropriate contraception for any female partners during treatment and for 90 days after last dose 4. Must be administered at an authorized treatment center where dosing protocols and hospital stay requirements are followed according to the FDA label	

Exclusion Criteria

Therapy will not be covered if any of the below criteria are met:

- Use as first-line therapy (except for blinatumomab)
- Indication not approved by the FDA or supported by NCCN guidelines

Continuation Criteria

- Requests will be reviewed per criteria every three months
- Member has not had unacceptable toxicities
- Member has not had disease progression while receiving therapy

Considerations

- Please refer to the package insert for detailed dosing information.
- Prior authorization is obtained through the CDPHP pharmacy department.
- Some products require failure to systemic therapies. Some of the commonly used agents are listed below for reference in Table 1.

Table 1.

Proteasome inhibitors	Immunomodulatory agents	Anti-CD38 monoclonal antibodies
Kyprolis (carfilzomib)	Thalomide (thalidomide)	Darzalex (daratumumab)
Velcade (bortezomib)	Revlimid (lenalidomide)	Sarclisa (isatuximab)
Ninlaro (ixazomib)	Pomalyst (pomalidomide)	

References

		Updated	Accessed
1	Esfaniari A, Cassidy S, Webster R. Bispecific antibodies in oncology. Nature. March 2022. Available at https://www.nature.com/articles/d41573-022-00040-2	3/2022	12/2023
2	US Food and Drug Administration (FDA). Bispecific Antibodies: An Area of Research and Clinical Applications. Available at: https://www.fda.gov/drugs/news-events-human-drugs/bispecific-antibodies-area-research-and-clinical-applications	2/2024	10/2024
3	Acute Lymphoblastic Leukemia. NCCN Clinical Practice Guidelines in Oncology. Version 2.2024. Updated July 19, 2024.	10/2023	10/2024
4	Multiple Myeloma. NCCN Clinical Practice Guidelines in Oncology. Version 1.2025. Updated September 17, 2024.	9/2024	10/2024
5	B-Cell Lymphomas. NCCN Clinical Practice Guidelines in Oncology. Version 3.2024. Updated August 26, 2024.	8/2024	10/2024
6	Non-Small Cell Lung Cancer. NCCN Clinical Practice Guidelines in Oncology. Version 10.2024. Updated September 23, 2024	9/2024	10/2024
7	Blincyto® [prescribing information]. Thousand Oaks, CA. Amgen Inc.	6/2024	10/2024
8	Columvi™ [prescribing information]. South San Francisco, CA. Genentech, Inc.	6/2023	10/2024
9	Epkinly™ [prescribing information]. Plainsboro, NJ. Genmab US, Inc.	8/2024	10/2024
10	Lunsumio™ [prescribing information]. South San Francisco, CA. Genentech, Inc.	12/2022	10/2024

11	Rybrevant® [prescribing information]. Horsham, PA. Janssen Biotech, Inc.	9/2024	10/2024
12	Talvey™ [prescribing information]. Horsham, PA. Janssen Biotech, Inc.	8/2023	10/2024
13	Tecvayli® [prescribing information]. Horsham, PA. Janssen Biotech, Inc.	5/2024	10/2024
14	Elrexfio™ [prescribing information]. New York, NY. Pfizer Inc.	8/2023	10/2024
15	Imdelltra™ [prescribing information]. Thousand Oaks, CA. Amgen Inc.	5/2024	10/2024
16	Lynozyfic™ [prescribing information]. Tarrytown, NY. Regeneron Pharmaceuticals Inc.	7/2025	8/2025

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 9/10/2025

New: 2/2024

Revised	Reviewed
2/2025, 9/2025	

Revision Date	Changes Made
2/2025	Added Imdelltra and Ziihera; added additional FDA indications for Rybrevant, Epkinly, and Blincyto
9/2025	Added Lynozyfic

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BEHAVIORAL HEALTH RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: OPIOID TREATMENT PROGRAMS (OTP)

POLICY EFFECTIVE DATE:	9/1/24
Policy Control #:	1370/20.000460
Next Annual Review:	8/2026

DISCLAIMER

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PROCEDURE CODES

H0020, H0033, H0034, G2067, G2068, G2070, G2071, G2072, G2073, G2074, G2075, G2076, G2077, G2078, G2079, G2080, G2086, G2087, G2088, 96372, J0570, Q9991, Q9992

DESCRIPTION

Methadone, buprenorphine and naltrexone are FDA approved Medications for Addiction Treatment (MAT) for the treatment of opioid use disorder (OUD). Buprenorphine and naltrexone are available in long acting injectable (LAI) formulations. Methadone is full agonist at the mu opioid receptor subtype, buprenorphine is a partial agonist at the mu opioid receptor subtype and naltrexone is an antagonist at the mu receptor subtype. The goal of MAT for OUD is to prevent and/or treat opioid withdrawal (methadone and buprenorphine only), reduce opioid cravings, and to reduce the risk of opioid overdose in the context of OUD.

In the United States, the treatment of OUD with medications is governed by the Certification of Opioid Treatment Programs, 42 Code of Federal Regulations (CFR) 8. This regulation created a system to accredit and certify opioid treatment programs (OTPs). OTPs can provide medication for addiction treatment (MAT) and/or therapy for people diagnosed with OUD.

RELATED POLICIES/DOCUMENTS

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: OPIOID TREATMENT PROGRAMS (OTP)

N/A

POSITION STATEMENT

CDPHP administers benefits for outpatient MAT therapy, at OTPs to include both induction and maintenance phases of treatment, when all of the following criteria are met:

- Enrollee has a substance use benefit administered through CDPHP.
- Enrollee is an adult (or adolescent 16 years of age or older for buprenorphine)
- The enrollee's diagnosis of OUD is consistent with the criteria for OUD found in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5).
- The enrollee meets the required patient placement criteria outlined in the New York State Level of Care for Alcohol and Drug Treatment Referral 3.0 (LOCADTR 3.0)
- Services are provided only by a participating CDPHP OTP, including methadone maintenance programs, that are certified by the New York State Office Addiction Services and Supports and licensed by the federal government (OASAS) and in accordance with medical treatment protocols and program standards as defined by regulation 14 NYCRR Part 822 & 828. In other states, those facilities accredited by the J.C.A.H.O. as alcoholism or substance abuse treatment programs.

POLICY CONSIDERATIONS

Opioid treatment programs (OTP) offer medical and support services including counseling, educational, and vocational rehabilitation. OTP includes the Narcotic Treatment Program (NTP) as defined by the federal Drug Enforcement Agency (DEA) in 21 CFR Section 13. A physician serves as medical director and physician and nursing staff assess each individual and approve the plan of care. Clinical staff provide individual, family and group counseling. Patients are prescribed and delivered medication assisted treatment which is expected to be long term medication management of their chronic opioid use disorder.

For those OTP and methadone maintenance programs with a state-issued waiver to prescribe extended supplies of methadone, benefit for the methadone will be administered for those enrollees who have prescription drug benefits when the following criteria are met:

- The enrollee will obtain approved methadone at an OTP or methadone
- Maintenance clinic authorized to dispense such methadone supplies under
- OASAS regulations.
- Other narcotic medications will not be administered during the approval period for methadone unless authorization is requested by the methadone prescribing practitioner and approved by a Plan medical director.

Benefits for methadone therapy, and other medications used by OTP, are subject to limitations, as well as applicable cost share, as stated in the enrollee's contract.

EXCLUSIONS

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: OPIOID TREATMENT PROGRAMS (OTP)

Injectable methadone (J1230) products are not approved for the outpatient treatment of opioid dependence.

Treatment rendered by a provider in New York state that is not certified by the OASAS; in other states, those that are not accredited by the J.C.A.H.O. as alcoholism or substance abuse treatment programs.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP:	Subject to all terms and conditions noted above in the policy.

SOURCES

1. American Society of Addiction Medicine (ASAM) Placement Criteria for the Treatment of Substance Abuse Disorders Second Revised Edition, 2001.
2. FDA Center for Drug Evaluation and Research.
3. Department of Health & Human Services Code of Federal regulations, Title 42, Section 8.
4. New York State Office of Alcohol and Substance Abuse Services Regulations: https://www.oasas.ny.gov/regs/
5. New York State Office of Alcoholism and Substance Abuse Services: Guidelines for Level of Care Determination – LOCADTR 3.0, https://www.oasas.ny.gov/treatment/health/locadtr/documents/LOCADTRManual.pdf
6. Substance Abuse and Mental Health Services Administration. https://www.samhsa.gov/medication- assisted-treatment/opioid-treatment-programs
7. Centers for Medicaid and Medicare Services: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/Opioid-Treatment-Program

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: OPIOID TREATMENT PROGRAMS (OTP)

CPT® is a registered trademark of the American Medical Association

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POLICY APPROVAL DATES

New: 09/09

Revised: 01/11, 07/11, 09/11, 09/12, 09/15, 09/17, 09/18, 09/20, 8/23, 8/24

Reviewed: 07/11, 09/13, 09/14, 05/16, 09/16, 09/19, 03/20, 9/21, 9/22, 9/23, 8/25

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

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POLICY NAME: OPIOID TREATMENT PROGRAMS (OTP)

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
9/1/24	Updated description of medications used to treat opioid use disorder.
8/1/23	- Updated description of opioid use disorder medications and Opioid Treatment Programs - Updated position statement to reflect appropriate medications based on age
1/1/2020	Removed age limitation from the Select Plan/HARP section. Changed name of policy to "Opioid Treatment Programs" and expanded language to broaden the scope of medications permitted for long term treatment of opioid dependence, including several new G codes billable per CMS guidelines.

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MEDICAL POLICY

Medical Policy Title	**Out-of-Network Services**
Policy Number	**11.01.14**
Current Effective Date	**August 1, 2026**
Next Review Date	**January 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. For the purposes of this policy, "in-network" is determined based on the member's subscriber contract and whether the member's subscriber contract is included under the health care provider's participation agreement. To make a coverage decision with respect to a service that is out-of-network for a member, the member's subscriber contract and any required network adequacy standards must be applied.

II. The following definitions and clarifications are also relevant in making coverage decisions:

A. Emergency Condition

An Emergency Condition is a medical or behavioral condition that manifests itself by acute symptoms of sufficient severity, including severe pain, such that a prudent layperson, possessing an average knowledge of medicine and health, could reasonably expect the absence of immediate medical attention to result in **ANY** of the following conditions:

1. Placing the health of the person afflicted with such condition or, with respect to a pregnant woman, the health of the woman or her unborn child, in serious jeopardy or, in the case of a behavioral condition, placing the health of the person or others in serious jeopardy;
2. Serious impairment to such person's bodily functions;
3. Serious dysfunction of any bodily organ or part of such person;
4. Serious disfigurement of such person.

B. Emergency Services

Emergency Services, with respect to an Emergency Condition, are:

1. A medical screening examination that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate the Emergency Condition; **AND**
2. Within the capabilities of the staff and facilities available at the hospital, such further medical examination and treatment as are required to stabilize the patient, i.e., with

respect to an Emergency Condition, to provide such medical treatment of the condition as may be necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the patient from a facility or, in the case of a pregnant woman, to deliver a newborn child (including the placenta).

C. In-Network Services

Covered services provided by a Participating Provider and, if required by the member's subscriber contract, provided, arranged or authorized in advance by the member's primary care provider. In-Network Services are covered at the in-network benefit level, which generally has the lowest cost-sharing obligation for the member.

D. Network Adequacy Standards

Network Adequacy Standards are the requirements, set forth in the New York Insurance and Public Health Laws, regarding the Health Plan's obligation to ensure that its provider network is adequate to meet the health needs of its members and provide an appropriate choice of providers sufficient to render the services covered under the member's subscriber contract. Network adequacy standards apply to all insurance products, including health maintenance organization (HMO), point-of-service (POS), preferred provider organization (PPO), exclusive provider organization (EPO), and indemnity contracts and certificates, including stand-alone dental and vision policies and student health insurance policies; and to Article 47 self-funded municipal cooperative plans. Similar standards apply to Medicare Advantage products. Network Adequacy Standards do not apply to self-funded health plans other than Article 47 plans, unless their plan documents include such standards.

E. Non-Participating Provider (Out-of-Network Provider)

A facility, professional provider, or ancillary provider (e.g., laboratory, pharmacy, or durable medical equipment supplier) that does not have a contract with the Health Plan to provide health services under a member's subscriber contract is a Non-Participating (or Out-of-Network) Provider. Some providers may have a contract with the Health Plan for only particular products and are Non-Participating Providers for all other products. Members generally have a higher cost-share when they receive services from a Non-Participating Provider.

F. Out-of-Network Services

Covered services that are provided by a Non-Participating Provider are Out-of-Network Services. Not all products include coverage for non-emergent Out-of-Network Services. When a member's subscriber contract includes coverage for Out-of-Network Services, and the member chooses to receive a non-emergent covered service from a Non-Participating Provider, benefits are generally provided at the out-of-network benefit level.

G. Out-of-Network Referral

If there is no Participating Provider with the appropriate training and experience to treat a member, or when Network Adequacy Standards require it, the Health Plan must authorize a referral to a Non-Participating Provider, and the Non-Participating Provider's services must be covered at the member's in-network benefit level. An Out-of-Network Referral must be made available to any member covered under an HMO, POS, PPO, EPO, or indemnity contract or certificate, including a stand-alone dental or vision policy, a student health insurance policy, or under an Article 47 self-funded municipal cooperative plan. Similar Out-of-Network Referral requirements are applicable to Medicare Advantage plans. Out-of-Network Referral requirements do not apply to self-funded health plans other than Article 47 plans, with the exception of referrals for preventive care services under the Affordable Care Act that are unavailable in-network.

H. Participating Provider (In-Network Provider)

A facility, professional provider, or ancillary provider (e.g., laboratory, pharmacy, or durable medical equipment supplier) that has a contract with the Health Plan to provide health services under a member's subscriber contract is a Participating Provider (or In-Network Provider). Some providers may have a contract with the Health Plan for only particular products and are Participating Providers for only those products. A list of Participating Providers and their locations is available on our website or upon your request to the Health Plan. The list will be revised from time to time by the Health Plan.

I. Service Area

The geographic area, designated by the Health Plan and, if required, approved by the New York State Department of Health, in which we will arrange and/or provide benefits to our members, as described in the member's subscriber contract.

J. Surprise Bill

A bill for covered health care services, other than emergency services, received by a member for services provided under **EITHER** of the following circumstances:

1. The services are performed by a non-participating physician at a participating hospital or ambulatory surgical center, where a participating physician is unavailable; or are performed by a non-participating physician without the member's knowledge or when unforeseen medical services arise at the time the health care services are provided. A bill received for health care services when a participating physician is available, but the member has elected to obtain services from a non-participating physician, is not a Surprise Bill.
2. The services are performed by a Non-Participating Provider, where the services were referred by a participating physician to the Non-Participating Provider without the explicit written consent of the member acknowledging that the participating physician is referring the member to a Non-Participating provider and that the referral may result in costs not covered by the Health Plan. For purposes of a Surprise Bill, a referral to a Non-Participating Provider occurs when:

a. health care covered services are performed by a Non-Participating Provider in the participating physician's office or practice during the course of the same visit;

b. the participating physician sends a specimen taken from the member in the participating physician's office to a non-participating laboratory or pathologist; **OR**

c. for any other covered service performed when a Participating Provider refers the member to a Non-Participating Provider when a referral is required under the member's subscriber contract.

K. Urgent Care

Medical care for an illness, injury or condition serious enough that a reasonable person would seek care right away, but not so severe as to require Emergency Services. Urgent Care is typically available after normal business hours, including evenings and weekends. Urgent Care is covered within or outside our Service Area, when rendered by a participating or non-participating physician or free-standing Urgent Care facility, subject to the provisions of the subscriber member contract. Please refer to the Schedule of Benefits section of the member's contract for cost-sharing requirements, day or visit limits, and any preauthorization, referral, or notification requirements that apply to these benefits.

III. In-Network Benefits for Contracts Covering In-Network and Out-of-Network Services

A. Services are medically necessary for coverage at the In-network benefit level under ANY of the following circumstances:

1. The member receives an Out-of-Network Referral authorizing medically necessary Non-Participating Provider Services at the in-network benefit level (Refer to Policy Statement II.G. Out-of-Network Referral);

2. The member receives Emergency Services from a Non-Participating Provider to stabilize and treat an Emergency Condition. This does not include follow-up or routine care provided in a hospital emergency department;

3. The member's subscriber contract specifically includes language which covers specific care/treatment at the in-network benefit level for the services received from a Non-Participating Provider;

4. For members with a positive or negative diagnosis of malignancy, coverage may be provided for a second medical/surgical opinion received from a Non-Participating Provider, in the event of a positive or negative diagnosis of cancer or a recurrence of cancer or a recommendation of a course of treatment for cancer, upon referral of a Participating Provider. (Refer to Corporate Medical Policy #10.01.10 Second Medical and Surgical Opinions);

5. Coverage may be available for a Surprise Bill (as defined in Policy Statement II. J.), when all of the requirements for reimbursement are met (e.g., benefits are assigned to the Non-Participating Provider in writing).

IV. In-Network Benefits for Contracts Not Providing Out-of-Network Benefits:

A. In-network benefits may also be available for care or services received from a Non-Participating Provider under **ANY** of the following circumstances:

1. Coverage may be provided for compassionate reasons, for covered, medically necessary care or services, including office visits and associated treatment (e.g., chemotherapy), received outside the Health Plan's Service Area, for a member with life-threatening disease (e.g., malignancy, end-stage renal disease requiring hemodialysis) for up to four (4) weeks per contract year;
2. Coverage may be provided for monitoring and/or care, received while a member is outside the Health Plan's Service Area, who is required to assure the stability of a member with a high-risk condition and active treatment issues (e.g., severe heart failure, complicated hypertension) for up to four (4) weeks per contract year;
3. Coverage may be provided for Emergency Services or Urgent Care;
4. For members with a positive or negative diagnosis of malignancy, coverage may be provided for a second medical/surgical opinion received from a Non-Participating Provider, in the event of a positive or negative diagnosis of cancer or a recurrence of cancer or a recommendation of a course of treatment for cancer, upon referral of a Participating Provider (Refer to Corporate Medical Policy #10.01.10 Second Medical and Surgical Opinions);
5. The member has an Out-of-Network Referral authorizing medically necessary Non-Participating Provider Services at the in-network benefit level (Refer to II.G. Out of Network Referral);
6. Coverage may be available for a Surprise Bill (as defined in Policy Statement II. J.) when all of the requirements for reimbursement are met (e.g., benefits bare assigned to the Non-Participating Provider in writing);
7. Except under the above circumstances, the following services are generally not covered when rendered by a Non-Participating Provider: Routine care or services the need for which could reasonably be foreseen (e.g., physical examinations, screening tests, regularly scheduled laboratory tests such as routine monitoring of anticoagulation therapy); services provided to a member or dependent living away from home, such as a college student; and therapies/treatments or subsequent visits when a member began treatment with a Participating Provider (e.g., continuation of physical therapy).

V. Continuing Care

A. For a member in an ongoing, medically necessary course of treatment with a Participating Provider who leaves the network, coverage is available for continued, ongoing treatment from this now Non-Participating Provider for up to 90 days, or, if a member is pregnant, through postpartum care. If the provider was terminated by the Health Plan due to fraud, imminent harm to patients, or final disciplinary action by a state board or agency that

impairs the provider's ability to practice, continued treatment by this now Non-Participating Provider will not be covered.*

B. For members new to the Health Plan and engaged in an ongoing, medically necessary course of treatment with a Non-Participating Provider, coverage is available for services performed by the Non-Participating Provider for up to 60 days from the effective date of the member's subscriber contract. The ongoing course of treatment must be for a life-threatening disease or condition or a degenerative and disabling condition or disease. The ongoing course of treatment may also be pregnancy. For members in their second or third trimester of pregnancy, in-network benefits may be applied through delivery and postpartum care related to delivery. Members are responsible for any in-network cost sharing applicable to these services.*

*Please refer to the following website for Medicaid Managed Care Postpartum Care timeframes: [accessed 2025 Dec 15]. Available from: https://health.ny.gov/health_care/medicaid/program/update/2023/no06_2023-03.htm#postpartum

VI. Behavioral Health Episode of Continuing Care for Managed Medicaid, Health and Recovery Plan, and Dual-Special Needs Plan Members:

For a member in an ongoing, medically necessary course of ambulatory mental health treatment, other than ambulatory detoxification and withdrawal services, with a New York State Office of Mental Health (OMH) Licensed Provider who is a Non-Participating Provider or with a OMH Licensed Provider who leaves the network, coverage will be available for services performed by the Non-Participating Provider for 24 months after a member product change or 24 months after the change in the network status of the provider when **ALL** of the following criteria are met:

A. The services were provided in the same geographic area;

B. The services were provided at least twice during the six (6) months preceding January 1, 2023, by the same provider; and

C. The services are for the treatment of the same or related behavioral health condition.

Please refer to the following website for more information:

New York State Department of Health [Internet]. Medicaid Managed Care/Family Health Plus/HIV Special Needs Plan/Health and Recovery Plan Model Contract. March 1, 2019 [accessed 2025 Dec 15]. Available from: https://www.health.ny.gov/health_care/managed_care/docs/medicaid_managed_care_fhp_hiv-snp_model_contract.pdf

RELATED POLICIES

Not Applicable

POLICY GUIDELINE(S)

I. Preauthorization requirements do not apply to Emergency Services.

II. Coverage is not provided at the in-network benefit level for services rendered by Non-Participating Providers for variations of surgical methods, adjunct procedures or enhancements (e.g., computerized or robotic components), including less-invasive techniques, that are not utilized by Participating Providers qualified to treat a member's health condition, unless there is published scientific evidence that the variation or additional technology results in incrementally improved results over the surgical methods available in-network or as directed by an external appeal agent.

III. If there is a request for OON Referral and Health Plan can find a qualified and available par provider, Health Plan will deny the request for OON referral.

DESCRIPTION

In general, HMO and EPO products cover only services rendered by Participating Providers. POS and PPO contracts provide different levels of benefits, depending on whether the provider is a Participating Provider or Non-Participating Provider.

In-network benefits are provided for covered services that a member receives from a Non-Participating Provider when the member has an Out-of-Network Referral, or services were rendered under a Surprise Bill. In-network benefits may also be provided, under specific conditions, for covered services received from a Non-Participating Provider when a member is traveling or temporarily residing outside of our Service Area for work, recreation, or education (for example, college students). Coverage of services other than Emergency Services is subject to applicable preauthorization requirements.

Members covered under comprehensive products (i.e., products that provide major medical-type benefits, rather than limited benefits) may request review of the denial of a request for a referral to a Non-Participating Provider through the grievance review process by submitting specific information from a physician regarding the lack of training and experience of available Participating Providers. Medical Review staff will review the information submitted and identify Participating Providers, if any, with the appropriate training and experience to treat the member's condition. A Medical Director will make the determination to uphold or overturn a denial of a request for referral to a Non-Participating Provider.

For Emergency Services and Surprise Bills, members are only responsible for applicable in-network cost-sharing. Balance billing for Emergency Services and Surprise Bills is subject to review by an independent dispute resolution entity.

SUPPORTIVE LITERATURE

Not Applicable

PROFESSIONAL GUIDELINE(S)

Not Applicable

REGULATORY STATUS

Refer to Centers for Medicare and Medicaid Services (CMS) and Coverage for NYS Medicaid Managed Care/Harp Product Members Sections.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
	Not Applicable

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HCPCS Codes

Code	Description
	Not Applicable

ICD10 Codes

Code	Description
	Not Applicable

REFERENCES

Not Applicable

SEARCH TERMS

Out-of-Area Services, Out-of-Network Services

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Out-of-Network Services are not addressed in National or Regional Medicare coverage determinations or policies. However, the Medicare Benefit Policy Manual Chapter 16_General Exclusions from Coverage addresses Services Not Provided within the United States (Section 60) [accessed 2025 Dec 15].

COVERAGE FOR NYS MEDICAID MANAGED CARE/HARP PRODUCT MEMBERS

Coverage is not provided for services that are not urgent or emergent outside of New York State when services are available in New York State. The Plan contracts with a network of health care practitioners and providers to provide health care services for Medicaid Managed Care members. Care must be received by contracted network providers to be covered by the Plan. Exceptions to this requirement are based on medical necessity, outlined in the above policy, and must be approved by a Health Plan Medical Director.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 04/97

Revised: 04/98, 01/99, 01/00, 08/01, 07/02, 03/03, 12/03, 10/04, 06/05, 03/09, 11/09, 11/10, 09/12, 11/12, 11/13, 11/14, 03/15, 11/15, 11/17, 11/18, 7/26

Reviewed: 05/06, 04/07, 03/08, 11/1, 11/16, 11/19, 11/20, 11/21, 11/22, 11/23, 11/24, 11/25

Date	Summary of Changes
8/1/2026	• Transitioned Out-of-Network Care policy, 1370/20.000145 to Lifetime HealthCare Companies policy template.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: OVARIAN AND INTERNAL ILIAC VEIN EMBOLIZATION FOR PELVIC CONGESTION SYNDROME

POLICY EFFECTIVE DATE:	1/1/19
Policy Control #:	1370/20.000499
Next Annual Review:	January, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

DESCRIPTION

Pelvic Congestion Syndrome (PCS) is most commonly described as continuous or intermittent noncyclic pain, localized to the pelvic region, which lasts for six or more months in the absence of known pelvic pathology. Although this condition is primarily found in women it can also be found in men. The syndrome occurs during the reproductive years, is commonly associated with pain, including during or after menses or intercourse, and is often aggravated by prolonged standing. The underlying etiology is thought to be related to varices of the ovarian veins, leading to pelvic vascular congestion. Because there are many etiologies of chronic pelvic pain, PCS is often a diagnosis of exclusion, with the identification of varices using a variety of imaging methods, such as magnetic resonance imaging, computed tomography, or contrast venography.

There is no standard treatment approach for PCS, and the optimum treatment is unknown. Instead, therapy is individualized and based on symptoms. Medical therapy is generally the first line of treatment, as it is low risk and non-invasive. Other methods, such as embolization has been proposed as an alternative to surgical treatment for patients who fail medical therapy with analgesics. Embolization therapy involves the occlusion of blood flow through the ovarian and internal iliac veins with coils, glue, or chemical sclerosants.

PROCEDURE CODES

37241

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: OVARIAN AND INTERNAL ILIAC VEIN EMBOLIZATION FOR PELVIC CONGESTION SYNDROME

POSITION STATEMENT

CDPHP considers embolization of ovarian veins, with or without the internal iliac veins, medically necessary for the treatment of pelvic congestion syndrome when all of the following criteria is met:

- Pelvic region pain has persisted for six or more months.
- The enrollee has had a definitive diagnostic venography, CT, or MRI.
- The enrollee is refractory to medical management, including analgesics and hormonal therapy (unless contraindicated).

POLICY CONSIDERATIONS

The evaluation of women with chronic pelvic pain starts by taking a complete history that includes urinary, gastrointestinal, gynecologic, musculoskeletal, sexual, and psychosocial symptoms.

Diagnosis of PCS is based upon a combination of characteristic symptoms, tenderness on physical exam, and documentation of pelvic vein dilation or incompetence, after exclusion of other causes for these nonspecific findings.

The embolization procedure may be performed with the use of metallic coils or foam/gel sclerotherapy.

EXCLUSIONS

CDPHP considers ovarian and iliac embolization for PCS experimental and/or investigational when criteria stated above is not met.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. Centers for Medicare & Medicaid Services (CMS). National coverage determination (NCD) for therapeutic embolization (20.28). Accessed November 13, 2018, https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=52&ncdver=1&DocID=20.28&ncd_id=230.6&ncd_version=1&basket=nc

d%25253A230%25252E6%25253A1%25253AVabra+Aspiratorbra&bc=gAAAAAgAAAAAAA%3D%3D&

2. Hayes, Inc. Health Technology Brief (ARCHIVED). Percutaneous transcatheter coil embolization for pelvic congestion syndrome (PCS). http://www.hayesinc.com. Published March 2, 2017. Accessed October 24, 2018.
3. MCG Health. Ovarian and internal iliac vein embolization. 22nd edition. Accessed November 13, 2018. http://www.mcg.com
4. National Institute for Health Research (NHS) Health Technology Assessment: The relationship between pelvic vein incompetence and chronic pelvic pain in women; systematic reviews of diagnosis and treatment effectiveness, January, 2016, https://www.ncbi.nlm.nih.gov/pubmed/26789334
5. Gloviczki, P. et al, The care of patients with varicose veins and associated chronic venous diseases: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. Published May 2011. https://www.jvascsurg.org/article/S0741-5214(11)00327-2/pdf
6. UpToDate, Inc. Evaluation of chronic pelvic pain in women. http://www.uptodate.com. Updated January 2018. Accessed November 14, 2018.
7. UpToDate, Inc. Vulvovaginal varicosities and pelvic congestion syndrome. http://www.uptodate.com. Updated June 2018. Accessed November 12, 2018.
8. Lopez, A. Embolization for Pelvic Congestion Syndrome: The latest techniques in treating pelvic venous incompetence, Endovascular Today, Vol. 15, No. 4, April, 2016. https://evtoday.com/pdfs/et0416_F2_Lopez.pdf

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POLICY APPROVAL DATES

New: 01/19

Revised:

Reviewed: 01/20, 01/21, 01/22, 1/23, 1/24, 1/26

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MEDICAL POLICY

Medical Policy Title	**Ovarian and Internal Iliac Vein Endovascular Occlusion as a Treatment of Pelvic Congestion Syndrome**
Policy Number	**4.01.10**
Current Effective Date	**January 1, 2027**
Next Review Date	**September 2027**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Endovascular occlusion of the ovarian and/or internal veins has not been medically proven to be effective and, therefore, is considered **investigational** for the treatment of pelvic congestion syndrome.

RELATED POLICIES

Corporate Medical Policy

7.01.47 Varicose Vein Treatments

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

The American College of Obstetricians and Gynecologists (ACOG) defines chronic pelvic pain as "pain symptoms perceived to originate from pelvic organs/structures typically lasting more than six months. It is often associated with negative cognitive, behavioral, sexual and emotional consequences as well as with symptoms suggestive of lower urinary tract, sexual, bowel, pelvic floor, myofascial, or gynecological dysfunction." Therefore, diagnostic criteria may be difficult to discern, as well as multifactorial in nature.

Pelvic congestion syndrome (PCS) has also been known as pelvic venous disorder, pelvic venous insufficiency, pelvic venous incompetence, or pelvic venous reflux, with the nomenclature often being used interchangeably. PCS is proposed to be a cause of chronic pelvic pain, deriving from varicosities in the ovarian or internal iliac veins. It is described as a syndrome of variable pain location and intensity, associated with dyspareunia and postcoital pain, is aggravated by standing or exercise and typically occurs during the reproductive years. It is estimated that up to 47% of women have pelvic varicosities, and although common, not all women with pelvic varicosities experience chronic pelvic pain, and conversely, chronic pelvic pain is reported by women without evidence of pelvic congestion. The diagnosis of PCS is typically one of exclusion, utilizing different imaging methods such as

magnetic resonance imaging (MRI), computed tomography (CT), laparoscopy or contrast venography.

Conservative treatment options for PCS include psychotherapy, non-steroidal anti-inflammatories, and hormonal therapy. For patients who do not respond to these initial therapies, surgical ligation of the ovarian vein may be considered. Embolization and sclerotherapy are two treatments that have been proposed as less- invasive alternatives which consist of accessing the vasculature via catheter through the jugular or femoral arteries. Under imaging guidance, the catheter is directed through the femoral vein to the veins in question. Once in place, the vein will either be injected with medication (sclerotherapy), and/or coils, plugs, glue, liquid embolic agents, gelatin sponge or powder (Gelfoam) will be inserted to occlude the impacted veins (embolization). The procedure is typically performed on an outpatient basis.

Surgical procedures are not subject to regulation by the United States Food and Drug Administration (FDA); however, various products used in vein embolization (e.g., coils, vascular plugs, glue, liquid embolic agents, Gelfoam) and their delivery assist devices are subject to regulation. Several products have been cleared through the 510 (k) process for uterine fibroid embolization and/or embolization of hypervascular tumors and arteriovenous malformations (e.g., Embosphere Microspheres, Cook Incorporated Polyvinyl Alcohol Foam Embolization Particles, Contour Emboli PVA).

SUPPORTIVE LITERATURE

The literature regarding outcomes of individuals with PCS who receive pelvic vein embolization consists of randomized studies, comparative studies, case series, and systematic reviews. However, the literature has been described by the Journal of Vascular and Interventional Radiology (Black et al 2010) as, and still remains, "limited due to non-standardized reporting, incomplete follow-up, and the use of variable measures of outcome".

In a systematic review by Daniels et al (2016) with a search of databases dating from inception to November of 2013, authors aimed to critically review the effectiveness of embolization of incompetent pelvic veins. No language or study design restrictions were applied in the search criteria. Of the studies identified, 140 full texts were retrieved, and 22 articles were included in the final review. Of those included, 20 were case series, one study was unable to be reliably assessed after translation, and only one was a randomized trial, which was deemed poor quality by the authors (Chung and Huh, 2003), as it compared embolization to hysterectomy and was likely subject to several biases. Authors state that all estimates of effectiveness come from what they believe to be prospective case series of 1,308 women, with early relief of pain noted in approximately 75% of 162 women in six case series, which was sustained. One-third of the studies that were selected did not clearly describe intended outcome measures or the collection process, had no report of symptoms at two time points, and few stated the impacts on menstruation and fertility. Although the data supported the safety and efficacy of embolization, the quality of the evidence is poor.

In a retrospective study of 617 patients diagnosed with pelvic venous disorders, DeGregorio et al (2020) aimed to determine the efficacy and safety of pelvic vein embolization. A total of 520 women were included in the analysis. Inclusion criteria involved a diagnosis of varicose veins in the pelvis

with a diameter of 6 mm or more based on doppler ultrasound (US), and symptoms greater than six months. Patients underwent embolization of the four main pelvic veins when possible, and follow-up consisted of VAS survey and doppler US. Technical success was defined as embolization of the four main pelvic veins and occurred in 84.4% of patients. Of the total patients treated, 261 women underwent embolization using coils and 259 with Amplatzer vascular plugs (AVP). The average follow-up time frame was 58.7 months and a total of 484 patients (93.07%) completed five years of follow-up. VAS improved from 7.63 to 0.91 at the five-year mark. Results showed 26 patients (5%) experienced symptom recurrence. There were nine cases of coil migration (1.9 %). The authors state late migration of metallic devices to the lung can be seen in routine chest radiographs and could be an important concern. Discussion remains as to the homogeneity of endovascular therapeutic modalities, the selection of the embolic agents, and the number of veins needed to be treated.

A systematic review conducted by Hanna et al (2024) evaluated the efficacy of embolotherapy, primarily coil and plug embolization, for the treatment of PCS. A total of 25 studies were included with a combined total of 2038 patients. Across the included studies, technical success rates exceeded 95%, indicating that embolization procedures were reliably performed. Symptom improvement was reported in 70–90% of patients, with many experiencing significant reductions in chronic pelvic pain within three to six months post-procedure. The review also noted low complication rates, typically under 5%, with most adverse events being minor and self-limiting. Follow-up durations ranged from six months to two years, and long-term data suggested sustained symptom relief in the majority of treated patients. The authors emphasized the need for standardized outcome measures and larger randomized trials to strengthen the evidence base.

To date, no randomized controlled trials have been published comparing endovascular occlusion for PCS with a relevant comparator or sham/placebo treatment. Hindering the development of clinical trials with sound methodology are the varying definitions of pelvic pain, as well as the lack of specified explicit diagnostic criteria for PCS. Several consensus panels have been funded over time attempting to identify research priorities (Black et al, 2010; Champaneria et al, 2016; Khilnani et al, 2019) to address these limitations. International panels have met to create a discriminative classification instrument for PCS, but to date, the tools have not been validated or widely accepted.

There is insufficient evidence to conclude that there is a cause-effect relationship between venous congestion and chronic pelvic pain. Randomized controlled trials using well-defined eligibility criteria and relevant comparators or sham/placebo treatments are needed to determine the effects of the treatment on health outcomes.

PROFESSIONAL GUIDELINE(S)

In a 2020 practice bulletin on chronic pelvic pain, the American College of Obstetricians and Gynecologists (ACOG) does not address embolization for treating chronic pelvic pain. ACOG states that PCS is a proposed cause of chronic pelvic pain related to pelvic venous insufficiency, and although venous congestion appears to be associated with chronic pelvic pain, evidence is insufficient to conclude that there is a cause-and-effect relationship. Furthermore, there is no consensus on the

definition of this condition, and the diagnostic criteria are variable. Further research is needed to establish consistency in diagnosis and homogeneity of studies.

The Society for Vascular Surgery and American Venous Forum published a clinical practice guideline for the care of patients with varicose veins and related chronic venous disorders in 2011; reaffirmed in 2023. The guidelines include the recommendations related to treatment of pelvic congestion syndrome. Medical management is not included among recommendations; the guideline states that "Pharmacologic agents to suppress ovarian function, such as medroxyprogesterone or gonadotropin-releasing hormone, may offer short-term pain relief, but their long-term effectiveness has not been proven." Additionally, the guidelines recommend:

- Treatment of pelvic congestion syndrome and pelvic varices with coil embolization, plugs, or transcatheter sclerotherapy, used alone or together (grade 2B: weak recommendation, moderate quality of evidence).
- If less invasive treatment is not available or has failed, surgical ligation and excision of ovarian veins to treat reflux is recommended (grade 2B: weak recommendation, moderate quality of evidence).

REGULATORY STATUS

Various products (e.g., coils, vascular plugs, glue, liquid embolic agents, Gelfoam) and/or delivery-assist devices could be used to embolize the vein(s) and therefore could be subject to FDA regulation.

The United States Food and Drug Administration (FDA) regulates medical devices. All products and/or delivery-assist devices that could be used to embolize the vein(s), including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Aug 5]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 Aug 5]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
37241 (*E/I)	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the intervention; venous, other than hemorrhage (e.g., congenital or acquired venous malformations, venous and capillary hemangiomas, varices, varicoceles). *E/I for the ICD-10-CM diagnosis codes listed below.
75894 (*E/I)	Transcatheter therapy, embolization, any method, radiological supervision and interpretation. *E/I for the ICD-10-CM diagnosis codes listed below.

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
I86.2	Pelvic varices
N94.89	Other specified conditions associated with female genital organs and menstrual cycle
R10.2	Pelvic and perineal pain

REFERENCES

American College of Obstetricians and Gynecologists. ACOG Practice Bulletin No. 218: Chronic Pelvic Pain. Obstet Gynecol. 2020 Mar;135(3):e98–e109.

Amin TM, et al. The effect of pelvic pathology on uterine vein diameters. Ultrasound J. 2021; 13(7):1-12.

Black CM, et al. Research reporting standards for endovascular treatment of pelvic venous insufficiency. Journal of Vascular and interventional Radiology. 2010 Jun; 21(6):796-803.

Champaneria R, et al. The relationship between pelvic vein incompetence and chronic pelvic pain in women: systematic reviews of diagnosis and treatment effectiveness. Health Technol Assess. 2016 Jan;20(5).

Chung M and Huh C. Comparison of treatments for pelvic congestion syndrome. Tohoku Journal of Experimental Medicine. 2003; 201(3):131-138.

Daniels JP, et al. Effectiveness of embolization or sclerotherapy of pelvic veins for reducing chronic pelvic pain: A systematic review. J Vasc Interv Radiol. 2016 Oct; 27(10):1478-1486.

De Gregorio M, et al. Pelvic venous disorders in women due to pelvic varices: Treatment by embolization: Experience in 520 patients. J Vasc Interv Radiol. 2020 Jun; 31:1580-1589.

Emad M, et al. Ovarian vein surgical ablation versus endovascular technique for treatment of pelvic vein incompetence. J Vasc Surg Venous Lymphat Disord. 2023 Jul; 11(4):801-808.

Gloviczki P, et al. The care of patients with varicose veins and associated chronic venous diseases: clinical practice guidelines of the society for vascular surgery and the American venous forum. J Vasc Surg. May 2011; 53(5 Suppl): 2S-48S.

Gloviczki P, et al. The 2023 society for vascular surgery, American venous forum, and American vein and lymphatic society clinical practice guidelines for the management of varicose veins of the lower extremities. Part II: Endorsed by the Society of Interventional Radiology and the Society for Vascular Medicine. J Vasc Surg Venous Lymphat Disord. Jan 2024; 12(1): 101670.

Hanna J, et al. Efficacy of embolotherapy for the treatment of pelvic congestion syndrome: a systematic review. Ir J Med Sci. 2024 Jun;193(3):1441-1451.

Johnson NR, et al. [Internet]. Vulvovaginal varicosities and pelvic congestion syndrome. UpToDate. 2023 Aug [accessed 2025 Aug 9] Available from: Vulvovaginal varicosities and pelvic congestion syndrome - UpToDate

Khilnani NM, et al. Research priorities in pelvic venous disorders in women: Recommendations from a multidisciplinary research consensus panel. J Vasc Interv Radiol. 2019; 30:781-789.

Meissner MH, et al. The symptoms-varices-pathophysiology classification of pelvic venous disorders: a report of the American Vein and Lymphatic Society International Working Group on Pelvic Venous Disorders. Phlebology. 2021; 36(5)342-360.

Strong SM, et al. A retrospective cohort study of patient risk factors and pelvic venous reflux patterns on treatment outcomes with pelvic vein embolisation. Vasc Endovascular Surg. 2024 Oct;58(7):733-174.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based upon review, ovarian and internal iliac vein endovascular occlusion as a treatment of pelvic congestion syndrome is not specifically addressed in a National or Local Medicare coverage determination or policy. However, there is currently a National Coverage Determination (NCD) for Therapeutic Embolization (20.28).

NCD - Therapeutic Embolization (20.28) [accessed 2025 Jul 18]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Primary hyperoxaluria type 1 (PH1) is a rare, inherited disorder of the liver characterized by the overproduction of oxalate. PH1 occurs via an autosomal recessive mutation in the gene AGXT that codes for the liver enzyme alanine: glyoxylate aminotransferase (AGT) which is responsible for glyoxylate metabolism. In people with PH1, excess oxalate accumulates in the kidneys and urinary tract. Oxalate deposits then combine with calcium, to form calcium oxalate, the main component of kidney and bladder stones. Signs and symptoms of PH1 vary in severity and may begin any time from infancy to early adulthood. Symptoms usually include recurrent kidney stones, blood in the urine, and urinary tract infections. Left untreated, PH1 can result in end-stage renal disease (ESRD).

PH1 affects approximately four individuals per million in the United States and Europe, with an estimated 1,300 to 2,100 diagnosed cases. 24-hour urine collection can be used to demonstrate markedly increased urinary excretion of oxalate (i.e., greater than 1 mmol/1.73 m^2 per day [90 mg/1.73 m^2 per day]). A urinary oxalate to creatinine ratio from a spot urine sample may also be used to determine increased oxalate excretion in patients where 24-hour urine collection is difficult, such as infants and small children. Genetic testing is used to confirm the presence of the AGXT mutation and differentiate PH1 from other types of primary hyperoxaluria. A liver biopsy may also be used to demonstrate AGT enzyme deficiency. The only curative treatment for PH1 is liver transplantation. Because many patients with PH1 will progress to ESRD by adolescence or early adulthood if untreated or disease is undetected, the best outcomes to date for PH1 have included combined liver and kidney transplantation.

Oxlumo (lumasiran) is the first FDA-approved treatment specifically for PH1 and is indicated to lower urinary and plasma oxalate levels in pediatric and adult patients with PH1. Oxlumo reduces the amount of available glyoxylate, a substrate for oxalate production, by targeting hydroxyacid oxidase 1 (HAO1) messenger RNA in hepatocytes through RNA interference, subsequently decreasing glycolate oxidase enzyme levels. Oxlumo is available in a single-dose vial and is intended to be administered as a subcutaneous injection by a healthcare professional. Adverse events in clinical trials included injection site reactions (> 20%), abdominal pain, and the formation of anti-lumasiran antibodies – although these antibodies are not currently thought to be clinically significant.

Rivfloza (nedosiran) is the second FDA-approved treatment for PH1 and is indicated for the lowering of urinary oxalate levels in children nine years of age and older and adults with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function. Rivfloza, like Oxlumo, works via RNA interference, but with a different target: hepatic lactate dehydrogenase (LDH) which is thought to be responsible for the final step in oxalate synthesis. Rivfloza can be self-administered or administered by caregivers. The most significant adverse event seen in clinical trials was injection site reactions.

While both Oxlumo and Rivfloza have proven efficacious in reducing urinary oxalate levels, the long-term impact on renal function is not well defined. Secondary and exploratory analyses of the ILLUMINATE trials for Oxlumo have shown stabilization or improvement in kidney stone event rates and eGFR, however analysis following the full 54 weeks of treatment are needed to confirm the results. For Rivfloza, no significant differences were detected between groups in the rate of change for eGFR. Further data are needed to evaluate the impact of treatment on renal function and transplantation outcomes.

Summary

Effective Date of Policy:	7/13/2026
Indications	Primary Hyperoxaluria Type 1 (PH1)
ICD10 Diagnosis Codes	E72.53
Availability	Oxlumo: 94.5 mg/0.5 mL solution for subcutaneous injection, single-dose vial Rivlfoza: 80 mg/0.5 mL single-dose vial; 128 mg/0.6 mL and 160 mg/1 mL single-dose pre-filled syringe
HCPCS Code	Oxlumo: J0224 Rivfloza: no specific code as can also be self-administered
Duration	Initial: 6 months Continuation: 12 months

Required Criteria for Initial Approval		
All of the following conditions for the requested indication must be met in order to approve therapy.		
Indication	**Inclusion**	**Recommended Dosing**

Oxlumo (lumasiran)
 	
Primary Hyperoxaluria Type 1 (PH1)
(FDA approval)
ICD10: E72.53
 	
Medical benefit
	• Medication is prescribed by or in consultation with a specialist knowledgeable in the management of primary hyperoxaluria type 1 (e.g., nephrologist, urologist)
	• Enrollee has a diagnosis of PH1 confirmed by genetic testing that detects mutations of the alanine: glyoxylate aminotransferase (AGT) gene **OR** Liver biopsy confirming deficiency in AGT
	• Enrollee has had metabolic screening that demonstrates with increased urinary oxalate levels through one of the following:
	  ○ 24-hour urinary excretion of oxalate > 1 mmol/1.73 m^2 (> 90 mg/1.73 m^2) **OR**
	  ○ Elevated oxalate: creatinine ratio in spot urine samples greater than normative value for age (see Table A below) **OR**
	  ○ Plasma oxalate levels greater than or equal to 20 umol/L
	  ▪ For individuals on hemodialysis, this improvement must reflect a pre-dialysis level
	• Documentation that the patient has made efforts to increase fluid intake to at least 3 L/m^2 BSA per day
	• Concurrent use of pyridoxine (vitamin B6) OR previous trial of at least 3 months of pyridoxine with no significant improvement observed (e.g., < 30% reduction in urine oxalate concentration after at least 3 months of therapy)
	• Enrollee has not previously received a kidney or liver transplant (curative treatment of PH1)
	• Must not be receiving peritoneal dialysis or combined peritoneal/hemodialysis
	• Current body weight and requested dose regimen must be submitted for initial review and each recertification request
		Dosing is body weight based:
		• Less than 10 kg
		  ○ Loading Dose: 6 mg/kg once monthly for 3 doses
		  ○ Maintenance Dose: 3 mg/kg once monthly, beginning 1 month after the last loading dose
		• 10 kg to less than 20 kg
		  ○ Loading Dose: 6 mg/kg once monthly for 3 doses
		  ○ Maintenance Dose: 6 mg/kg once every 3 months (quarterly), beginning 1 month after the last loading dose
		• 20 kg and above
		  ○ Loading Dose: 3 mg/kg once monthly for 3 doses
		  ○ Maintenance Dose: 3 mg/kg once every 3 months (quarterly), beginning 1 month after the last loading dose
		• For patients on hemodialysis: Administer Oxlumo after hemodialysis if administered on dialysis days

Rivfloza (nedosiran)
 	
Primary Hyperoxaluria Type 1 (PH1)
(FDA approval)
ICD10: E72.53
 	
Medical or Rx benefit
	• Medication is prescribed by or in consultation with a specialist (e.g., nephrologist, urologist) knowledgeable in the management of primary hyperoxaluria type 1
	• Must be ≥ 2 years of age
	• Enrollee has a diagnosis of PH1 confirmed by genetic testing that detects mutations of the alanine: glyoxylate aminotransferase (AGT) gene **OR** Liver biopsy confirming absent or significantly reduced AGT activity
	• Enrollee has had metabolic screening that demonstrates with increased urinary oxalate levels through one of the following:
	  ○ 24-hour urinary excretion of oxalate > 1 mmol/1.73 m^2 (> 90 mg/1.73 m^2) **OR** elevated oxalate: creatinine ratio in spot urine samples greater than normative value for age (see Table A below) **AND**
	  ○ Urinary excretion of glycolate
	• Documentation that the patient has made efforts to increase fluid intake to at least 3 L/m^2 BSA per day
	• Concurrent use of pyridoxine (vitamin B6) **OR** previous trial of at least 3 months of pyridoxine with no significant improvement observed
	• Must have an eGFR ≥ 30 mL/min/1.73 m^2
	• Enrollee has not previously received a kidney or liver transplant (curative treatment of PH1)
	• Must not have clinical evidence of systemic oxalosis
		Dosing is age and body weight based:
		• Adults and adolescents 12 years and older
		  ○ Greater than or equal to 50 kg: 160 mg once monthly (Pre-filled syringe, 1 mL)
		  ○ Less than 50 kg: 128 mg once monthly (Pre-filled syringe, 0.8 mL)
		• Children 9 to 11 years
		  ○ Greater than or equal to 50 kg: 160 mg once monthly (Pre-filled syringe, 1 mL)
		  ○ Less than 50 kg: 3.3 mg/kg once monthly, not to exceed 128 mg (Vial, dose volume rounded to nearest 0.1 mL)

	• **For new starts and recertification requests for all lines of business except Medicare; Does NOT apply to Medicare B (Medicare Advantage):** Requests for Rivfloza (medical benefit only) will require documentation of an inability to self-inject. Does NOT apply to Medicare B (Medicare Advantage) ○ For pediatric patients < 18 years of age, documentation must also include the inability of a caregiver to administer the medication • Current body weight and requested dose regimen must be submitted for initial review and each recertification request	

Exclusion Criteria

Therapy will not be covered if any of the following exist:

- Oxlumo or Rivfloza will not be approved for the treatment of other primary hyperoxalurias (i.e., Type 2, Type 3) or hyperoxaluria caused by increased dietary consumption of oxalate, bowel resection, or fat malabsorption due to small bowel disease or cystic fibrosis
- Oxlumo or Rivfloza will not be considered for coverage after kidney or liver transplantation
- Rivfloza will not be approved in combination with Oxlumo

Continuation Criteria

- Recertification will be every 12 months and require documentation that the patient is tolerating therapy AND
  - There was a reduction in urinary excretion of oxalate from baseline (improvement is reaching near normal (< 1 mmol/1.73 m^2 per day) urinary oxalate excretion) OR
  - There was a reduction in plasma oxalate from baseline
    - For individuals on hemodialysis, this improvement must reflect a pre-dialysis level.
- Current body weight and requested dose regimen must be submitted for each recertification request
- For new starts and recertification requests for all lines of business except Medicare: Requests for Rivfloza (medical benefit only) will require documentation of an inability to self-inject. Does NOT apply to Medicare B (Medicare Advantage)

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department
- Rivfloza: Quantity limit: 2 vials per 30 days / 1 prefilled syringe per 30 days

Table A.

Normative values for molar oxalate to creatinine ratio (mmol/mmol) from spot urine sample	
Infants ≤ 6 months	< 0.32 to 0.36
Children between 7 months and 24 months	< 0.13 to 0.17
Children between 2 and 5 years	< 0.098 to 0.1
Children between 6 and 14 years	< 0.07 to 0.08
Patients > 16 years	< 0.04

References

		Accessed
1	OXLUMO (prescribing information). Cambridge, MA: Alnylam Pharmaceuticals, Inc.; 2023.	10/2024
2	Niaudet P. Primary hyperoxaluria. In: Post T, ed. UpToDate. UpToDate; 2023. Accessed November 27, 2023. www.uptodate.com	11/2023
3	Monico CG, Rossetti S, Schwanz HA, et al. Comprehensive mutation screening in 55 probands with type 1 primary hyperoxaluria shows feasibility of a gene-based diagnosis. J Am Soc Nephrol. 2007;18(6):1905.	10/2023
4	Sas DJ, Enders FT, Mehta RA, et al. Clinical features of genetically confirmed patients with primary hyperoxaluria identified by clinical indication versus familial screening. Kidney Int. 2020;97(4):786. Epub 2019 Dec 13.	10/2023

5	National Organization for Rare Disorders. Primary Hyperoxaluria. Available at: https://rarediseases.org/rare-diseases/primary-hyperoxaluria/	10/2023
6	Demoulin N, Aydin S, Gillion V, Morelle J, Jadoul M. Pathophysiology and Management of Hyperoxaluria and Oxalate Nephropathy: A Review. *American Journal of Kidney Diseases*. 0272-6836. doi: https://doi.org/10.1053/j.ajkd.2021.07.018	10/2023
7.	RIVFLOZA (prescribing information). Plainsboro, NY; Novo Nordisk Inc.; 2023	10/2024
8.	Kang C. Lumasiran: A Review in Primary Hyperoxaluria Type 1. Drugs. 2024 Jan 22. doi: 10.1007/s40265-023-01987-1. Epub ahead of print. Erratum in: Drugs. 2024 Mar 15;: PMID: 38252335.	3/2024
9.	Martin-Higueras C, Borghese L, Torres A, et al. Multicenter Long-Term Real World Data on Treatment With Lumasiran in Patients With Primary Hyperoxaluria Type 1. Kidney Int Rep. 2023 Oct 6;9(1):114-133. doi: 10.1016/j.ekir.2023.10.004. PMID: 38312792; PMCID: PMC10831356.	3/2024
10.	Bacchetta J, Lieske JC. Primary hyperoxaluria type 1: novel therapies at a glance. Clin Kidney J. 2022 May 17;15(Suppl 1):i17-i22. doi: 10.1093/ckj/sfab245. PMID: 35592618; PMCID: PMC9113449.	3/2024
11.	Gupta A, Somers MJG, Baum MA. Clin Kidney J. 2022 May 17; 15(Suppl 1):i9-813.doi: 10.1092/ckj/sfab232. PMID: 35592620; PMCID: PMC9113429.	10/2024
12.	Groothoff, J.W., Metry, E., Deesker, L. *et al.* Clinical practice recommendations for primary hyperoxaluria: an expert consensus statement from ERKNet and OxalEurope. *Nat Rev Nephrol* **19**, 194–211 (2023). https://doi.org/10.1038/s41581-022-00661-1	10/2024

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE CHOICES: Oxlumo and Rivlfoza: Subject to all terms and conditions noted in above application.
Rivfloza: Not applicable if requested under Part D.

SELECT/HARP PLAN: For requests under medical benefit: Subject to all terms and conditions noted in above application.

Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program.

CDPHP Pharmacy Services 7/13/2026

New: 2/2021

Date	Notes
02/2022, 02/2023, 2/2024	Reviewed with no changes
4/2024	Addition of Rivfloza to policy with specific criteria for coverage
2/2025	Revised Oxlumo. Included full dosing recommendations. Added trial of concurrent use of pyridoxine (vitamin B6). Removed trial of Oxlumo from Rivloza criteria.

2/2026	• Revised Rivfloza
	  ○ Added age requirement and eGFR requirement
	  ○ Added documentation of an inability to self-inject for all lines of business except Medicare
	• Added Current body weight and requested dose regimen must be submitted for initial review and each recertification request for both agents
	• Clarified specialist must be knowledgeable in the management of primary hyperoxaluria type 1 for both agents
	• Added documentation that the patient has made efforts to increase fluid intake to at least 3 L/m^2 BSA per day for both agents
	• Updated transplant to kidney and liver transplant for both agents

7/2026	• Added not receiving peritoneal dialysis for Oxlumo • Clarified current body weight should be submitted for initial Rivfloza requests

This Pharmacy Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI), and Capital District Physicians' Health Care Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: PAIN MANAGEMENT SERVICES

POLICY EFFECTIVE DATE:	8/1/2026
Policy Control #:	1370/20.000105
Next Annual Review:	September, 2027

DISCLAIMER

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DESCRIPTION

Pain management services include procedures and/or modalities utilized to enhance the functional abilities and physical and psychological well-being of a patient with chronic pain.

According to the Practice Guidelines for Chronic Pain Management: A Report by the American Society of Anesthesiologists Task Force on Chronic Pain Management, chronic pain is defined as *pain of any etiology not directly related to neoplastic involvement, associated with a chronic medical condition, or extending in duration beyond the expected temporal boundary of tissue injury and normal healing, and adversely affecting the function or well-being of the individual.* In addition, the pain has been refractory to repeated attempts at medical management and usually has been present for at least three to six months.

Conditions that cause chronic pain include: cancer and various degenerative disorders of the spine, such as spinal stenosis, spondylolysis, spondylolisthesis, degenerative scoliosis, idiopathic vertebrogenic sclerosis, diffuse idiopathic spinal hyperostosis, and segmental instability.

The goal of chronic pain management is to achieve optimal pain control, recognizing that a pain-free state may not be achievable; minimize adverse outcomes; enhance functional abilities and

physical and psychological well-being; and enhance the quality of life for patients with chronic pain.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

- Biofeedback, 1370/20.000067
- Coverage with Evidence Development for Medicare Advantage, 1370/20.000517
- Non-Covered Technologies, 1370/20.000444
- Technology Assessment and Policy Development, 1370/20.000153

Payment Policies:

- Adjunct and Non-Standard Technology, 1550/20.000187
- Mandated Benefits for State Funded Programs, 1550/20.000188

POSITION STATEMENT

Outpatient Pain Management Services for Chronic Pain
CDPHP administers benefits for outpatient pain management meeting the criteria outlined below.

General Requirements

- Services are recommended by a primary care or attending physician.
- Patient has experienced chronic pain for three months or more.
- Patient has failed to respond to more conservative methods of treatment including physical therapy modalities, chiropractic treatments, cognitive-behavioral techniques, administration of pharmacological agents (e.g., non-steroidal anti-inflammatory agents, narcotic agents) unless such methods are contraindicated.
- Upon request, member has undergone a mental health evaluation by a mental health provider, and any primary psychiatric conditions have been treated, where indicated.
- A pain relief and rehabilitation treatment plan must be established. Pain management services should be tailored to the needs of the individual patient with differentiated treatment for acute and chronic pain.

General Documentation Requirements

The medical record* must contain documentation that fully supports the medical necessity for services outlined within this policy. Such documentation includes, but is not limited to, the following:

- Relevant medical history
- Physical examination
- Results of pertinent diagnostic tests or procedures
- Procedure notes must be legible and include sufficient detail to allow reconstruction of the procedure.

Required elements of the note include:

- Description of the techniques employed
- Site(s) of injections
- Drugs and doses with volumes and concentrations as well as pre- and post-procedural pain assessments

*Refer to the individual sections of injection therapies in the policy for specific documentation requirements.

The following services are covered when performed in accordance with criteria outlined below. Only one invasive modality or procedure will be considered medically necessary at a time.

Injection Therapies

Injections for the treatment of acute, subacute, and chronic back pain may be given for either diagnostic purposes or therapeutically (to treat the pain), and may include trigger point injections, epidural steroid injections, facet joint injections, sacroiliac joint injections, and/or peripheral nerve blocks. Although the evidence for the efficacy of these diagnostic and therapeutic injections discussed below is not strong, several have gained widespread use as alternatives to more invasive interventions and are often included as part of a comprehensive pain management program.

CDPHP administers benefits for injection therapies for managing chronic pain in accordance with Medicare national coverage determinations and the American Society for International Pain Physicians (ASIPP) Guidelines for Interventional Techniques in Chronic Spinal Pain (2013).

Trigger Point Injections (20552, 20553)

Trigger point injection is one of the many modalities utilized in the management of chronic pain. Trigger point injections are injections of a local anesthetic, with or without a steroid medication, into a painful area of a muscle that contains the trigger point. The purpose of a trigger point injection is to relax the area of intense muscle spasm, effectively inactivate the trigger point, and provide prompt symptomatic relief.

Initial Trigger Point Injection

POLICY NAME: PAIN MANAGEMENT SERVICES

Trigger point injections (TPI) will be considered medically reasonable and necessary to treat myofascial pain caused by trigger points when all the following requirements are met:

1. There is a focal area of pain in the skeletal muscle.
2. There is clinical evidence of a trigger point defined as pain in a skeletal muscle that is associated with at least two of the following findings: the presence of a hyperirritable spot and/or taut band identified by palpation and possible referred pain AND
3. The physical examination identifies a focal hypersensitive bundle or nodule of muscle fiber harder than normal consistency with or without a local twitch response and referred pain AND
4. Non-invasive conservative therapy is not successful as first line treatment OR movement of a joint or limb is limited or blocked OR the TPI is necessary for diagnostic confirmation

Subsequent TPI
Repeat trigger point injections in previously injected trigger points will be considered medically reasonable and necessary to treat myofascial pain syndrome when all the following requirements are met:

1. There is a positive pain response from the most recent TPI defined as providing consistent minimum of 50% relief of primary (index) pain after the TPI measured by the SAME pain scale* at baseline and post-injection **AND**
2. Consistent pain relief from the most recent previous TPI lasting at least six weeks **AND**
3. The myofascial pain has reoccurred and is causing objective functional limitations measured by a functional scale obtained at baseline and after TPI which demonstrated at least 50% improvement from the previous TPI.

*Note: The scales used to measure pain and/or disability must be documented in the medical record. Acceptable scales include but are not limited to verbal rating scales, Numerical Rating Scale (NRS) and Visual Analog Scale (VAS) for pain assessment, and Pain Disability Assessment Scale (PDAS), Oswestry Disability Index (ODI), Oswestry Low Back Pain Disability Questionnaire (OSW), Quebec Back Pain Disability Scale (QUE), Roland Morris Pain Scale, Back Pain Functional Scale (BPFS), and the PROMIS profile domains to assess function.

Limitations: No more than three (3) TPI sessions will be reimbursed per rolling 12 months.

Requirements:

1. Patients should be part of an ongoing conservative treatment program and documentation to support the patient is actively participating in a rehabilitation program, home exercise program, or functional restoration program is in the medical record.
2. Trigger point primary index pain must be measured prior to the injection at the beginning of the session.
3. The post procedure pain level must be measured after the TPI at the conclusion of the

session using the same scale* utilized at baseline.

4. When documenting the percentage of pain relief from the primary (index) pain compared to the post-injection pain levels, it is insufficient to report only a percentage of pain relief and/or a nonspecific statement of the duration of pain relief. The documentation should include a specific assessment of the duration of relief being consistent or inconsistent with the agent used for the injection and the specific dates the measurements were obtained using the SAME pain scale* used at baseline.
5. When documenting the ability to perform previously painful movements and activities of daily living (ADLs) it is insufficient to provide a vague or nonspecific statement regarding the improvement of previously painful movements and activities of daily living (ADLs). The documentation should include a functional assessment to show clinically meaningful improvement with painful movements and ADLs, if this metric is used to justify the efficacy of the TPI Providers should use established and measurable goals and objective scales to assess functionality and ADLs measures.

Limitations:

1. A TPI involves the use of a local anesthetic and does not include injections of biologics (e.g., platelet rich plasma, stem cells, amniotic fluid, etc.) and/or any other injectates.
2. It is not considered medically reasonable and necessary to perform TPI into multiple muscle groups in different anatomical regions during the same session.
3. It is not considered medically reasonable and necessary to perform multiple blocks (ESI, sympathetic blocks, facet blocks etc.) during the same session as TPI.
4. Trigger points injections for treatment of headache, neck pain, or low back pain in absence of actual trigger points, diffuse muscle pain, a chronic pain syndrome, lumbosacral canal stenosis, fibromyalgia, non-malignant multifocal musculoskeletal pain, complex regional pain syndrome, sexual dysfunction/pelvic pain, whiplash, neuropathic pain, and hemiplegic shoulder pain are considered investigational and therefore are not considered medically reasonable and necessary.
5. Use of fluoroscopy or MRI guidance for performance of TPI is not considered reasonable and necessary.
6. The use of ultrasound guidance for the performance of TPI is considered investigational.
7. Trigger point injections used on a routine basis, e.g., on a regular periodic and continuous basis, for patients with chronic non-malignant pain syndromes are not considered medically necessary.

Other Considerations:

Medical record must clearly document the evaluation leading to the diagnosis of the trigger point in an individual muscle, identification of the affected muscle(s), reason for selecting the trigger point injection as a therapeutic option, and whether it is being used as an initial or subsequent treatment.

Only one trigger point injection procedure (20552 or 20553) can be reported per date of service, no matter how many sites or regions are injected.

"Dry needling" (20560, 20561) of trigger points is considered experimental, investigational, or unproven due to insufficient scientific evidence to support clinical efficacy and/or effects on health outcomes.

Trigger point injection using botulinum toxin (Botox) is considered experimental/investigational/unproven due to insufficient scientific evidence to support clinical efficacy and/or effects on health outcomes.

Tendon Sheath, Ligament, Ganglion Cysts, Carpal and Tarsal Tunnel Injections (20526, 20550, 20551, 20612, 28899)

Injection into tendon sheaths, their origins or insertions, ligaments, or ganglion cysts is indicated to relieve substantial pain and/or significant functional disability that results from inflammation or other pathological changes in those structures.

CDPHP considers tendon sheath, ligament, ganglion cysts, and carpal and tarsal tunnel injections medically necessary when:

- Other conservative therapy has not provided acceptable relief; is contraindicated, or not appropriate; and
- There is a reasonable likelihood that injection will significantly improve the patient's pain and/or functional disability.
- Proper use of this modality should be part of an overall management plan including diagnostic evaluation in order to clearly identify and properly treat the primary cause.

Diagnostic Phase

A maximum of two injections will be covered at minimum intervals of one week, preferably two, to diagnose the origin of pain and achieve a therapeutic effect. Additional injections are not considered medically necessary if no clinical response is achieved.

Therapeutic Phase

In the treatment or therapeutic phase, injections should be repeated only as medically necessary. No more than four injections are considered medically necessary in a consecutive 12-month period.

- Frequency should be two months or longer between each injection provided that there is initial pain relief with diagnostic injections of greater than or equal to 75-100 percent with

the ability to perform previously painful maneuvers, and a persistent pain relief of greater than or equal to 50 percent is maintained for at least six weeks with the continued ability to perform previously painful maneuvers.

Other Considerations:

Medical record must include a procedural note documenting reason for the injection at any particular site. If multiple sites are injected, documentation to substantiate that all the injections are reasonable and necessary must be present.

In general, most conditions that require injections into the tendon sheaths, ligaments, or ganglion cysts should be resolved with one to three injections.

When a given specific tendon, ligament, tunnel, or cyst is injected, it will be considered one injection service regardless of the number of injections administered at that specific anatomical location on a single date of service.

Modifier 50 should not be reported with CPT codes 20551, 20552, 20553, or 20612, but may be reported, when appropriate, with CPT codes 20550 and 20526.

Epidural Steroid Injections (ESI): 64480, 64484

Epidural steroid injections (ESIs) have been used as a non-surgical modality to treat low back and neck pain. These procedures typically involve the injection of a solution containing corticosteroids and/or anesthetic into the epidural space, although saline may be included at times.

The ESI can be performed in three ways. Interlaminar (IESI) approaches the epidural space from the posterior spine between the two vertebral laminae near the midline. In the transforaminal approach (TFESI), the injectant is delivered through the neuroforamen dorsal to the nerve root within the intervertebral foramen. The caudal approach (CESI) enters through the sacral hiatus at the sacral canal to access the epidural space.

The treatment of individuals with spinal disorders, including pain, can be complex, and it is recommended that all individuals being considered for interventional spinal procedures undergo a thorough evaluation and be treated following development of a comprehensive care plan.

A "session" is defined as all epidural or spinal procedures performed on a single day.

CDPHP considers epidural steroid injections (ESIs) medically necessary when the following three criteria are met:

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1. History, physical examination, and concordant radiological image-based diagnostic testing supporting one of the following:

- Lumbar, cervical, or thoracic radiculopathy, radicular pain and/or neurogenic claudication due to disc herniation, osteophyte or osteophyte complexes, severe degenerative disc disease, producing foraminal or central spinal stenosis **OR**
- Post-laminectomy syndrome; **OR**
- Acute herpes zoster associated pain

AND

2. Radiculopathy, radicular pain and/or neurogenic claudication is severe enough to greatly impact quality of life or function. An objective pain scale or functional assessment must be performed at baseline (prior to interventions). The same scale* must be repeated at each follow-up for assessment of response.

AND

3. Pain duration of at least four (4) weeks, and the inability to tolerate noninvasive conservative care or medical documentation of failure to respond to four (4) weeks of noninvasive conservative care **or** acute herpes zoster refractory to conservative management where a four (4) week wait is not required.

*Note: The scales used to measure pain and/or disability must be documented in the medical record. Acceptable scales include but are not limited to verbal rating scales, Numerical Rating Scale (NRS) and Visual Analog Scale (VAS) for pain assessment, and Pain Disability Assessment Scale (PDAS), Oswestry Disability Index (ODI), Oswestry Low Back Pain Disability Questionnaire (OSW), Quebec Back Pain Disability Scale (QUE), Roland Morris Pain Scale, Back Pain Functional Scale (BPFS), and the PROMIS profile domains to assess function.

Diagnostic/Therapeutic Injections

No more than four (4) epidural injection sessions (CPT codes 64480 or 64484) may be reported per spinal region in a rolling 12-month period regardless of the number of levels involved.

Transforaminal epidural steroid injections (TFESIs) involving a maximum of two (2) levels in one spinal region are considered medically reasonable and necessary. It is important to recognize that most conditions would not ordinarily require ESI at two (2) levels in one spinal region.

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Caudal epidural steroid injections (CESIs) and interlaminar epidural steroid injections (ILESIs) involving a maximum of one level are considered medically reasonable and necessary.

Repeat ESI when the first injection directly and significantly provided improvement of the condition being treated may be considered medically reasonable and necessary when the medical record documents at least 50% of sustained improvement in pain relief and/or improvement in function measured from baseline using the same scale* for at least three months. If a patient fails to respond well to the initial ESI, a repeat ESI after 14 days can be performed, using a different approach, level and/or medication if appropriate, with the rationale and medical necessity for the second ESI documented in the medical record.

Limitations of Coverage:

It is not considered medically reasonable and necessary to perform multiple blocks (ESI, sympathetic blocks, facet blocks, trigger point injections, etc.) during the same session as ESIs, with the exception of a facet synovial cyst and ESI performed in the same session.

Use of Moderate or Deep Sedation, General Anesthesia, and Monitored Anesthesia Care (MAC) is usually unnecessary or rarely indicated for these procedures and therefore not considered medically reasonable and necessary. Even in patients with a needle phobia and anxiety, typically oral anxiolytics suffice. In exceptional and unique cases, documentation must clearly establish the need for such sedation in the specific patient.

ESIs to treat non-specific low back pain (LBP), axial spine pain, complex regional pain syndrome, widespread diffuse pain, pain from neuropathy from other causes, cervicogenic headaches are considered investigational and therefore are not considered medically reasonable and necessary.

It is not considered medically reasonable and necessary for more than one spinal region to be injected in the same session.

It is not medically reasonable and necessary to perform CESIs or ILESIs bilaterally.

It is not medically reasonable and necessary to prescribe a predetermined series of ESIs.

Steroid dosing should be the lowest effective amount.

It generally would not be considered medically reasonable and necessary for treatment with ESI to extend beyond 12 months. Frequent continuation of epidural steroid injections over 12 months may trigger a focused medical review. Use beyond twelve months requires the following:

a. Pain is severe enough to cause a significant degree of functional disability or vocational disability.
b. ESI provides at least 50% sustained improvement of pain and/or 50% objective improvement in function (using same scale as baseline).
c. Rationale for the continuation of ESIs including but not limited to patient is high-risk surgical candidates, the patient does not desire surgery, recurrence of pain in the same location relieved with ESIs for at least three months.
d. The primary care provider must be notified regarding continuation of procedures and prolonged repeat steroid use.

ESIs should not be performed when contraindicated including but not limited to suspected or active localized spinal infection, significant systemic infection, compressive lesions of the spinal cord, conus medullaris or cauda equina, suspicion or major risk factors for cancer.

Facet Joint Interventions (64491, 64492, 64494, 64495) (64634, 64636)

Facet Joint Interventions generally consist of four types of procedures: Intraarticular (IA) Facet Joint Injections, Medial Branch Blocks (MBB), Radiofrequency Ablations (RFA) or Facet Joint Denervation and Facet cyst rupture/aspiration.

A facet joint injection is an injection of a long-acting local anesthetic agent and/or steroid into the paravertebral facet joint, medial branch nerve or facet joint nerve under fluoroscopic guidance. Facet joints, also called zygapophysial joints, are located on the posterior spine on each side of the vertebrae where it overlaps the neighboring vertebrae. The facet joints provide stability and give the spine the ability to bend and twist.

Medial Branch Blocks (MBB) involve the placement of local anesthetic and possibly a corticosteroid near the medial branch nerve which supplies the sensory innervation to a specific facet joint.

Facet Joint Denervation or Radiofrequency Ablation (RFA) is a general term used to describe the minimally invasive procedure that uses thermal energy generated by the radiofrequency current to deprive the facet joint of its nerve supply. The procedure is also known as a Medial Branch Radiofrequency Neurotomy (Ablation) because it is used to thermally remove the medial branch nerve by using electrical current to create thermal energy to coagulate the adjacent tissues around the targeted medial branch nerve.

Facet cyst rupture/aspiration is an intra-articular facet joint injection performed with synovial cyst aspiration.

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Definitions:

A zygapophyseal (aka facet) joint "level" refers to the zygapophyseal joint or the two medial branch (MB) nerves that innervate that zygapophyseal joint.

A "session" is defined as all injections/blocks/RF procedures performed on one day and includes medial branch blocks (MBB), intraarticular injections (IA), facet cyst ruptures, and RFA ablations.

A "region" is all injections performed in cervical/thoracic or all injections performed in lumbar/sacral regions.

CDPHP considers facet joint interventions medically necessary for the diagnosis and treatment of chronic pain in patients who meet ALL the following criteria:

- There is no non-facet pathology per clinical assessment or radiology studies that could explain the source of the patient's pain, such as fracture, tumor, infection, or significant deformity.
- Moderate to severe chronic neck or low back pain, predominantly axial, that causes functional deficit measured on pain or disability scale.*
- Pain present for minimum of 3 months with documented failure to respond to noninvasive conservative management (as tolerated).
- Absence of untreated radiculopathy or neurogenic claudication (except for radiculopathy caused by facet joint synovial cyst).

  *Pain assessment must be performed and documented at baseline, after each diagnostic procedure using the same pain scale for each assessment. A disability scale must also be obtained at baseline to be used for functional assessment (if patient qualifies for treatment).

Diagnostic Facet Joint Procedures (IA or MBB) (64491-64495):

The primary indication of a diagnostic facet joint procedure is to diagnose whether the patient has facet syndrome. Intraarticular (IA) facet block(s) are considered reasonable and necessary as a diagnostic test only if medial branch blocks (MMB) cannot be performed due to specific documented anatomic restrictions or there is an indication to proceed with therapeutic intraarticular injections. These restrictions must be clearly documented in the medical record and made available upon request.

Diagnostic procedures should be performed with the intent that if successful, radiofrequency

ablation (RFA) procedure would be considered the primary treatment goal at the diagnosed level(s).

A second diagnostic facet procedure is considered medically necessary to confirm validity of the initial diagnostic facet procedure when administered at the same level. The second diagnostic procedure may only be performed a minimum of two weeks after the initial diagnostic procedure. Clinical circumstances that necessitate an exception to the two-week duration may be considered on an individual basis and must be clearly documented in the medical record.

For the first diagnostic facet joint procedure to be considered medically reasonable and necessary, the patient must meet the criteria outlined under indications for facet joint interventions.

A second confirmatory diagnostic facet joint procedure is considered medically reasonable and necessary in patients who meet ALL the following criteria:

- The patient meets the criteria for the first diagnostic procedure; AND
- After the first diagnostic facet joint procedure, there must be a consistent positive response of at least 80% relief of primary (index) pain (with the duration of relief being consistent with the agent used)

Frequency limitation: For each covered spinal region no more than four (4) diagnostic joint sessions will be reimbursed per rolling 12 months, in recognition that the pain generator cannot always be identified with the initial and confirmatory diagnostic procedure.

Therapeutic Facet Joint Procedures (IA) (64491-64495):

Therapeutic facet joint procedures are considered medically reasonable and necessary for patients who meet ALL the following criteria:

- The patient has had two (2) medically reasonable and necessary diagnostic facet joint procedures with each one providing a consistent minimum of 80 percent relief of primary (index) pain (with the duration of relief being consistent with the agent used); AND
- Subsequent therapeutic facet joint procedures at the same anatomic site results in at least consistent 50 percent pain relief for at least three (3) months from the prior therapeutic procedure or at least 50 percent consistent improvement in the ability to perform previously painful movements and ADLs as compared to baseline measurement using the same scale; AND

- Documentation of why the patient is not a candidate for radiofrequency ablation (such as established spinal pseudarthrosis, implanted electrical device)

Frequency limitation: For each covered spinal region no more than four (4) therapeutic facet joint (IA) sessions will be reimbursed per rolling 12 months.

Facet Cyst Aspiration/Rupture (64999):

Intra-articular facet joint injection performed with synovial cyst aspiration is considered medically necessary when both of the following criteria are met:

- Advanced diagnostic imaging study (e.g., MRI/CT/myelogram) confirm compression or displacement of the corresponding nerve root by a facet joint synovial cyst; AND
- Clinical and physical symptoms related to synovial facet cyst are documented

Frequency limitation: Cyst aspiration/rupture may be repeated once and only if there is 50% or more consistent improvement in pain for at least three (3) months.

Limitations of Coverage:

Facet joint interventions done without CT or fluoroscopic guidance are considered not reasonable and necessary. This includes facet joint interventions done without any guidance, performed under ultrasound guidance, or with magnetic resonance imaging (MRI).

Use of Moderate or Deep Sedation, General Anesthesia, and Monitored Anesthesia Care (MAC) is not considered medically reasonable and necessary during facet procedures of IA, MBB, and facet cyst aspiration/rupture.

The use of Moderate Anesthesia for RFA will be considered in individual cases with documentation of medical necessity such as a longstanding well-documented history of inability to cooperate, medical conditions that would prohibit performance of the procedure, or inability to remain motionless. Patient anxiety or preference alone is not sufficient justification. Routine use of Moderate Sedation or Monitored Anesthesia Care (MAC) or use of General Anesthesia or Deep Sedation for RFA is not considered reasonable and necessary.

It is not expected that patients will routinely present with pain in both cervical/thoracic and

lumbar spinal regions. Therefore, facet joint interventions (both diagnostic and therapeutic) are limited to one spinal region per session.

It is not routinely necessary for multiple blocks (e.g., epidural injections, sympathetic blocks, trigger point injections, etc.) to be provided to a patient on the same day as facet joint procedures. Multiple blocks on the same day could lead to improper or lack of diagnosis. If performed, the medical necessity of each injection (at the same or a different level[s]) must be clearly documented in the medical record. For example, the performance of both paravertebral facet joint procedures(s) and a transforaminal epidural injection (TFESI) at the same or close spinal level at the same encounter would not be expected unless a synovial cyst is compressing the nerve root. In this situation, TFESI may provide relief for the radicular pain, while the facet cyst rupture allows nerve root decompression. Frequent reporting of multiple blocks on the same day may trigger a focused medical review.

Facet joint intraarticular injections and medial branch blocks may involve the use of anesthetic, corticosteroids, anti-inflammatories and/or contrast agents, and does not include injections of biologicals or other substances not FDA designated for this use.

One to two levels, either unilateral or bilateral, are allowed per session per spine region. The need for a three or four-level procedure bilaterally may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal. A session is a time period, which includes all procedures (i.e., medial branch block (MBB), intraarticular injections (IA), facet cyst ruptures, and RFA ablations that are performed during the same day.

If there is an extended time, two years or more, since the last RFA and/or there is a question as to the source of the recurrent pain then diagnostic procedures must be repeated.

Therapeutic intraarticular facet injections are not covered unless there is justification in the medical documentation on why RFA cannot be performed. Facet joint procedures in patients for the indication of generalized pain conditions (such as fibromyalgia) or chronic centralized pain syndromes are considered not reasonable and necessary. Individual consideration may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal.

In patients with implanted electrical devices, providers must follow manufacturer instructions and extra planning as indicated to ensure safety of procedure.

Peripheral Nerve Blocks (64400, 64405, 64415, 64416, 64417, 64418, 64420, 64421, 64425, 64430, 64445, 64446, 64447, 64448, 64449, 64450, 64455, 64999)

Peripheral nerves can be the cause of pain in a variety of conditions. Sometimes the nerves are the source of the pain and sometimes the nerves merely are carrying impulses from painful

tissues. Examples may include: postherniorrhaphy pain (ilioinguinal/iliohypogastric/ genitofemoral), iliac crest harvest syndromes (cluneal nerve, lateral femoral cutaneous nerve), carpal tunnel syndrome (median nerve), Morton's neuroma, facial pain, and headaches (trigeminal and occipital nerve).

Peripheral nerve blocks may be used for both diagnostic and therapeutic purposes. Diagnostically, a peripheral nerve block allows the clinician to isolate the specific cause of pain in an individual patient. The injection of local anesthetic, with or without steroid, may also provide an extended therapeutic benefit. If the patient does not achieve sustained relief, a denervation procedure via chemical, cryoneurolysis, or radiofrequency may not be effective at providing long-term relief.

CDPHP considers peripheral nerve blocks medically reasonable and necessary for normally temporary conditions, such as the following indications, for diagnostic and therapeutic purposes:

- When pain appears to be due to a classic mononeuritis, but neuro-diagnostic studies have failed to provide a structural explanation. In this scenario, selective peripheral nerve blockade can usually clarify the situation (for diagnostic purposes and not long-term treatment).
- When peripheral nerve injuries/entrapment or other extremity trauma leads to complex regional pain syndrome.
- When selective peripheral nerve blockade is used diagnostically in those cases in which the clinical picture is unclear (for diagnostic purposes and not long-term treatment).
- When an occipital nerve block is used to confirm the clinical impression of the presence of occipital neuralgia. Chronic headache/occipital neuralgia can result from chronic spasm of the neck muscles as the result of either myofascial syndrome or underlying cervical spinal disease. It may be unilateral or bilateral, constant, or intermittent. Nerve injury secondary to localized head trauma or trauma to the nerve from a scalp laceration can also cause this condition. Most commonly it is caused by an entrapment of the occipital nerve in its course from its origin from the C2 nerve root to its entrance into the scalp through the mid portion of the superior nuchal line. Blockage of the occipital nerve can confirm the clinical impression of occipital neuralgia particularly if the clinical picture is not entirely typical. If only temporary relief of symptoms is obtained, neurolysis of the greater occipital nerve may be considered via multiple techniques including radiofrequency and cryoanalgesia. In addition, the lesser and third occipital nerves can be involved in the pathology of headaches and can be treated in a similar manner.
- When the suprascapular nerve block is used to confirm the diagnosis of suspected entrapment of the nerve. Entrapment of the suprascapular nerve as it passes through the suprascapular notch can produce a syndrome of pain within the shoulder with weakness of supraspinatus and infraspinatus muscles. When the history and

examination point to the diagnosis, a suprascapular nerve block leading to relief of pain can confirm it. This may be followed by injection of depository steroids that sometime provide lasting relief.

- When the trigeminal nerve is blocked centrally at the trigeminal ganglion, or along one of the three divisions or at one of the many peripheral terminal branches (i.e., supraorbital nerve).
- Nerve blocks as preemptive analgesia:

A. When a single injection peripheral nerve block provides post-surgical pain control

1. During the transition to oral analgesics.

2. In those procedures which cause severe pain normally uncontrolled by oral analgesics.

3. In cases otherwise requiring control with intravenous or parenteral narcotics.

4. In cases where the patient cannot tolerate treatment with narcotics due to allergy or side effects, etc.

B. When a continuous peripheral nerve block provides the same as above, and furthermore may provide extended (i.e., one to five or more days) relief as a result of chronic administration of anesthetic.

Limitations of Coverage:

In general, signs and symptoms that justify peripheral nerve blocks should be resolved after one to three injections. Up to three peripheral nerve blocks per anatomic site (e.g., specific nerve, plexus or branch as defined by the CPT code description) may be performed in a six-month period of time.

More than two anatomic sites (e.g., specific nerve, plexus or branch as defined by the CPT code description) injected at any one session will be denied. If the member does not achieve progressively sustained relief after receiving two to three repeat peripheral nerve block injections on the same anatomical site, then alternative therapeutic options should be explored.

There is insufficient evidence to support the use of peripheral nerve blocks in the treatment of diabetic peripheral neuropathy, peripheral neuropathies caused by other underlying systemic diseases or peripheral neuropathies causes such as degenerative or idiopathic reasons. Medical management using systemic medications is clinically indicated for the treatment of these conditions.

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"Dry needling" of ganglion cysts, ligaments, neuromas, peripheral nerves, tendon sheaths and their origins/insertions, or any tissue are non-covered procedures.

Other Considerations:

Additional management using medications, behavioral therapy, and physical therapy should be used (when appropriate) in conjunction with peripheral nerve block.

Spinal Cord (Dorsal Column) Stimulator (63650, 63655, 63661, 63662, 63663, 63664, 63685, 63688)

A device (L8680-L8683, L8685-L8689) that is used to electrically stimulate a member's spinal cord to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed on the member's spinal cord, and an external transmitter for transmitting the stimulating pulses across the member's skin to the implanted receiver. Spinal cord (dorsal column) stimulation involves the surgical implantation of neurostimulator electrodes within the dura mater (via laminectomy) or the percutaneous insertion of electrodes in the epidural space.

CDPHP considers implantation of spinal cord (dorsal column) stimulators medically necessary for the treatment of chronic, intractable pain secondary to the following indications:

- Failed back surgery syndrome (FBS) with predominant low back pain and significant radicular pain.
- Complex regional pain syndrome affecting a limb (i.e., reflex sympathetic dystrophy)
- Inoperable chronic ischemic limb pain secondary to peripheral vascular disease
- Last resort treatment of moderate to severe (documented 5 or more on a 10-point VAS scale) chronic neuropathic pain of the following origins that has been present for 12 or more months:
    - Lumbosacral arachnoiditis
    - Radiculopathies
    - Phantom limb/stump pain
    - Peripheral neuropathy (including diabetic peripheral neuropathy-DPN*)
    - Post-herpetic neuralgia
    - Intercostal neuralgia
    - Cauda equina injury
    - Incomplete spinal cord injury
    - Plexopathy

A. A trial of percutaneous spinal cord (dorsal column) stimulation to predict whether a spinal

cord (dorsal column) stimulator will induce significant pain relief in members with chronic pain will be considered medically necessary when all of the criteria listed below are met:

- Services must be recommended by the physician after consultation with a pain management specialist.
- Psychological evaluation has been completed to exclude any major mental disability or drug habituation that would negatively influence the outcome of the treatment.
- The implantation of the stimulator is a late resort (the patient is not considered a candidate for further surgical intervention).
- Other more conservative treatment modalities (pharmacological, surgical, physical, or psychological therapies) have been tried unsuccessfully for a minimum of 6 months or are contraindicated.

  *The following additional criteria applies to coverage for the indication of diabetic peripheral neuropathy-DPN only:

- Demonstrated glycemic control (HA1c of < 8) for a minimum of 6 months.

B. Placement of a permanent spinal cord stimulator (dorsal column) stimulator may be considered medically necessary and eligible for coverage when the above medical necessity criteria for a trial treatment of spinal cord stimulation (dorsal column) stimulation are met, the trial is performed, and the individual has demonstrated pain relief of at least 50% for a minimum of 48 hours (documented on VAS scale) with the temporarily implanted electrode as documented in the medical record.

CDPHP considers spinal cord (dorsal column) stimulation experimental and investigational for all indications other than those listed above, including but not limiting to, cervical disease-causing neck, upper extremity pain, and/or headache.

The implantation of a spinal cord (dorsal column) stimulator is covered under the medical/surgical benefit. Any external components used to control the device and to recharge the transmitter are considered DME and will be subject to the terms and conditions of the enrollee's contract.

Based upon our criteria and assessment of the peer-reviewed literature, the replacement of an existing high frequency or non-high-frequency dorsal column SCS and dorsal root ganglion (DRG) stimulator for individuals who have had a positive pain relief response from the existing DCS is considered medically appropriate when **EITHER** of the following criteria are met:

A. The existing stimulator and/or battery/generator is malfunctioning, cannot be repaired,

and is no longer under warranty; or

B. Revision of the electrode percutaneous array(s) or electrode plate/paddle(s) is required.

Based upon our criteria and assessment of the peer-reviewed literature, replacement of a functioning non-high frequency dorsal column SCS with a high-frequency SCS is considered not medically necessary.

Other considerations for outpatient pain management services

In general, it is not considered appropriate to provide an interlaminar epidural/intrathecal injection, a transforaminal selective epidural, facet joint/nerve block, sacroiliac joint injection, lumbar sympathetic block, or other nerve block on the same day. Therefore, only one invasive procedure per date of service is considered reasonable and necessary.

Fluoroscopic guidance (77003) is considered an integral part of the injection procedure 62324, 62326, 62327) and therefore, is not separately reimbursed.

Administration of local anesthetics is considered an integral part of the injection procedure and therefore, are not separately reimbursed.

HCPCS drug codes may be allowed in addition to the procedure when in conjunction with an office-based pain management program.

The application of physical, noninvasive modalities (i.e., electrical stimulation, ultrasound, and others) is considered global to the office visit.

EXCLUSIONS

The following are considered experimental/investigational:

- Biofeedback
- Cognitive behavioral techniques when provided as a stand-alone service
- Cryotherapy (e.g., iovera° cryoneurolysis) for treatment of any indication including, but not limited to, knee osteoarthritis or before/during/after total knee replacement surgery (64640, C9808, C9809)
- Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disk (62287, S2348)
- Endoscopic epidural adhesiolysis (64999)
- Intraarticular and extraarticular facet joint prolotherapy
- Intradiscal radiofrequency thermomodulation (22899)

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- Intradiscal steroid injection (22899)
- Intra-facet implants
- Nerve blocks or injections for the treatment of multiple neuropathies or peripheral neuropathies caused by underlying systemic disease
- Non-thermal modalities for facet joint denervation including chemical, low-grade thermal energy (less than 80 degrees Celsius), laser neurolysis, and cryoablation
- Percutaneous intradiscal electrothermal annuloplasty [IDET] (22527)
- Percutaneous lysis of epidural adhesions, Racz procedure (62263, 62264)
- Peripheral nerve blocks for conditions other than those stated within this policy, to include treatment of chronic conditions (e.g., chronic knee pain, osteoarthritis (i.e., genicular nerve branches 64454, 64624) **Exception**: Genicular nerve branches (64454 and 64624) are covered for Medicare Advantage LOB. See Medicare Advantage section below for coverage criteria.
- Prolotherapy (M0076)
- Radiofrequency denervation (ablation) of the nerves that innervate the sacroiliac joint (L5, S1, S2, S3) whether performed using traditional or cooled radiofrequency (< 80 degrees Celsius) (64625) or pulsed radiofrequency (64999).
- Ultrasound guidance for facet joint injection(s) and epidural steroid injection(s) (0213T-0218T, 64999).

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy to include the following: Coverage is available for percutaneous image guided lumbar decompression (PILD) for individuals with lumbar spinal stenosis when criteria in the Coverage with Evidence Development for Medicare Advantage, 1370/20.000517 policy are met. • Genicular nerve blocks (64454, 64624) are covered to include treatment of chronic conditions (e.g., chronic knee pain, osteoarthritis, post-surgical pain management, based on the criteria outlined above in the Peripheral Nerve Block section of this policy. • Dry needling (20560, 20561) is covered for chronic low

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	back pain (cLBP). • Peripheral nerve stimulator: (64555, 64575, 64590, 64595, 64999, 64567) to treat chronic intractable pain.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy with the following exceptions: The following treatments for chronic low back pain are not eligible for reimbursement as they are considered ineffective, or experimental and investigational: • Prolotherapy (M0076) • Systemic corticosteroids for **chronic** low back pain • **Therapeutic** facet joint steroid injections in the lumbar and sacral regions with or without CT or fluoroscopic image guidance (up to two **diagnostic** facet steroid injections will continue to be covered for codes 64494, 64495) • Injections of steroids into intervertebral discs; and • Continuous or intermittent traction (97012) • 0216T, 0217T, and 0218T are not covered for therapeutic or diagnostic facet steroid injections Functional electrical stimulators (63650, 63655, 63685, 63688, 64555, 64575, 64580, 64585, 64590, 64595, L8680-L8689), when used in the treatment of spinal cord and head injury, cerebral palsy, and upper motor neuron disease. Coverage of FES is available for indications other than those listed above when medically necessary. Implantable infusion pumps (62350-62370, 95990, 95991) are covered for: - Delivery of an opioid for pain management purposes only when there is a diagnosis of cancer. - Delivery of other substances when medically necessary. Note: For individuals who had infusion pumps implanted for **any diagnosis** prior to November 1, 2013, CDPHP will continue to cover the pumps, related supplies, and drugs.

SOURCES

1. Practice Guidelines for Chronic Pain Management A Report by the American Society of Anesthesiologists Task Force on Pain Management, Chronic Pain Section; Anesthesiology Vol. 86, No. 4, April 1997 pp. 995-1004
2. CDPHP Board Certified Consultants/Participating Physician
3. Medicare Part B Policies/Other payors
4. Houpt, JC; Conner, ES; McFarland, EW: Experimental Study of Temperature Distributions and Thermal Transport during Radiofrequency Current Therapy of the intervertebral disc. Spine 1996 Aug, pp. 1808-12
5. Bagley, Grant; Bisquier, Erica; Honemann, Dorothy: Quality of Care Information Coverage Policies; Prolotherapy for Chronic low back pain Decision Memorandum
6. VanKleef, M; Barendse, GA; Kessels, A; Voets, HM; Weber, WE; Delange, S: Randomized Trial of Radiofrequency lumbar facet denervation for chronic low back pain. Spine, 1999 Sep 15, 24 (18), pp. 1934-1942
7. Krames, Elliot: Chronic Pain: Interventional Pain Management, Appropriate when less invasive therapies fail to provide adequate analgesia. Medical Clinics of North America, Vol. 83, No. 3, May 1999, pp. 787-808.
8. Cho, J; Park, Y; Chung, SS: Percutaneous radiofrequency lumbar facet rhizotomy in mechanical low back pain syndrome. Steretotact Funct Neurosurg 1997, 68 (1-4 PT 1), pp. 212-217
9. Jerosch, J; Castro, WH; Halm, H; Muller-Silvergieter, G: Long-term results following percutaneous facet
   coagulation. Z Orthoplre Grenzgeb, 1993 May June, 131(3), pp. 241-247.
10. Bigos, S. et al: Acute low back problems in adults. Clinical Practice Guideline No. 14, AHCPR Publication No. 95-0642, Rockville, MD. Agency for Health Care Policy and Research, Public Health Services, US Dept. of Health and Human Services, December 1994.
11. Mehta, M. and Wynn Parry, CB: Mechanical back pain and the facet joint syndrome. Disabil Rehabil 1994 Jan-Mar, 16 (1), pp. 2-12
12. Shealy, CN: Facet denervation in the management of back and sciatica pain. Clin Orthop and Rel Res 1976; 15, pp. 157-164
13. Stolker, RJ et al: Percutaneous facet denervation in chronic thoracic spinal pain. Acta Neurocher (Wien) 1993, 122:82-90
14. Shealy, CN: Percutaneous radiofrequency denervation of spinal facets: treatment for chronic back pain and sciatica. J. Neurosurg 1975; 43:448-451
15. Bogduk, N et al: Technical limitations to the efficacy of radiofrequency neurotomy for spinal pain. Neurosurgery 1987; 20: 529-535
16. Oudenhoven, RC. The Role of laminectomy, facet rhizotomy and epidural steroids. Spine

1979; 4 (2): 145-147
17. Savitz, MH. Percutaneous radiofrequency rhizotomy of the lumbar facets: ten years' experience. Mount Sinai Journal of Medicine 1991 Mar; 58 (2): 177-8
18. North RB et al. Radiofrequency lumbar facet denervation: analysis of prognostic factors. Pain 1994 Apr; 57 (1): 77-83
19. Goupille P; Cotty P; Fouquet B; Alison D; Laffont J; Valat JP. Denervation of the posterior lumbar vertebral apophyses by thermocoagulation in chronic low back pain. Results of the treatment of 103 patients. Revue du Rhumatisne, 1993 Nov 30; 60 (11): 791-6
20. Lord sm; Barnsley L; Wallis BJ; McDonald CJ; Bogduk N. Pecutaneous radio – frequency neurotomy for chronic cervical zygapophyseal – joint pain. N Engl J Med – 1996 Dec. 5; 335 (23): 1721-6.
21. Saal JS; Management of chronic discogenic low back pain with a thermal intradiscal catheter. A preliminary result, Spine, 2000 Feb 1; 25(3): 382-8.
22. Saal JS; Saal JA; Intradiscal Electrothermal Treatment for Chronic Discogenic Low Back Pain, Spine, 2000; 25:2622-2627.
23. Karasek M; Bogduk, N; Twelve Month Follow Up of a Controlled Trial of Intradiscal Thermal Anuloplasty for Back Pain Due to Internal Disk Disruption, Spine 2000; 25:2601-2607.
24. Derby, Eek, Chen, O'Neill, Ryan; Intradiscal Electrothermal Annuloplasty (IDET): A Novel Approach for Treating Chronic Discogenic Back Pain; Neuromodulation 3 (2), 82-88.
25. Medicare Part B Answer Book, Anesthesia Services, 10201-10206, 2001 Edition.
26. AHCPR, Acute Pain Management: Operative or Medical Procedures and Trauma, Clinical Practice Guideline No. 1, AHCPR Publication No. 92-0032: February 1992.
27. Miaskowski C. et al., Anesthesia-based pain services improve the quality of postoperative pain management, Pain 80, 1999, 23-29.
28. Other Payers
29. Clinical practice guidelines for chronic non-malignant pain syndrome patients II: An evidenced based approach. Accessed: 04/17/03. www.guideline.gov
30. Upstate Medicare Division, Part B Local Medical Review Policy (implanted catheter /pump for opioid infusion via intrathecal epidual drug delivery system) accessed 04/16/03.
31. Empire Medicare Services MNB-99-3 April 1999 (implanted catheter /pump for opioid infusion via intrathecal epidural drug delivery system) accessed 04/10/03.
32. American Family Physician (Trigger Points: Diagnosis and Management February 15, 2002)
33. Center for Medicare & Medicaid Services, Empire Medicare Services Local Medical Review Policy, Kyphoplasty, effective 10/21/03.
34. Practice Guidelines for Chronic Pain Management, An Updated Report by the American Society of Anesthesiologists Task Force on Chronic Pain Management and the American Society of Regional Anesthesia and Pain Medicine, 2010, http://www.google.com/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CB4QFjAAahUKEwiWkaDQn5DHAhUMNT4KHf68ALY&url=http%3A%2F%2Fwww.asahq.org%2F~%2Fmedia%2Fsites%2Fasahq%2Ffiles%2Fpublic%2Fresources%2Fstandards-guidelines%2Fpractice-guidelines-for-chronic-pain-management.pdf&ei=3h3BVZaqLYzq-AH--YKwCw&usg=AFQjCNEvbzI-ivnd_Y3NQCRwLwfb7rnX5w&bvm=bv.99261572,d.cWw

35. National Government Services, Inc. Local Coverage Determination (LCD): Pain Management (L28529), effective 12/16/14, https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=28529&ContrId=301&ver=96&ContrVer=1&CntrctrSelected=301*1&Cntrctr=301&name=National+Government+Services%2c+Inc.+(National+Government+Services%2c+Inc.+(13282%2c+A+and+B+and+HHH+MA
36. National Government Services, Inc. Local Coverage Determination (LCD): Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy (L35336) effective 12/16/14, https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=28529&ContrId=301&ver=96&ContrVer=1&CntrctrSelected=301*1&Cntrctr=301&name=National+Government+Services%2c+Inc.+(National+Government+Services%2c+Inc.+(13282%2c+A+and+B+and+HHH+MA
37. National Government Services, Inc. Local Coverage Determination (LCD): Lumbar Epidural Injections (L35338), effective 12/16/14, https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35338&ContrId=301&ver=5&ContrVer=1&CntrctrSelected=301*1&Cntrctr=301&name=National+Government+Services%2c+Inc.+(National+Government+Services%2c+Inc.+(13282%2c+A+and+B+and+HHH+MAC%2c+J+-+K))&DocType=Active&LCntrctr=301*1&bc=AgACAAIAAAAAAA%3d%3d&
38. Agency for Health Care and Research Technology Assessment: Pain Management Injection Therapies for Low Back Pain, March 20, 2015 http://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/id98TA.pdf
39. American Society of Interventional Pain Physicians (ASIPP), An Update of Comprehensive Evidence based Guidelines for Interventional Techniques in Chronic Spinal Pain. Part II: Guidance and Recommendations, 2013. http://www.painphysicianjournal.com/2013/april/2013;16;S49-S283.pdf
40. American Society of Interventional Pain Physicians (ASIPP), Diagnostic Utility of Selective Nerve Root Blocks in the Diagnosis of Lumbosacral Radicular Pain: Systematic Review and Update of Current Evidence, 2013. http://www.painphysicianjournal.com/2013/april/2013;16;SE97-SE124.pdf
41. New York State Medicaid Update: Limitation for Coverage for Functional Electrical Stimulation (FES), Volume 29, No. 10, September 2013, http://www.health.ny.gov/health_care/medicaid/program/update/2013/2013-09.htm
42. New York State Medicaid Update: Coverage Guidelines for Implantable Infusion Pump for Opioid Administration for Purposes of Pain Management, Volume 29, No. 10, September 2013, http://www.health.ny.gov/health_care/medicaid/program/update/2013/2013-09.htm
43. National Institute for Health and Care Excellence (NICE). IPG452 Occipital nerve stimulation for intractable chronic migraine. 2013. Accessed at: http://publications.nice.org.uk/occipital-nerve-stimulation-for-intractable-chronic-migraine-ipg452
44. Hooten WM, Timming R, Belgrade M, Gaul J, Goertz M, Haake B, Myers C, Noonan MP, Owens J, Saeger L, Schweim K, Shteyman G, Walker N. Institute for Clinical Systems

Improvement. Assessment and Management of Chronic Pain. Updated November 2013.
45. Hayes Medical Technology Directory. Occipital Nerve Stimulation for Chronic Cluster Headache and Chronic Migraine Headache. Winifred Hayes, Inc. May 30, 2012. Updated review May 4, 2015.
46. Hayes Health Technology Brief. Electrical Stimulation of the Occipital Nerve for Treatment of Occipital Neuralgia. Winifred Hayes, Inc. December 29, 2011. Updated review, January 6, 2014.
47. Hayes Medical Technology Directory. Trigger Point Injections for Myofascial Pain. Winifred Hayes, Inc. December 24, 2013. Updated review December 10, 2014.
48. Hayes Medical Technology Directory. Dry Needling for Myofascial Pain in Adults. Winifred Hayes, Inc. December 4, 2013. Updated review November 20, 2014.
49. Hayes Medical Technology Directory: Epidural Steroid Injections for Cervical Radiculopathy. Winifred Hayes, Inc. September 6, 2013. Updated review July 21, 2015.
50. Hayes Medical Technology Directory: Epidural Steroid Injections for Low Back Pain and Sciatica. Winifred Hayes, Inc. January 30, 2013. Updated review January 22, 2015.
51. Hayes Brief Report: Sacroiliac Joint Injections with Corticosteroids for Treatment of Chronic Low Back Pain. Winifred Hayes, Inc. October 9, 2014.
52. Hayes Search & Summary Report: Genicular Nerve Block for Knee Pain. May 28, 2015.
53. National Government Services, Inc. Local Coverage Determination (LCD): Peripheral Nerve Blocks (L36850), effective 5/1/17, www.ngsmedicare.com
54. National Government Services, Inc. Local Coverage Determination (LCD): Facet Joint Interventions for Pain Management (L35936), effective 4/25/21, www.ngsmedicare.com.
55. National Government Services, Inc. Local Coverage Determination (LCD): Epidural Steroid Injections for Pain Management (L39036), effective 12/5/21. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39036&ver=8&bc=0
56. Hayes Medical Technology Evolving Evidence Review. The iovera System for Knee Osteoarthritis.
57. Hayes Medical Technology Evolving Evidence Review. The The iovera System for Pain Associated with Total Knee Arthroplasty.
58. National Government Services, Inc Local Coverage Determination (LCD): Sacroiliac Joint Injections and Procedures (L39455), effective 3/19/2023, https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39455&ver=4&keyword=sacroiliac&keywordType=starts&areaId=s65&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1
59. Hayes Evidence Analysis Research Brief: Genicular Artery Embolization for Treatment of Knee Osteoarthritis, August 28, 2023
60. National Government Services, Inc. Local Coverage Determination (LCD): Trigger Point Injections (L39662), effective 4/1/2024, https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39662&ver=5&bc=0.

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POLICY NAME: PAIN MANAGEMENT SERVICES

POLICY APPROVAL DATES

New:	07/93
	01/95, 05/96, 06/98, 08/99, 12/99, 09/00, 02/01, 08/01, 01/02, 09/02, 05/03, 03/04, 01/05, 09/07, 07/08, 03/09, 01/10, 05/10, 05/12, 07/12, 01/13, 05/13, 11/13, 01/14, 05/14, 09/15, 01/16, 09/16, 09/17, 01/18, 05/19, 09/19, 09/20, 9/21, 5/22, 9/22, 5/23, 9/23, 11/23, 3/24, 7/24, 9/24, 11/24, 3/25, 5/25, 9/25, 11/25,
Revised:	1/26, 3/26, 7/26
Reviewed:	10/05, 10/06, 05/11, 09/18, 9/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
8/1/2026	Policy updated to remove Percutaneous peripheral nerve stimulation (PNS), Peripheral nerve field stimulation (PNFS) under exclusions as these services are now addressed in new policy, Implantable and Invasive Neuromodulation Systems, 1.01.60
1/1/2026	Updated exclusions section to remove items that are no longer experimental. Remove the following codes from the policy as Healthhelp will be reviewing: 62320 62321 62322 27096 62323 64451 64479 64483 64490 64493 64633 64634 64635 64636

	0274T 0275T 22526 G0260 Removed deleted code 0720T and updated with replacement code 64567.
12/1/2025	Under exclusions, removed RFA of the occipital nerve and added guidance for RFA of occipital nerve under nerve blocks.
9/1/2025* *No change to effective date for this update	Clarified coverage criteria under Facet Joint Denervation per updated LCD L35936 effective 7/17/25.
9/1/2025	Added PNS/PNFS as experimental for any indication with exception under Medicare Advantage.
3/1/2025 *No change to effective date of policy	Added new codes that were effective 1/1/2025 C9808 and C9809 to Exclusions section.
3/1/2025	Added Exclusion for peripheral nerve field stimulation (PNS/PNFS) to relieve pain and improve function in patients with refractory chronic lower back pain. Added exclusion for radiofrequency ablation of the occipital nerve for occipital neuralgia/headache. Added criteria for replacement of spinal cord (dorsal column) stimulator.
1/1/2025	Revised all criteria in Trigger Point Injections section. Revised this statement in the Epidural Steroid Injections section: Steroid dosing should be the lowest effective amount. Revised the criteria for anesthesia in the Facet Joint Interventions section.
3/1/2024* *No change to effective date for this update	Added coverage information for genicular nerve blocks (64454, 64624) to the Medicare Advantage section. Added additional criteria for nerve blocks as preemptive analgesia under the Peripheral Nerve Blocks section.
3/1/2024	Added additional criteria and indications for spinal cord (dorsal column) stimulator.
1/1/2024	Completely revised the Sacroiliac Joint Injection section.

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POLICY NAME: PAIN MANAGEMENT SERVICES

9/1/2023	Added Cryotherapy (e.g., iovera° cryoneurolysis) to the exclusions section. Under exclusions, clarified Radiofrequency denervation (ablation) of the sacroiliac joint.
1/1/2023	Completely revised the Epidural Injections section. Removed section on termed code 72275.
5/1/2022	No content change. Under Medicaid section, clarified coverage/noncoverage for implantable infusion pumps.
1/1/2022	Completely revised the section for Facet Joint Injections, Medical Branch Nerve Blocks, and Facet Joint Radiofrequency Neurotomy which are now collectively referred to in the policy as Facet Joint Interventions. Added additional Exclusions for Facets Joint Interventions.
1/1/21	Updated coding for dry needling, sacroiliac joint injections, and peripheral nerve blocks. Added section on Epidurography (72275). Updated coding and verbiage for radiofrequency denervation (ablation) in the Exclusions section.
1/1/2020	Termed code removed from policy.

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MEDICAL POLICY

Medical Policy Title	**Pain Management Techniques for Knee Pain**
Policy Number	**7.01.100**
Current Effective Date	**January 1, 2027**
Next Review Date	**July 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Ablation or Denervation Techniques

I. Radiofrequency ablation (RFA)/denervation (including cooled and pulsed) of genicular nerves to treat pain is considered **investigational** for all indications, including, but not limited to, knee pain/osteoarthritis (OA).

II. Cryoneurolysis/cryoablation to treat pain associated with knee OA or total knee arthroplasty (TKA) is considered **investigational**.

Injection Treatments for Knee Pain

III. The addition of an IPACK block to multimodal analgesia regimens to reduce post-operative pain or improve functional performance is considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

7.01.42 Radiofrequency Facet and Sacroiliac Joint Ablation/Denervation

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Radiofrequency Ablation

Nerve RFA is a minimally invasive treatment method that involves the use of heat and coagulation necrosis to destroy tissue. A needle electrode is inserted through the skin and into the tissue to be ablated. A high-frequency electrical current is applied to the target tissue, causing a small sphere of tissue to coagulate around the needle by the heat generated. It is theorized that the thermal lesioning of the nerve destroys peripheral sensory nerve endings, resulting in the alleviation of pain.

Cooled radiofrequency (RF) treatment is a variation of nerve RFA, using a special device that applies

more energy at the desired location without excessive heat diffusing beyond the area, causing less tissue damage away from the nerve. The goal of ablating the nerve is the same. COOLIEF (Haylard Health, Inc.) cooled RF treatment is a minimally invasive outpatient procedure that uses cooled radiofrequency energy to target the sensory nerves causing pain. COOLIEF circulates water through the device while heating nervous tissue, to create a treatment area that is larger than conventional RF treatments. This combination targets the pain-causing nerves without excessive heating and is proposed to relieve hip and knee pain associated with OA.

Nerve RFA is different from pulsed RF treatment, which has been investigated for different types of pain. The mechanism of action of pulsed RF treatment is uncertain, but it is thought not to destroy the nerve, or, if it does produce some degree of nerve destruction, to cause less damage than standard RFA. Some studies refer to pulsed RF treatment as ablation.

Cryoneurolysis

Cryoneurolysis is being investigated to alleviate pain in knee OA and to manage pain following TKA. Temperatures of -20° to -100°C applied to a nerve cause Wallerian (anterograde axonal) degeneration, with disruption of nerve structure and conduction. However, maintenance of the perineural and epineural elements of the nerve bundle purportedly allows near complete regeneration and recovery of nerve function in about three to five months. The iovera cryoablation system is a portable handheld device that applies percutaneous and targeted delivery of cold to superficial peripheral nerves.

IPACK

The IPACK block (infiltration between the popliteal artery and capsule of the posterior knee) is a regional anesthesia technique used to manage posterior knee pain especially after a total knee replacement (TKR) or other knee surgery. It is a relatively recent innovation that provides anesthesia without causing motor weakness particularly of the tibial or common peroneal nerve. The purpose is to provide posterior knee analgesia by targeting the articular branches of nerves in innervating the posterior capsule of the knee. It is used as a supplement to abductor canal blocks (which covers anterior and medial pain) for comprehensive motor sparing analgesia. IPACK is performed under guided ultrasound with the individual in a supine or lateral position. A linear or curved transducer is used to identify the femoral condyles, popliteal artery, and the posterior capsule. A needle is inserted in-plane from medial to lateral, or lateral to medial depending on the preference. Local anesthetic (typically 15-20 ml of ropivcacine or bupivacaine) is injected into the interspace between the popliteal artery and posterior capsule of the femur.

SUPPORTIVE LITERATURE

Radiofrequency Ablation

Gupta and colleagues (2017) completed a systematic review aimed at analyzing published studies on RFA (conventional, pulsed, or cooled radiofrequency) for patients suffering from OA of the knee, as well as patients post-TKA who have developed refractory disabling chronic knee pain. The systematic review was intended to provide an overview of the current knowledge regarding variations in procedures, nerve targets, adverse events, and temporal extent of clinical benefit. Seventeen

publications were identified in the search, including articles investigating conventional, pulsed, or cooled RFA. These studies primarily targeted either the genicular nerves or used an intra-articular approach. Of the studies, five were small-sized, randomized, controlled trials, although one involved diathermy radiofrequency ablation. There were eight retrospective or prospective case series and four case reports. Utilizing the strength of evidence grading, the study identified a low level of certainty to suggest a superior benefit between targeting the genicular nerve, an intra-articular approach, or targeting the larger nerves such as femoral and tibial nerves. It also identified a low level of certainty supporting the superiority of any specific RFA procedure modality. The majority of the studies reported positive patient outcomes, but the inconsistent procedural methodology, inconsistent patient assessment measures, and small study sizes limit the applicability of any specific study to clinical practice. The authors concluded that, overall, the studies showed promising results for the treatment of severe chronic knee pain by RFA at up to one year, with minimal complications. Numerous studies, however, yielded concerns about procedural protocols, study quality, and patient follow-up. RFA can offer substantial clinical and functional benefit to patients with chronic knee pain due to OA or post-TKA.

Qudsi-Sinclair and colleagues (2017) published the results of a double-blinded, randomized, controlled trial comparing traditional RF neurolysis (n=14) to local anesthetic and corticosteroid block (n=14) of the genicular nerves for treatment of persistent pain following TKA. Subjects were followed for one year after treatment and evaluated for pain evolution, knee functionality, quality of life, and degree of patient satisfaction. At three and six months, both groups demonstrated a reduction in pain and significant joint function improvement, with similar results in both groups, including improvement in quality of life and disability and a reduced need for analgesics. The authors could not recommend one treatment option over another and suggested that further clinical trials are needed to establish safety and efficacy. The study is limited by small sample population and short-term outcomes.

While there are a few studies in the published peer-reviewed literature which lend support to improvement in pain after ablative treatment, these studies are limited by variability in RF technique, small sample populations, and differences in patient selection criteria. At present, there is insufficient evidence in the peer-reviewed scientific literature evaluating RF ablative treatment for chronic knee pain. Strong, evidence-based conclusions regarding the effects of this technology on health outcomes cannot be made. Additional well-designed studies involving larger populations and long-term outcomes are needed, to support safety and efficacy and to determine how this treatment compares to other medical and surgical treatments for knee pain.

In 2018, Davis and colleagues completed a prospective, multicenter, randomized, crossover clinical trial comparing the safety and effectiveness of cooled RF with corticosteroid injection in the management of knee pain from OA in 151 subjects with chronic knee pain lasting six months or more that was unresponsive to conservative modalities. Knee pain (Numeric Rating Scale [NRS]), Oxford Knee Score, overall treatment effect (Global Perceived Effect), analgesic drug use, and adverse events were compared between cooled RFA and intra-articular steroid (IAS) cohorts at one, three, and six months after intervention. At six months, the cooled RF group had more favorable outcomes in NRS with pain reduction of 50% or greater in 74.1% versus 16.2% of IAS cases. Non-responders consisted of 25.9% in the cooled RFA group and 83.8% in the steroid group. At six months, mean Oxford Knee Score was 35.7 in the cooled RFA group versus 22.4 in the steroid group, and mean

improved Global Perceived Effect was 91.4% versus 23.9%, respectively. There was no change in the average daily dose of opioids at six months between the groups. No procedure-related serious adverse events were identified. While the authors concluded that the findings of this study indicated that cooled RFA for genicular nerve ablation is superior to a single corticosteroid injection in osteoarthritic subjects for managing knee pain, the limitations of this study included the following: the comparison group (IAS subjects) underwent a singular injection rather than multiple injections, and the six-month time point at which the primary outcome was assessed is not consistent with the expected duration of effectiveness of a steroid injection; this was an open label trial, and so, not all study site observers were blinded to procedures; medication diaries were not used to record medication usage in this study, which introduced potential for error and/or inability to identify acute changes in medication dosage during the study; and the effect of each treatment on opioid use for OA-related knee pain could not be specifically measured because patients in both study groups used opioids for medical indications other than OA-related knee pain.

In a single, blind, randomized, controlled trial, El-Hakeim and colleagues (2018) studied the efficacy of fluoroscopic-guided radiofrequency neurotomy of the genicular nerves for alleviation of chronic pain and improvement of function in patients with knee OA. A total of 60 patients with chronic knee OA received either radiofrequency neurotomy of the genicular nerves (n=30), considered Group A, or conventional analgesics only (n=30), identified as Group C. For Group C, the following treatments were prescribed: oral paracetamol (max of 1 gram in six hours), Diclofenac sodium 75mg BID, and physiotherapy, if needed. The outcomes measures included visual analog scale (VAS), Western Ontario and McMaster Universities Index (WOMAC), and Likert scale for patient satisfaction in the second week, third week, and sixth month. The authors found significant differences in the VAS in the second week, third week, and sixth month between the two groups, and a significant difference in total WOMAC index in the sixth month only. A high percentage ratio of the patients (63.3%) in the conventional Group C received physiotherapy during the follow-up period. No diagnostic block was done prior to radiofrequency, which is a limitation in the study. The authors concluded that RF could ameliorate pain and disability in chronic knee OA in a safe and effective manner.

In 2019, Davis and colleagues published a follow-up study investigating the longer-term durability of analgesic effects of cooled RFA for knee pain from OA. A total of 58 patients (82%) from the original IAS cohort who were dissatisfied with their IAS treatment after six months were allowed to crossover to receive cooled RFA treatment. In addition, 58 patients who received cooled RFA were followed for an additional six months, for a total of 12 months' follow-up. At 12 months, 52 patients (78%) in the originally treated cooled RFA group contributed data to the primary endpoint. Diminished pain relative to baseline greater than or equal to 50% was reported as 65% (34/52) after 12 months, and the OKS mean score was 34.3, an increase in baseline by 17.3 points after 12 months. In the crossover group, 49% (18/37) of patients experienced a 50% or more decrease in pain from baseline at six months. No serious adverse events identified were related to cooled RFA. Opioid use stayed consistent with baseline during the trial. The authors are unclear why a difference in analgesic response was seen in the originally treated group (65% at 12 months) and the crossover group (49% at six months); however, the study was not powered or designed to draw conclusions from the crossover group. The authors concluded that statistically significant and clinically relevant pain relief and functional improvements were sustained 12 months following cooled RFA treatment of OA-

related knee pain and dysfunction. This study was partially funded by Halyard Health.

Almeida et al (2025) conducted a systematic review and meta-analysis of the efficacy and safety of minimally invasive treatments (RFA, genicular nerve blocks (GNB), and cryoneurolysis) targeting the genicular nerves for management of knee OA pain. The primary outcome were pain intensity, physical function, and serious adverse events. Analysis was conducted on 25 randomized control trial (RFA n=16, GNB n=8, and cyroneurolysis n=1) involving 2049 participants. Secondary outcomes included quality of life, global perceived effect, general adverse events, and withdrawal due to side effects. Key results showed the certainty of evidence was consistently low to very low across all comparisons. RFA may provide some short-term relief at 4 weeks compared to the sham group 4 weeks (Mean difference -1.70, on a 0-10 scale). There was little to no difference in pain at 24-48 weeks, or improvement in function observed at any time and no serious adverse events reported. GNB showed limited and very uncertain evidence. Only one trial suggests small reduction in pain and moderate functional improvements at 4 weeks. For cryoneurolysis very low certainty of evidence was found. Only one trial showed small improvement in pain at 4 weeks and no significant effects at 12 or 24 weeks. This study had a high risk of bias. Lack of blinding, and inadequate outcome measurement protocols were found in 17 out of 25 studies included. Most trials had small sample sizes with short follow up duration. The authors concluded that RFA and other genicular nerve targeting procedures provide at best a modest, short-term benefit in knee OA pain management. There was no reliable evidence that these treatments improve function or quality of lifelong terms.

Cryoneurolysis

A randomized, controlled trial with 180 patients (Radnovich 2017) compared cryoneurolysis with sham treatment in patients who had knee OA. Cryoneurolysis resulted in a greater decrease in WOMAC pain, WOMAC total, and VAS score at 30 days, compared with sham-treated controls. Subsequent measurements showed no significant benefit of cryoneurolysis on WOMAC score at 60 days or in VAS scores at 60 or 90 days. As the trial progressed, patients were able to more accurately guess their treatment group assignment, which may have biased results in favor of active treatment. Several technical issues, including the optimal number of applications for each nerve, the duration of treatment, and the duration of thawing before moving the cannula, have yet to be resolved. Perioperative cryoneurolysis has shown mixed results in reducing opioid prescriptions/use in patients undergoing TKA (Dasa 2016; Mihalko 2021). Larger, well-designed trials are needed to determine the effects on health outcomes.

IPACK

In a 2020 double-blinded randomized controlled trial, Vichainarong and colleagues evaluated the efficacy of an IPACK block added to local infiltration analgesia and continuous adductor canal block after TKA. A total of 72 patients were randomized to receive either LIA with CACB (control group) or IPACK block with LIA and CACB (intervention group). The primary outcome measure was cumulative intravenous morphine consumption in the first 24 hours post-operatively, as well as secondary outcomes of numerical pain scores, incidence of posterior knee pain, performance test results, patient satisfaction, LOS, and adverse effects. The results indicated no significant intergroup difference in terms of morphine consumption within 24 hours post-operatively (LIA+CACB; 1.31±1.85 mg versus iPACK+LIA+CACB; 0.61±1.25 mg, p=0.08). There were no clinically significant differences

in the overall pain scores between the groups, however, the lower Timed Up and Go test scores on postoperative days one and two, along with a shorter LOS, were found in the iPACK+LIA+CACB group ($p<0.05$). Researchers concluded that the addition of the IPACK to the LIA and CACB does not reduce postoperative opioid consumption nor improve analgesia, but it may improve immediate functional performance and reduce the LOS following TKA.

A systematic review and meta-analysis (Mou 2021) evaluated level one evidence to determine whether the IPACK block offered analgesic benefits to existing multimodal analgesia regimens. Data on a total of 467 patients who underwent total replacement (TKA) from five randomized controlled studies were included in the analysis. While four studies compared the difference between ACB+IPACK and ACB alone, only one assessed the difference between ACB+LIA+IPACK and ACB+LIA. The primary outcome of pain scores with rest and activity, as well as secondary outcomes of cumulative opioid consumption, cumulative distance ambulated, and length of stay (LOS) were compared between intervention and control groups. While the results indicated significantly improved pain scores with rest or activity at 12 hours post-operatively, no such benefit was observed at subsequent time points throughout the postoperative period. Additionally, IPACK supplementation did not reduced opioid consumption, especially in the first 24 hours after procedure, nor did it improve other secondary outcomes of distance ambulated or LOS. Authors noted heterogeneity among included studies as a limiting factor in conducting meta-analysis of additional secondary outcomes. Researchers concluded that the addition of IPACK block to multimodal analgesic regiments does not improve post-operative opioid consumption nor improve functional performance but may offer immediate analgesic benefit after TKR.

Guo et al (2022) conducted a systematic review and met analysis of the effectiveness of combining iPACK block (infiltration between the popliteal artery and capsule of the posterior knee) with adductor canal block (ACB) in managing postoperative pain after total knee arthroplasty (TKA). Included in this analysis were fourteen studies with a total of 758 patients. Primary outcome measures included the visual analog scale (VAS) for pain score, post operative pain measured at 8-hour phase, 12-hour phase, 24-hour phase, 48-hour phase, at discharge, including at rest and with activity. Postoperative morphine consumption, postoperative quadriceps strength, postoperative range of motion, postoperative walking distance, time up and go to (TUG) test, hospital stay, and the incidents of postoperative nausea and vomiting (PONV) were measured. VAS at rest and with activity were significantly lower in the ACB+iPACK group compared to ACB alone (at rest SMD=−0.75, 95%CI, with activity, SMD=−0.61). Postoperative cumulative morphine consumption was significantly reduced in the ACB+iPACK group (SMD: −0.33, 95%CI:95%. Range of motion improved at all measure time points (SMD: 7.69, 95%CI). Walking distance was better in ACB+iPACK group (SMD: 0.28, 95%CI. Overall TUG score improve performance was noted on post operative day1 and post operative day 2. Hospital stays were shorter in the ACB +iPACK group and there was no significant difference between group on quadricep muscle strength and incidence of postoperative nausea and vomiting. There were significant clinical and methodological heterogeneity in this study. Some experiments used general anesthesia while others used spinal anesthesia. There was discrepancy in the timing of nerve block administration. Some researchers performed nerve blocks prior to surgery while other performed after the surgery. The Egger test suggested some degree of publication bias in VAS scores at certain time points. Overall researchers concluded that adding iPACK to ACB improves

pain control, reduced opioid use, enhances functional recovery, and shortens hospital stays without increasing adverse effects in the management of pain after TKA.

PROFESSIONAL GUIDELINE(S)

American Academy of Orthopaedic Surgeons (AAOS) 2021 evidence-based clinical practice guideline for the management of osteoarthritis of the knee (Non-Arthroplasty) states denervation therapy may reduce pain and improve function in patients with symptomatic osteoarthritis of the knee (strength of recommendation: limited). The Denervation Therapy recommendation has been downgraded two levels because of inconsistent evidence and bias.

REGULATORY STATUS

Radiofrequency Ablation

The United States Food and Drug Administration (FDA) regulates radiofrequency ablative devices as medical devices. All radiofrequency ablative devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Jun 11]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2026 Jun 11]

There are several RF generators and probes that have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the Section 510(k) process. In 2005, the SInergy (Kimberly-Clark/Baylis), a water-cooled single-use probe, was cleared by the FDA, listing the Baylis Pain Management Probe as a predicate device. It is intended for use with an RF generator, to create RF lesions in nervous tissue.

In 2011, the NeuroTherm NT 2000 (NeuroTherm) was cleared for marketing by the FDA through the Section 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for use in lesioning neural tissue. Existing predicate devices included the NeuroTherm NT 1000, Stryker Multi-Gen, and Cosman G4 RF Generator.

In 2013, the Cryo-Touch IV (iovera; Myoscience) was cleared for marketing by the FDA through the Section 510(k) process. Predicate devices were the Cryo-Touch II and Cryo-Touch III.

In December 2016, the COOLIEF Cooled Radiofrequency Kit (Halyard Health Inc., Alpharetta, GA) was cleared by the FDA through the Section 510(k) process for the creation of RF heat lesions in nervous tissue for the relief of pain. The kit includes a fluid delivery system for commonly used fluid agents, limited to contrast medium, saline, and/or anesthetic solution delivery at the target site.

CODE(S)

- Codes may not be covered under all circumstances.

- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
64450 (E/I)	Injection(s), anesthetic agent(s), and/or steroid; other peripheral nerve or branch
64640 (E/I)	Destruction by neurolytic agent; other peripheral nerve or branch (when applied to genicular nerve(s))
64999	Unlisted procedure, nervous system
0441T (E/I)	Ablation, percutaneous, cryoablation, includes imaging guidance; lower extremity distal/peripheral nerve (when applied to genicular nerve(s))

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
M17.0-M17.9 (E/I)	Knee osteoarthritis (code range)
M25.561-M25.569 (E/I)	Pain in knee (code range)

REFERENCES

Ajrawat P, et al. Radiofrequency procedures for the treatment of symptomatic knee osteoarthritis: a systematic review. Pain Med. 2020 Feb 1;21(2):333-348.

Almeida M, et al. Efficacy and safety of minimally invasive interventions targeting the genicular nerves for knee osteoarthritis: A meta-analysis. Osteoarthritis Cartilage. 2025 May;33(5):535-547.

American Academy of Orthopedic Surgeons [Internet]. Evidence-based clinical practice guideline: management of osteoarthritis of the knee (non-arthroplasty). 2021 Aug 31 [accessed 2026 Jun 11]. Available from: https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-knee/oak3cpg.pdf

Chen AF, et al. Cooled radiofrequency ablation compared with a single injection of hyaluronic acid for

chronic knee pain: A multicenter, randomized clinical trial demonstrating greater efficacy and equivalent safety for cooled radiofrequency ablation. J Bone Joint Surg Am. 2020 Sep 2;102(17):1501-1510.

Chen AF, et al. Cooled radiofrequency ablation provides extended clinical utility in the management of knee osteoarthritis: 12-month results from a prospective, multi-center, randomized, cross-over trial comparing cooled radiofrequency ablation to a single hyaluronic acid injection. BMC Musculoskelet Disord. 2020 Jun 9;21(1):363.

Chen AF, et al. Thermal nerve radiofrequency ablation for the nonsurgical treatment of knee osteoarthritis: A systematic literature review. J Am Acad Orthop Surg. 2020 Jul 22. Online ahead of print.

Cheppalli N, et al. Safety and efficacy of genicular nerve radiofrequency ablation for management of painful total knee replacement: a Systematic Review. Cureus. 2021 Nov;13(11):e19489.

Dasa V, et al. Percutaneous freezing of sensory nerves prior to total knee arthroplasty. Knee. 2016 Jun;23(3):523-528.

Davis T, et al. Prospective, multicenter, randomized, crossover clinical trial comparing the safety and effectiveness of cooled radiofrequency ablation with corticosteroid injection in the management of knee pain from osteoarthritis. Reg Anesth Pain Med. 2018 Jan;43(1):84-91.

Davis T, et al. Twelve-month analgesia and rescue, by cooled radiofrequency ablation treatment of osteoarthritic knee pain: results from a prospective, multicenter, randomized, cross-over trial. Reg Anesth Pain Med. 2019 Feb 16. [Epub ahead of print]

El-Hakeim EH, et al. Fluoroscopic guided radiofrequency of genicular nerves for pain alleviation in chronic knee osteoarthritis: a single-blind randomized controlled trial. Pain Physician 2018 Mar;21(2):169-177.

Guo J, et al. iPACK block (local anesthetic infiltration of the interspace between the popliteal artery and the posterior knee capsule) added to the adductor canal blocks versus the adductor canal blocks in the pain management after total knee arthroplasty: a systematic review and meta-analysis. Orthop Surg Res. 2022 Aug 12;17(1):387.

Gupta A, et al. Comparative effectiveness review of cooled versus pulsed radiofrequency ablation for the treatment of knee osteoarthritis: a systematic review. Pain Physician. 2017 Mar;20(3):155-171.

Hunter C, et al. Cooled radiofrequency ablation treatment of the genicular nerves in the treatment of osteoarthritic knee pain: 18- and 24-month results. Pain Pract. 2020 Mar;20(3):238-246.

Khan D, et al. Clinically significant hematoma as a complication of cooled radiofrequency ablation of the genicular nerves; a case series. Pain Med. 2020 Nov 7;21(7):1513-1515.

Kolasinski SL, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the management of osteoarthritis of the hand, hip, and knee. Arthritis Rheumatol. 2020 Feb;72(2):220-233.

Konya ZY, et al. Results of genicular nerve ablation by radiofrequency in osteoarthritis-related chronic refractory knee pain. Turk J Med Sci. 2020 Feb 13;50(1):86-95.

McCormick ZL, et al. The safety of genicular nerve radiofrequency ablation. Pain Med. 2021 Feb 23;22(2):518-519.

Mihalko WM, et al. Cryoneruolysis before total knee arthroplasty in patients with severe osteoarthritis for reduction of postoperative pain and opioid use in a single center randomized controlled trial. J Arthroplasty. 2021 May;36(5):1590-98.

Mou P, et al. Analgesia effects of IPACK block added to multimodal analgesia regiments after total knee replacement Medicine. 2021 June;100(22) [Epub 2021 June 4].

Qudsi-Sinclair S, et al. A comparison of genicular nerve treatment using either radiofrequency or analgesic block with corticosteroid for pain after a total knee arthroplasty: a double-blind, randomized clinical study. Pain Pract. 2017 Jun;17(5):578-588.

Radnovich R, et al. Cryoneurolysis to treat the pain and symptoms of knee osteoarthritis: a multicenter, randomized, double-blind, sham-controlled trial. Osteoarthritis Cartilage Aug. 2017;25(8):1247-1256.

Roberts SL, et al. Review of knee joint innervation: implications for diagnostic blocks and radiofrequency ablation. Pain Med. 2020 May 1;21(5):922-938.

Santana-Pineda MM, et al. A Randomized controlled trial to compare analgesia and functional improvement after continuous neuroablative and pulsed neuromodulative radiofrequency treatment of the genicular nerves in patients with knee osteoarthritis up to one year after the intervention. Pain Medicine. 2021 Mar; 22(3): 637-652.

Shanahan, EM et al. Genicular nerve block for pain management in patients with knee osteoarthritis: a randomized placebo-controlled trial. Arthritis & Rheumatology. 2023 Feb;75(2): 201-209.

Vichainarong C, et al. Analgesic efficacy of infiltration between the popliteal artery and capsule of the knee (iPACK) block added to local infiltration analgesia and continuous adductor canal block after total knee arthroplasty: a randomized clinical trial. Reg Anesth Pain Med. 2020; 45:872-879.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Induced Lesions of Nerve Tracts (NCD 160.1) [accessed 2026 Jun 11]

Peripheral Nerve Blocks (L36850) [accessed 2026 Jun 11]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.

- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

MEDICAL POLICY

Medical Policy Title	**Pancreas Transplant: (Pancreas Transplant Alone, Pancreas Transplant after Kidney Transplant, Simultaneous Pancreas Kidney Transplant): Islet Cell Transplant**
Policy Number	**07.02.01**
Current Effective Date	**7/1/2026**
Next Review Date	**March 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

POLICY STATEMENT(S)

Pancreatic Transplant Alone (PTA)

I. Pancreas transplant alone (PTA) is considered **medically appropriate** for candidates who meet **ALL** the following indications:

   A. Insulin dependent diabetes mellitus (IDDM) that is difficult to manage (e.g., labile);

   B. A history of frequent, acute, and severe metabolic complications (e.g., hypoglycemia, hyperglycemia, ketoacidosis) requiring medical attention;

   C. Consistent failure of insulin-based management to prevent acute complications; **and**

   D. Do not have advanced kidney disease (stage IV or V).

Pancreas After Kidney Transplant (PAK)

II. Pancreas transplant after kidney transplant (PAK) is considered **medically appropriate** for candidates who meet **ALL** the following indications:

   A. Diagnosis of IDDM;

   B. Have had a previous successful kidney transplantation for uremia or kidney failure;

   C. A history of frequent, acute, and severe metabolic complications (e.g., hypoglycemia, hyperglycemia, ketoacidosis) requiring medical attention;

   D. Consistent failure of insulin-based management to prevent acute complications; **and**

   E. Does not have advanced kidney disease (stage IV or stage V).

Simultaneous Pancreas-Kidney Transplantation (SPK)

III. Simultaneous transplant of the pancreas is considered **medically appropriate** for candidates who meet **ALL** the following indications:

   A. For uremic IDDM individuals who have no immediate life-threatening conditions;

B. A history of frequent, acute, and severe metabolic complications (e.g., hypoglycemia, hyperglycemia, ketoacidosis) requiring medical attention; **and**

C. Consistent failure of insulin-based management to prevent acute complications.

IV. A second pancreas transplant after a failed primary transplant is considered **medically appropriate** in individuals who still meet transplant criteria.

V. Autologous islet cell transplantation is considered **medically appropriate** as an adjunct to a total or near-total pancreatectomy in individuals with chronic pancreatitis.

VI. Allogeneic pancreatic islet cell transplantation of a U.S. Food & Drug Administration (FDA) approved cellular therapy product i.e., donislecel-jujn, (Lantidra) is considered **investigational** for the treatment of type 1 diabetes.

VII. Recipient Selection Guidelines

A. Each individual considered for pancreas transplantation will have an evaluation completed by the transplant center for potential difficulties that would complicate and diminish the success of transplantation. Consideration will be given to the individual's risk of death without transplantation, along with the presence and severity of potential contraindications to transplantation. Candidates considered for transplant must be psychologically stable, demonstrate motivation and compliance, and have no ongoing problems with drug or alcohol abuse.

B. The following conditions are absolute contraindications to PTA, PAK, SPK and islet cell transplantation:

1. Presence of malignancy (other than non-melanomatous skin cancers), unless malignancy has been completely resected or unless (upon medical review) it is determined that malignancy has been treated, there is a small likelihood of recurrence, and acceptable future risks;
2. Ongoing or recurring infections that are not effectively treated;
3. Serious cardiac or other insufficiencies and an inability to tolerate transplant surgery;
4. Demonstrated non-compliance, which places the organ at risk by not adhering to medical recommendations;

C. Pancreas transplant is considered a relative contraindication in human immunodeficiency virus (HIV) positive individuals, unless **ALL** of the following criteria are met:

1. CD4 count is greater than 200 cells/mm3;
2. HIV-1 ribonucleic acid RNA is undetectable;
3. Stable anti-retroviral therapy for greater than three (3) months;
4. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections, Kaposi's sarcoma, or other

neoplasm);

5. Meets all other criteria for transplantation.

RELATED POLICIES

Corporate Medical Policy

07.02.04 Kidney Transplantation

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Segmental Living Donation Guidelines

A. Any person who gives consent to be a live organ donor should be competent, willing to donate, free from coercion, medically and psychologically suitable, fully informed of the risks and benefits as a donor, and fully informed of the risks, benefits, and alternative treatment available to the recipient. The benefits to both donor and recipient must outweigh the risks associated with the donation and transplantation of the living donor organ.

B. Prior authorization is contract dependent. Approval for all transplants, including arrangements with an approved transplant center, may be required.

C. The benefits of glycemic control must be weighed against the risks associated with transplant surgery and subsequent chronic immunosuppression. The individual must demonstrate motivation and ability for self-care and have failed to obtain diabetic control.

D. A pre-emptive cadaveric or living kidney transplant should be carefully considered when the measured (actual urinary collection) creatinine clearance level or calculated glomerular filtration rate (GFR) (or other reliable formula) is less than 30 ml/min and with a rapid rate of decline.

II. Pre-transplant evaluation documentation must include the following clinical information, and, if testing cannot be performed, the rationale for not performing the testing must be included in the documentation:

A. Clinical Evaluation:

1. Confirmation of diagnosis;
2. Identification of comorbidities;
3. Current assessment of co-morbidities;
4. Management of co-morbidities; **and**
5. Consult notes (if applicable);

B. Psycho-Social Evaluation:

1. Identification of stressors (e.g., family support, noncompliance issues, motivational issues, alcohol, or smoking/substance abuse).

C. Performance Status:

1. Karnofsky performance score;
2. Palliative Performance Scale (PPS) score;
3. Eastern Cooperative Oncology Group (ECOG) performance status; **or**
4. Lansky Play-Performance Scale (for age 1 to 16 years).

D. Oral Health Evaluation;

E. Lab Tests:

1. CBC, metabolic profile;
2. Serologies: CMV; Hepatitis B and C; **and**
3. HIV Testing.

F. Cardiac Assessment:

1. 12 Lead EKG;
2. Stress test (exercise, nuclear, or dobutamine); **and**
3. Echo or Muga Scan.

G. Pulmonary Assessment:

1. Chest X-ray;
2. Pulmonary function tests (PFTs); for high-risk of respiratory failure (COPD, emphysema, alpha-1 antitrypsin deficiency, hepatopulmonary syndrome, or significant smoking history).

H. Age-Appropriate Screening Tests: Please refer to the U.S Preventive Services Task Force (USPSTF) [Internet] for a list of age-appropriate screening guidelines (e.g., colorectal cancer screening, cervical cancer screening for guidance). [accessed 2025 Feb 18]. Available from: https://uspreventiveservicestaskforce.org/uspstf/

III. Re-Authorization

A. Transplant re-authorization must be completed annually while actively waiting for a transplant. Re-authorization documentation must be within the past 11 months (unless specified) and include the following clinical information (if testing is unable to be performed, the rationale must be included in the documentation). If the individual's health condition has not changed from the previous year some testing may not be applicable.

B. Clinical Evaluation:

1. Updated list of diagnoses to include identification of comorbidities, current assessment, and treatment plan;
2. Specialty consultation notes (if applicable);

C. Current functional ability as evidenced by current Karnofsky performance score (KPS), Palliative Performance Scale (PPS) score, ECOG, or Lansky Play-Performance Scale.

D. Follow- up Oral Health Evaluation

E. Lab Tests:

1. CBC, metabolic profile;
2. Serologies: CMV Hepatitis B and C; **and**
3. HIV testing (If applicable);

F. Cardiac Assessment:

1. 12 Lead EKG (If applicable);
2. Stress (exercise, nuclear, or dobutamine) (If applicable); and Echo or Muga scan (If applicable);

G. Pulmonary Assessment:

1. Chest X-ray (If applicable);
2. Pulmonary function tests (PFTs) for high-risk for respiratory failure (COPD, emphysema, alpha-1-antritrypsin deficiency, hepatopulmonary syndrome, or significant smoking history) (If applicable); **and**

H. Age-appropriate Screening Tests: Please refer to the USPSTF website for a list of age-appropriate screening guidelines (e.g., colorectal cancer screening, cervical cancer screening for guidance). [accessed 2026 Feb 25]. Available from: https://uspreventiveservicestaskforce.org/uspstf/

DESCRIPTION

Pancreas Transplant Alone (PTA)

A pancreas transplant is a surgical procedure that involves replacing a diseased or nonfunctioning pancreas with a healthy pancreas from a deceased or living donor. This procedure is primarily performed on individuals with IDDM who have had severe complications or are experiencing significant challenges in managing their blood sugar level. The benefits of a pancreas transplant can be not only lifesaving but can improve quality of life. A pancreas transplant can eliminate the need for insulin therapy, reduce the risk of diabetes related complications (neuropathy, retinopathy, and cardiovascular issues), and can help better manage blood sugar levels.

Pancreas after Kidney Transplant (PAK)

Pancreas transplant after a kidney transplant is a surgical procedure where a healthy pancreas is transplanted into an individual who has already received a kidney transplant. This approach is primarily aimed at individuals with IDDM who have undergone kidney transplantation and still struggle with severe diabetes management. The pancreas is usually transplanted in a separate surgical procedure after a kidney transplant has taken place.

Simultaneous Pancreas and Kidney Transplant (SPK)

A SPK is a surgical procedure that involves the transplantation of both a kidney and a pancreas during the same surgical session. This approach is primarily intended for individuals with IDDM and chronic kidney disease, or end stage renal failure. The goal is to restore kidney function, insulin production, reduce or eliminate the need for insulin therapy, improve blood glucose control and overall metabolic health. The surgeon connects the donor pancreas and kidneys to the recipient's blood vessels and urinary system. Often times, both transplanted organs may come from one deceased donor. It is also possible for the kidneys to come from a living donor (a family member or friend) and the pancreas from a deceased donor.

SPK is intended for individuals who have already developed end-stage diabetic nephropathy. The renal transplant is meant to be lifesaving, while the transplanted pancreas is indicated to slow, arrest, or reverse retinopathy or neuropathy. Additionally, the new pancreas may help the transplanted kidney function longer than if it had been transplanted without an accompanying pancreas.

Islet Cell Transplantation

Allogeneic pancreatic islet cell transplantation is a medical procedure in which islet cells (also called islets of Langerhans) are extracted from a deceased donor's pancreas using a specialized process. The extracted cells are then injected into the recipient's liver through the portal vein. The goal is for the transplanted islet cells to function in the liver and produce insulin. This procedure is primarily aimed at individuals with type 1 diabetes who have severe blood sugar control issues and cannot manage their condition with conventional therapies. The success of islet cell transplantation varies, with many recipients requiring insulin again within a few years after the transplantation.

There are inherent risks with all transplant surgeries, which include rejection of the new organ, infection, and complications from surgery. The individuals must take lifelong immunosuppressive medications to prevent organ rejection which can have side effects and increase the risk of infection. Transplant surgeries require careful medical management and continuous follow up to ensure the success of the transplant and overall health of the individual.

SUPPORTIVE LITERATURE

Pancreas Transplant

Parajuli et al (2019) described a single center's experience with 635 pancreas and kidney transplant individuals (611 SPK, 24 PAK). Transplants were performed between 2000 and 2016. The mean length of time between kidney transplant and pancreas transplant was 23.8 months in the PAK

group. Pancreas rejection rates at 1-year post-transplant were 4% and 9% with PAK and SPK, respectively. During the entire study period, PAK individuals were more likely to experience pancreas rejection (38% vs. 16%; p=.005). Kidney and pancreas graft survival rates did not differ between groups at 1 year or at last follow-up. Pancreas graft survival rates for PAK and SPK at 1 year were 100% and 89%, respectively. Death censored pancreas graft failure rates for PAK and SPK at last follow-up were 13% and 25%, respectively. Individual survival at last follow-up was similar between groups (71% with PAK vs. 68% with SPK; p=.79).

The FDA (2023) approved donislecel-jujn for the treatment of adults with type 1 diabetes who are unable to approach target HbA1C because of repeated episodes of severe hypoglycemia despite intensive diabetes management and education. The FDA approval was based on a phase 1/2 trial in individuals with brittle type 1 diabetes complicated by hypoglycemic unawareness, metabolic lability with documented severe hypoglycemia, or ketoacidosis despite intensive insulin therapy (N=10); a single-arm, open-label phase 3 trial with similar eligibility criteria (N=20); and an expanded access protocol with similar eligibility criteria.

In the FDA analysis of these trials (as described in the product labeling), median participant age was 46.5 years (range, 21 to 67 years); 80% of participants were female, 100% were White, and 97% were of non-Hispanic ethnicity. Individuals received up to 3 islet cell infusions; among 30 participants in the approval trials, 11 received 1 islet cell infusion, 12 received 2 infusions, and 7 received 3 infusions. Twenty-five participants (83%) achieved exogenous insulin independence (defined as not requiring exogenous insulin to achieve adequate glycemic control) of any duration, including 4 individuals (13.3%) with independence for less than 1 year, 12 individuals (36.7%) with independence for 1 to 5 years, and 9 individuals (33.3%) with independence for more than 5 years. Mean duration of exogenous insulin dependence in the phase 1/2 and phase 3 studies were 5.1 years and 3.2 years, respectively.

Serious adverse reactions were reported in 90%, including 2 deaths (7%) from multiorgan failure with sepsis (1.6 years after first infusion) and progressive confusion, global atrophy, and micro-ischemic disease (9.7 years after first infusion); most serious adverse reactions were attributed to immunosuppression. Infections were reported in 26 individuals (87%), totaling 211 episodes, one of which was classified as life-threatening and 22 as severe. Malignancy was reported in 11 subjects (37%), including 12 skin cancers and one each of post-transplant lymphoproliferative disease, breast cancer, and thyroid cancer. Common adverse events included, but were not limited to nausea, fatigue, anemia, diarrhea, abdominal pain, asthenia, headache, and hyponatremia. Most adverse reactions were low-grade by Common Terminology Criteria for Adverse Events, version 5; the most common grade ≥ 3 adverse events included low density lipoprotein elevations (37%), anemia (27%), and pneumonia (17%).

The FDA Biologics License Application Clinical Review Memorandum states numerous protocol deviations across the above studies that could impair the interpretation of both efficacy and safety data, as well as providing examples of missing and incongruent data and insufficient data monitoring during the study. The fact that the studies were conducted at a single site raises concern and other factors that might have affected occurrence or duration of insulin independence were not able to be

elucidated from the existing studies, including cell product factors (number of cells, viability, purity, and potency) and delivery device (e.g., type of catheter). Available from: https://www.fda.gov/vaccines-blood-biologics/lantidra [accessed 2026 Mar 19].

PROFESSIONAL GUIDELINE(S)

Current Organ Procurement and Transplantation Network (OPTN) policy permits HIV positive transplant candidates. The American Society of Transplantation (2019) published a guideline on solid organ transplantation in HIV-infected individuals for kidney-pancreas transplants, the following criteria for transplantation are suggested:

- Cluster of differentiation 4 count > 200 cells/mL for at least 3 months (insufficient data to recommend for or against transplantation in individuals with counts > 100 cells/mL and no history of opportunistic infection);
- undetectable HIV viral load while receiving antiretroviral therapy; documented compliance with a stable antiretroviral therapy regimen;
- absence of active opportunistic infection and malignancy;
- absence of chronic wasting or severe malnutrition; and appropriate follow-up with providers experienced in HIV management and ready access to immunosuppressive medication therapeutic drug monitoring (Blumberg et al 2019).

Effective March 15, 2021, the Organ Procurement and Transplantation Network (OPTN) has launched a new policy for matching kidney and pancreas transplant candidates with organs from deceased donors. The new policy is projected to increase equity in transplant access for candidates nationwide. It replaces distribution based on donation service area (DSA) and OPTN region with a more consistent measure of distance between the donor hospital and the transplant hospital for each candidate.

According to the 2021 American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) consensus report, β-cell replacement may serve as a therapeutic option for individuals who experience severe metabolic complications including severe hypoglycemia and hypoglycemia unawareness. Whole pancreas transplant and pancreatic islet transplantation both require lifelong immunosuppression. The ADA/EASD suggests carefully considering the risks versus benefit of β-cell replacement because of the need for chronic immunosuppression. The consensus report does note that these approaches have not been compared to newer closed-loop technology, which could avoid immunosuppression altogether.

The ADA addresses pancreas and islet transplantation in the Pharmacologic Approaches to Glycemic Treatment section of the 2026 Standards of Care in Diabetes stating that "successful pancreas and islet transplantation can normalize glucose levels and mitigate microvascular complications of type 1 diabetes, however, people receiving these treatments require lifelong immunosuppression to prevent graft rejection and/or recurrence of autoimmune islet destruction, and given the potential adverse effects of immunosuppressive therapy, pancreas transplant should be reserved for people with type 1

diabetes undergoing simultaneous kidney transplant, following kidney transplantation or for those with recurrent ketoacidosis or severe hypoglycemia despite optimized glycemic management."

REGULATORY STATUS

Organ transplants, as surgical procedures, do not require U.S. Food and Drug Administration (FDA) approval. The Health Resources Services Administration (HRSA) oversees the transplantation of vascularized human organs through the Organ Procurement and Transplantation Network (OPTN). For more information view the OPTN: https://www.hrsa.gov/optn [accessed 2026 February 27].

On June 28, 2023, the FDA approved Lantidra (donislecel-jujn), an allogeneic (donor) pancreatic islet cellular therapy. Lantidra was approved for the treatment of adults with type 1 diabetes who are unable to approach target glycosylated hemoglobin (average blood glucose levels) because of repeated episodes of severe hypoglycemia (low blood sugar) despite intensive diabetes management and education. The primary mechanism of action of Lantidra is the secretion of insulin by the infused allogeneic islet beta cells. In some individuals with type 1 diabetes, these infused cells can produce enough insulin, so the individual no longer needs to take insulin to control their blood sugar levels. Lantidra is administered as a single infusion into the hepatic (liver) portal vein. An additional infusion of Lantidra may be performed depending on the individual's response to the initial dose. A total of three infusions may be performed based on the individual's response. Lifelong immunosuppression is required to maintain islet cell viability.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
48160	Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells
48552	Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each
48554	Transplantation of pancreatic allograft
48556	Removal of transplanted pancreatic allograft
50340	Recipient nephrectomy (separate procedure)

Code	Description
50360	Renal allotransplantation, implantation of graft; without recipient nephrectomy
50365	with recipient nephrectomy
50370	Removal of transplanted renal allograft
0584T*	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; percutaneous (*E/I for Lantidra use)
0585T*	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; laparoscopic (*E/I for Lantidra use)
0586T*	Islet cell transplant, includes portal vein catheterization and infusion, including all imaging, including guidance, and radiological supervision and interpretation, when performed; open (*E/I for Lantidra use)

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HCPCS Codes

Code	Description
G0341*	Percutaneous islet cell transplant, includes portal vein catheterization and infusion (*E/I for Lantidra use)
G0342*	Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion (*E/I for Lantidra use)
G0343*	Laparotomy for islet cell transplant, includes portal vein catheterization and infusion (*E/I for Lantidra use)
S2102*	Islet cell tissue transplant from pancreas; allogeneic (*E/I for Lantidra use)

Code	Description
S2065	Simultaneous pancreas kidney transplantation

ICD10 Codes

Code	Description
E09.21-E09.29	Drug or chemical induced diabetes mellitus with diabetic nephropathy and kidney complications (code range)
E10.10-E10.9	Type 1 diabetes mellitus (code range)
E11.00-E11.9	Type 2 diabetes mellitus (code range)
E13.00-E13.29	Other specified diabetes mellitus with hyperosmolarity, or ketoacidosis, or kidney complications (code range)
E13.40-E13.59	Other specified diabetes mellitus with neurological or circulatory complications (code range)
E13.610-E13.9	Other specified diabetes mellitus with or without other specified complications, or without complications (code range)
M32.14	Glomerular disease in systemic lupus erythematosus
M32.15	Tubulo-interstitial nephropathy in systemic lupus erythematosus
M35.04	Sjogren syndrome with tubulo-interstitial nephropathy
N08	Glomerular disorders in diseases classified elsewhere
N16	Renal tubulo-interstitial disorders in diseases classified elsewhere
N18.1-N18.9	Chronic kidney disease (CKD) (code range)
T86.890-T89.899	Complications of other transplanted tissue (code range)

REFERENCES

American Diabetes Association Professional Practice Committee for Diabetes. 9. Pharmacologic approaches to glycemic treatment: standards of care in diabetes-2026. Diabetes Care. 2026;49(Suppl. 1):S183-S215.

Benjamens S, et al. A steady decline in pancreas transplantation rates. Pancreatology. 2019 Jan;19(1):31-38.

Blumberg EA, et al. American Society of Transplantation Infectious Diseases Community of Practice. Solid organ transplantation in the HIV-infected patient: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. Clin Transplant. 2019 Sep;33(9):e13499.

Esmeijer K, et al. Dutch Transplant Centers; Dutch Kidney Transplant Centres. Superior long-term

survival for simultaneous pancreas-kidney transplantation as renal replacement therapy: 30-year follow-up of a nationwide cohort. Diabetes Care. 2020 Feb;43(2):321-328.

Holt RIG, et al. The Management of Type 1 Diabetes in adults. a consensus report by the American Diabetes Association (ADA) and the European Association for the study of diabetes (EASD). Diabetes Care. 2021 Nov;44(11):2589-2625.

Jarmi T, et al. Comparing outcomes and cost between pancreas transplant and standard of care in patients with type 1 diabetes. Pancreas. 2022 May 1;51(5):483-489.

Jones JM, et al. Assessing solid organ donors and monitoring transplant recipients for human immunodeficiency virus, hepatitis B virus, and hepatitis C virus infection - U.S. Public Health Service Guideline, 2020. MMWR Recomm Rep. 2020 Jun 26;69(4):1-16.

Lombardo C, et al. Update on pancreatic transplantation in the management of diabetes. 2021 Aug 17. Endotext [Internet]. South Dartmouth (MA): MDText.com, Inc.; 2000.

Organ Procurement and Transplantation Network (OPTN). [Internet]. OPTN Policies. 2024 Dec 11; [accessed 2026 Jan 30] Available from: https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf

Parajuli S, et al. Outcomes after simultaneous kidney-pancreas versus pancreas after kidney transplantation in the current era. Clin Transplant. Dec 2019; 33(12).

Rickels MR, Robertson RP. Pancreatic islet transplantation in humans: Recent progress and future directions. Endocr Rev. 2019 Apr 1;40(2):631-668.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Pancreas Transplants (260.3) [accessed 2026 Feb 25]

NCD - Islet Cell Transplantation in the Context of a Clinical Trial (260.3.1) (cms.gov) [accessed 2026 Feb 25]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare

coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 2/26 **Revised**: 5/26 **Reviewed**:	
Date	**Summary of Changes**
7/1/2026* *No change to effective date for this update	• Annual review, no change to policy intent.
7/1/2026	• New

Policy/Procedure Name: Papzimeos (zopapogene imadenovec-drba) **Control Number: 1350/20.000582**

Disclaimer Notice

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If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Recurrent respiratory papillomatosis (RRP) is a rare disease caused by chronic human papillomavirus (HPV) infection that is characterized by wart-like growths (papillomas) in the respiratory tract that grows back after they have been removed. HPV is a common virus where 90% of infections clear or become undetectable within 2 years. HPV can be categorized into high-risk (HPV 16, 18, etc.) and low-risk (6, 11, etc.) subtypes. Persistent infection with high-risk HPV can result in malignant tumors. In RRP, approximately 90% of cases are caused by HPV 6 and 11 with HPV 16 and 18 causing the remaining.

RRP affects both adults and children and is transmitted through sexual contact or vaginal childbirth. RRP can be categorized as juvenile-onset or adult-onset. Juvenile-onset RRP (JORRP) is often diagnosed before 5 years of age and considered more aggressive and recurring while adult-onset RRP (AORRP) is diagnosed around 30-40 years of age. With the approval and increased utilization of the Gardasil-9 vaccine, the JORRP incidence rate decreased from 4 to 0.5 per 100,000 children. However, the vaccine has not made a significant impact in the adult population due to lack of utilization.

There are no guidelines addressing RRP and there are no approved therapies for RRP prior to Papzimeos (zopapogene imadenovec-drba). Standard of care is surgical debulking and debridement of papillomas. However, surgery does not address the underlying chronic HPV infection, resulting in the recurrence of papillomas. Disease severity varies significantly, with some cases resolving without treatment, other cases requiring only periodic intervention (e.g., a few surgeries throughout the patient's lifetime), and some aggressive cases requiring frequent medical intervention (e.g., multiple surgeries per year). The most common symptom is hoarseness, although patients can also experience difficulties speaking and breathing due to airway obstruction. Adjuvant therapies that decrease the size and growth of papillomas include intralesional cidofovir and intravenous (IV) bevacizumab.

Papzimeos is a nonreplicating adenoviral vector-based immunotherapy designed to express a fusion antigen of selected regions of human papillomavirus (HPV) proteins expressed in HPV 6- and 11-infected cells. Papzimeos stimulates an immune response to HPV 6 and HPV 11 proteins.

Papzimeos (zopapogene imadenovec-drba) was approved by the FDA as the first treatment option for RRP in adults on August 14, 2025. Approval was based on the results of phase 1/2 PRGN-2012-201, an open-label, single-arm study where patients received Papzimeos. Eighteen out of 35 patients (51%) in the efficacy population achieved a complete response (CR), defined as requiring no surgical intervention in the 12 months after treatment. Among the patients who achieved a CR, 15 maintained a CR at 24 months, for an overall CR rate of 43% at 24 months. Although HPV type was not noted as part of the trial inclusion or exclusion criteria, all patients in the PRGN-2012-201 trial had HPV type 6 or 11. Overall, fewer clinically indicated interventions were observed in the 12 months after treatment compared with the 12 months before treatment in 30 of 35 patients (86%); however, 34% of patients failed to achieve a complete response (CR) or partial response (PR).

Summary

Effective Date of Policy:	12/3/2025
Indications	Treatment of adults with recurrent respiratory papillomatosis
ICD10 Diagnosis Codes	There is currently no ICD-10 code for RRP
Availability	*Injection – 5 x 10^{11} particle unit/1 mL in a single dose vial*
Duration	12 weeks

Required Criteria for Initial Approval		
All of the following conditions for the requested indication must be met in order to approve therapy		
Indication	**Inclusion Criteria**	**Recommended Dosing Regimen**
Indication Recurrent respiratory papillomatosis (RRP)	1. Patient must be ≥ 18 years of age **AND** 2. Must be prescribed by, or in consultation with, a board-certified otolaryngologist (ENT), laryngologist, or head and neck surgical oncologist experienced in the management of recurrent respiratory papillomatosis (RRP) **AND** 3. Must have a diagnosis of histologically confirmed laryngotracheal recurrent respiratory papillomatosis (RRP) **AND** 4. Must have HPV serotype 6 or 11 positivity documented by PCR/ISH from airway lesions a. Archival tissue obtained from prior surgical debulking procedures is acceptable provided that the sample is representative of the current disease site and histology. Additionally, there must be no indication of a non-HPV-driven or transformed malignancy. 5. Documentation of eligible disease severity and prior treatment history must meet ONE of the following (a or b): a. ≥3 surgical interventions in the prior 12 months OR b. ≥2 surgical interventions in the prior 12 months with at least one of the following: i. Extensive anatomic involvement, such as multi-site laryngotracheal disease, pulmonary spread, or a Derkay total score ≥ 20 (or equivalent qualitative description of high burden) ii. Rapid recurrence requiring repeat surgery or visible regrowth within ≤ 12 weeks of prior debulking iii. Documentation of clinically significant functional impairment, confirmed by the treating ENT, as evidenced by: a) Airway compromise, such as, stridor, dyspnea, respiratory distress, or direct visualization of airway obstruction on laryngoscopy or bronchoscopy b) Severe dysphonia or voice dysfunction, supported by Voice Handicap Index (VHI-10) score in the severe range or equivalent	5×10^{11} particle unit (PU) per injection administered subcutaneously four times over a 12-week interval (initial dose, then 2, 6, and 12 weeks after the initial dose)

Exclusion Criteria

- Papzimeos will not be authorized for patients:
  - Currently receiving another investigational or systemic immunotherapy for RRP
  - With prior or concurrent use of investigational gene, cell, or immunotherapy for RRP
  - With a history of severe adverse reaction to adenoviral or other viral vector-based therapies (e.g., anaphylaxis, cytokine release syndrome, severe systemic inflammatory response)

Continuation Criteria
• Papzimeos is indicated for a one-time treatment cycle of 4 doses and therefore will not be authorized for retreatment. Retreatment will be considered experimental/investigational when any FDA approved gene therapy, or any other gene therapy under investigation, has been previously administered.

Considerations
• Prior authorization is obtained through the CDPHP pharmacy department.

References

		Updated	Accessed
1.	Papzimeos [package insert]. Germantown, MD: Precigen, Inc.; 2025	8/25	11/25
2	Papzimeos (zopapogene imadenovec-drba). New Drug Review. IPD Analytics.	9/25	11/25
3	Recurrent Respiratory Papillomatosis. National Organization for Rare Disorders. Available at: https://rarediseases.org/rare-diseases/recurrent-respiratory-papillomatosis/	6/23	11/25

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE ADVANTAGE:	Not applicable.
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 12/3/2025

New: 12/2025

Revised	Reviewed

Revision Date	Changes Made

This Pharmacy Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI), and Capital District Physicians' Healthcare Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

BEHAVIORAL HEALTH RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: PARTIAL HOSPITAL PROGRAMS (PHP) & INTENSIVE OUTPATIENT PROGRAMS (IOP)

POLICY EFFECTIVE DATE:	1/1/2023
Policy Control #:	1370/20.000459
Next Annual Review:	12/2026

DISCLAIMER

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PROCEDURE CODES

H0015, H0035, S9480

DESCRIPTION

Partial hospitalization is a non-residential treatment program for individuals diagnosed with a psychiatric disorder who require comprehensive, structured, multidisciplinary treatment in a medically-supervised environment. Clinical diagnostic and treatment services are provided at a level of intensity equal to an inpatient setting, but on a less than 24-hour basis. Partial hospitalization is used as a time-limited service to stabilize acute symptoms and may, therefore, be used as a transitional level of care (step-down from inpatient) or as a standalone service to stabilize a deteriorating condition to avert hospitalization.

An intensive outpatient program (IOPs) is a time-limited, non-residential, facility-based program that provides treatment to persons diagnosed with a psychiatric disorder. Such programs focus on building skills and developing community supports to assist an individual in obtaining a specific residential, learning, working, or social goal(s), and require more intensive services than those available in traditional outpatient settings. These programs are appropriate when the individual's clinical condition improves or stabilizes and a structured, comprehensive, multidisciplinary program is no longer required. Intensive outpatient programs are considered to

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be an intermediate level of care between individual outpatient and partial hospitalization. Intensive outpatient programs are used as a time-limited service to stabilize acute symptoms and may, therefore, be used as a transitional level of care (step-down from partial hospital programs) or as a standalone service to stabilize a deteriorating condition to avert hospitalization.

RELATED POLICIES/DOCUMENTS

N/A

POSITION STATEMENT

CDPHP administers benefits for partial hospitalization/intensive outpatient programs when used as an alternative to inpatient psychiatric treatment and/or alcohol/substance treatment in accordance with criteria outlined below.

Partial Hospital Programs

The partial hospitalization program (PHP) is primarily considered to be an alternative to an admission or continued stay for inpatient psychiatric and/or alcohol/substance care. The partial hospitalization program may also be used for a transitional period to facilitate re-entry into the community from an inpatient psychiatric and/or alcohol/substance facility. This level of care is only used for a transitional period when a lower level of care would be inappropriate due to the patient's dysfunction or potential for becoming a danger to self or to others.

All of the following criteria must be met:

- The enrollee is not a resident at the program.
- Enrollees are seen at least weekly by a psychiatrist.
- Services are provided on a daily basis, four to eight hours per day, five days a week.
- Services offered are designed to address a mental health and/or alcohol/substance related disorder through an individualized treatment plan provided by a coordinated multidisciplinary treatment team.
- The enrollee has the capacity for reliable attendance and active participation in the treatment plan.

Intensive Outpatient Programs

The intensive outpatient program (IOP) is primarily considered to be an alternative to an admission or continued stay for inpatient psychiatric and/or alcohol/substance care. The intensive outpatient program may also be used for a transitional period to facilitate re-entry into the community from an inpatient psychiatric and/or alcohol/substance facility. This level of care

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is only used for a transitional period when a lower level of care would be inappropriate due to the patient's dysfunction or potential for becoming a danger to self or to others.

All of the following criteria must be met:

- Services are provided on a daily basis, three to four hours per day, three days per week. Services offered include medication evaluation and management; individual, group, and family psychotherapy and psycho-education and adjunctive services such as medical monitoring.

EXCLUSIONS

N/A

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	Benefits are provided for intensive outpatient programs relating to substance abuse. Benefits for intensive outpatient and partial hospital programs relating to mental health are not available under the Child Health Plus benefit package. Benefits for partial hospital programs relating to substance abuse are not available under the Child Health Plus benefit package.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP:	Benefits are provided for partial hospitalization programs relating to mental health. • Services are provided on a daily basis, four to seven hours per day. Benefits for intensive outpatient programs for mental health are not available. Benefits for intensive outpatient and partial hospital programs relating to alcohol and substance use disorder are available.

SOURCES

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: PARTIAL HOSPITAL PROGRAMS (PHP) & INTENSIVE OUTPATIENT PROGRAMS (IOP)

1. Member contract language
2. Transition of Behavioral Health Benefit into Medicaid Managed Care and Health and Recovery Program Implementation, October 2015, NYS DOH OMH OASAS.
3. InterQual® (Version 2024) Adult and Geriatric Psychiatry, Partial Hospitalization Program Level of Care
4. InterQual® (Version 2024) Adult and Geriatric Psychiatry, Intensive Outpatient Program Level of Care
5. InterQual® (Version 2024) Substance Use Disorders, Partial Hospitalization Program Level of Care
6. InterQual® (Version 2024) Substance Use Disorders, Intensive Outpatient Level of Care
7. InterQual® (Version 2024) Child and Adolescent Psychiatry, Partial Hospitalization Program Level of Care
8. InterQual® (Version 2024) Child and Adolescent Psychiatry, Intensive Outpatient Program Level of Care

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Date 1/6/25

CDPHP Behavioral Health

POLICY APPROVAL DATES

New: 09/09

Revised: 09/11, 01/13, 01/14, 01/15, 05/16, 01/17, 01/19, 10/21, 4/22, 5/23

Reviewed: 01/11, 01/16, 01/18, 1/20, 1/21, 12/22, 12/23, 12/24, 4/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

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POLICY NAME: PARTIAL HOSPITAL PROGRAMS (PHP) & INTENSIVE OUTPATIENT PROGRAMS (IOP)

Effective Date	Update
1/1/2023	Updated clinical criteria from MCG to Interqual.
1/1/2022	Added code S9480 - Intensive outpatient psychiatric services, per diem.

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MEDICAL POLICY

Medical Policy Title	**Patient Lifts**
Policy Number	**1.01.08**
Current Effective Date	**January 1, 2027**
Next Review Date	**July 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.

(Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Patient lifts are considered **medically appropriate** as durable medical equipment (DME) when **ALL criteria in both A and B** are met:

   A. Periodic movement is necessary to effect improvement, or to stop, or delay deterioration in the individual's condition;

   B. **ALL** the following criteria are met:

      1. Transfer between bed and chair, wheelchair or commode requires the assistance of more than one (1) person;
      2. Without the use of the lift, the individual would be confined to bed;
      3. An adequately trained person, other than the individual, is available to help operate the lift; **and**
      4. A motorized lift (e.g., Sara lift) is appropriate for coverage only if a hydraulic lift (e.g., Hoyer lift) is inadequate to meet the special medical needs of the individual.

II. Seat lift chair mechanisms are considered **medically appropriate** as DME for:

   A. The individual who has either of the following conditions:

      1. severe arthritis of the hip or knee; **or**
      2. severe neuromuscular disease; **AND**

   B. Meets **ALL** of the following criteria:

      1. All appropriate therapeutic modalities to enable the individual to transfer from a chair to a standing position (e.g., medication, physical therapy) have been tried and failed;
      2. The individual is completely incapable of standing up from a regular armchair or any chair in his/her home; **and**
      3. Once standing the individual is able to ambulate.

III. Patient lifts/seat lift chair mechanisms containing nonstandard features (e.g., convenience or luxury features such as combination scale and lift) where there exists a reasonably feasible and

medically appropriate alternative standard care are considered **not medically necessary or ineligible for coverage** based upon the member's subscriber contract.

DME Repair

IV. Repair of a medically necessary patient lift or its components not under warranty will be considered **medically appropriate** when the following criteria are met:
    A. Physician documentation includes **ALL** of the following:
        1. Date of DME initiation;
        2. Manufacturer warranty information, if applicable;
        3. Attestation that the individual has been compliant with the use of the DME and will continue to benefit from the use of the DME;
    B. The DME is no longer functioning adequately; and **BOTH** of the following criteria are met:
        1. Inadequate function interferes with activities of daily living; **and**
        2. Repair is expected to make the equipment fully functional (as defined by manufacturer).
    C. Repair of equipment damaged due to individual neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

DME Replacement

V. Replacement of a medically necessary patient lift or its components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:
    A. The DME is no longer functioning adequately and has been determined to be non-repairable or the cost of the repair is in excess of the replacement cost; **or**
    B. There is documentation that a change in the individual's condition makes the present unit non-functional and improvement is expected with a replacement unit.

VI. The replacement of a properly functioning patient lift, its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or to make the DME more aesthetically pleasing;

VII. The replacement of equipment damaged or lost due to individual neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

VIII. Accessories or components for patient lifts that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

1.01.00 Durable Medical Equipment (DME) and Devices, –Standard and Non-Standard

POLICY GUIDELINE(S)

I. Nonstandard features that are presumptively nonmedical in nature and used primarily and customarily for a nonmedical purpose, even though the item may have some remote medically related use, will not be considered "medical equipment" and are **ineligible for coverage**.

II. The following patient lifts are **ineligible for coverage** because the devices do not meet the criteria for durable medical equipment:

   A. Bath lifts (bathroom or toilet);

   B. Ceiling lifts (patient lifts mounted on tracks attached to the ceiling);

   C. Platform lifts;

   D. Stair gliders;

   E. Stairway chair/stair lifts;

   F. Powered wheelchair lifts (provides access to stairways or car trunks);

   G. Van lifts (used to a lift wheelchair into a truck or van).

DESCRIPTION

Patient Lifts

Patient lifts or similar transfer devices are assistive devices that enable the movement and positioning of an immobilized Individual to and from a sitting and/or supine position. The Hoyer lift is a manual device that uses hydraulics. The Sara lift is motorized and portable.

Seat Lift Chair Mechanisms

A seat lift chair is a lounge chair that has a motorized seat mechanism which, when activated, lifts the body from a sitting to a standing position. The seat also can lower the body from a standing to sitting position. It is an assistive device for individuals who are able to ambulate once they are in a standing position.

Bathroom Lifts

A bathroom lift is a device with which the individual can be transferred from the toilet/tub to another seat. Some items may be placed in a tub for lifting the individual in and out of the tub but may not necessarily be attached to the toilet, ceiling, floor, or wall of the bathroom.

Ceiling Lifts

A ceiling lift (Zero Lifting) is a device that incorporates a lift or walking sling mounted on tracks that are installed into the ceiling of the home/facility and allow for transfer of an individual.

SUPPORTIVE LITERATURE

Not Applicable

PROFESSIONAL GUIDELINE(S)

Not Applicable

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates patient lifts as medical devices. All patient lifts including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Jun 11]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls on our website by the date that the FDA posts the information on our website. Available from: Medical Device Recalls | FDA [accessed 2026 Jun 11]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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HCPCS Codes

Code	Description
E0621	Sling or seat, patient lift, canvas or nylon
E0625 (NMN)	Patient lift, bathroom or toilet, not otherwise classified
E0627	Seat lift mechanism, electric, any type
E0629	Seat lift mechanism, nonelectric, any type
E0630	Patient lift, hydraulic or mechanical, includes any seat, sling, strap(s), or pad(s)
E0635	Patient lift, electric, with seat or sling
E0637	Combination sit-to-stand frame/table system, any size including pediatric, with seat lift feature, with or without wheels

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

Home Medical Equipment Answer Book, 2003 Edition.

St. Anthony's Medicare Reference Manual. 2001 Mar;60-8.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Durable Medical Equipment Reference List (280.1) [accessed 2026 Jun 11]

NCD - Seat Lift (280.4) [accessed 2026 Jun 11]

LCD - Patient Lifts (L33799) [accessed 2026 Jun 11]

LCD - Seat Lift Mechanisms (L33801) [accessed 2026 Jun 11]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

Policy/Procedure Name: Pharmaceutical Management of Pompe Disease **Control Number: 1350/20.000433**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Pompe Disease is a rare, hereditary (autosomal-recessive), progressive neuromuscular disorder characterized by acid alpha-glucosidase (GAA) enzyme deficiency and therefore glycogen accumulation in muscle cells. It was initially thought of as a muscular disorder, as the glycogen accumulation leads to progressive muscle weakness. Other organs and body systems can be affected, including the heart, liver, and nervous system, pinning it a multisystem disorder.

Infantile-onset Pompe Disease (IOPD) typically presents before the age of 12 months, usually within a few months of birth. There are two types of IOPD, Classic and Non-classic. Classic presentation occurs in the first few months of life (median four months) with cardiomyopathy, hypotonia, myopathy, hepatomegaly, and heart defects. Non-classical usually appears by age 1-2, and has the same symptoms as noted above. They may experience cardiomegaly, but affected individuals usually do not experience heart failure. In totality, clinical findings for IOPD include cardiomegaly, respiratory distress, and can include muscle weakness, feeding difficulties, and failure to thrive. The pharmacotherapeutic approach includes enzyme replacement therapies (ERT) to help improve and manage this disease.

Late-onset Pompe Disease (LOPD) may present at any age and do not develop cardiomyopathy. Symptoms of LOPD usually present as muscle weakness more pronounced in the proximal muscles of the lower extremities, back pain, fatigue, and muscle cramps. LOPD is diagnosed either through gene sequencing or assessment of GAA enzyme activity. Clinical findings include abnormally high creatinine kinase (CK), alanine aminotransferase (ALT), aspartate aminotransferase (AST), and lactate dehydrogenase levels alongside reduced leukocyte GAA activity. Urine tests can also be done to test for elevated urine Hex4. A tissue biopsy showing vacuolar myopathy with excessive glycogen accumulation and increased acid phosphatase staining can also be used. GAA enzyme activity assays or mutation analyses must be done as a confirmatory diagnosis procedure. Typical treatment for LOPD includes ERT, and studies have shown that ERT improves muscle strength, pulmonary function, and other symptoms.

Lumizyme was approved in 2010 for LOPD and in 2014 had a label expansion to include IOPD. It is a recombinant formulation of the human enzyme GAA and is considered ERT as it is thought to be replacing the deficient GAA therefore reducing accumulated glycogen in heart and skeletal muscles to ultimately reduce the manifestations of the disease. The safety and efficacy of alglucosidase alfa was assessed in 57 treatment-naive IOPD patients, aged 0.2 month to 3.5 years at first infusion, in three separate clinical trials.

One of the trials studied a primary endpoint of death or need for invasive ventilatory support and found 83% of those treated with alglucosidase were alive without ventilatory support at 18 months versus 2% in the historical comparator cohort. The third IOPD study was an open-label, single-center trial in 18 IOPD patients who had a confirmed diagnosis of Pompe disease as identified through a newborn screening program. All patients were CRIM-positive (residual GAA enzyme activity of at least 1%). Patients were treated with alglucosidase alfa prior to six months of age. Sixteen patients reached 18 months of age at the time of analysis, and all (100%) were alive without invasive ventilator support. Alglucosidase alfa therapy was studied in LOPD and did have some modestly positive findings in terms of stability of FVC (versus reductions in placebo) and 6MWT improvements. There are several warnings associated with therapy and they include anaphylaxis and hypersensitivity reactions, immune-mediated reactions, risk of acute cardiorespiratory failure, cardiac arrhythmias, and risk of antibody development.

Nexviazyme is an enzyme replacement therapy and hence is responsible for replacing deficient enzymes. Avalglucosidase alfa is an exogenous source of the deficient enzyme GAA that is responsible for glycogen cleavage. Avalglucosidase alfa contains mannose-6-phosphate (M6P), which are able to bind to M6P receptors on the cell surface, which then allows avalglucosidase alfa to be internalized and transported to lysosomes for glycogen cleavage. Therapy was studied in 100 participants who were randomly allocated to receive either avalglucosidase alfa (n-51) or alglucosidase alfa (n-49). Importantly non-inferiority was shown between treatment with avalglucosidase alfa compared with alglucosidase alfa at week 49 for the primary outcome (Change From Baseline in Percent Predicted Forced Vital Capacity [FVC] in Upright Position at Week 49). Secondary endpoints did show a difference in treatment with avalglucosidase such as improvements in the 6MWT over treatment with alglucosidase. In terms of safety concerns in the trial, there were 5 trial withdrawals subjects, all in the alglucosidase alfa group, four were due to adverse events, including two infusion-associated reactions. Serious treatment-emergent adverse events were reported in eight participants who received avalglucosidase alfa and in 12 who received alglucosidase alfa. One participant treated with alglucosidase alfa died because of acute myocardial infarction determined to be unrelated to treatment. Antidrug antibody responses were similar in both groups. High and persistent titres (≥ 12 800) and neutralizing antibodies were more common with

alglucosidase alfa (in 16 [33%] participants) than with avalglucosidase alfa (ten [20%]).

Pombiliti (cipaglucosidase alfa-atga) and Opfolda (miglustat) were approved in 2023, to be used only in combination, for the treatment of adults with LOPD who weigh ≥ 40 kg and are not improving on their current ERT. Opfolda is an oral enzyme stabilizer that is given 1 hour before the Pombiliti infusion. The PROPEL trial studied a total of 123 patients (77% ERT-experienced and 23% ERT-naïve) who were randomized to receive Pombiliti and Opfolda or alglucosidase alfa plus oral placebo. Patients were considered ERT-experienced if they were previously receiving alglucosidase alfa at 20 mg/kg every 2 weeks for ≥ 24 months. Patients treated with Pombiliti and Opfolda in the overall trial population walked on average 21 meters farther from baseline as compared to those treated with alglucosidase alfa product and placebo, who walked 8 meters farther from baseline. The estimated treatment difference of 14 meters was not statistically significant (95% CI: −1, 28). For the secondary outcome, patients treated with Pombiliti and Opfolda in the overall population showed a mean change in sitting forced vital capacity (FVC) from baseline at Week 52 of −1.1% as compared with patients treated with alglucosidase alfa and placebo of −3.3%. The estimated treatment difference of 2.3% was statistically significant (95% CI: 0.02, 4.62). In both the primary and secondary outcomes, when the populations were analyzed separately, the ERT-experienced patients treated with Pombiliti and Opfolda showed favorable changes at Week 52 compared with ERT-naïve patients. Based on this data, the FDA indication is for patients who are ERT-experienced.

Summary	
Effective Date of Policy:	2/12/2026
Indications	Early-onset Pompe Disease, Late-onset Pompe Disease
ICD10 Diagnosis Codes	E74.02
Availability	Lumizyme (J0220 & J0221): 50mg alglucosidase alfa as lyophilized powder in single dose vial Nexviazyme (J0219): 100mg vial for reconstitution Opfolda (miglustat): 65 mg oral capsule Pombiliti (J1203): 105 mg cipaglucosidase alfa-atga as lyophilized powder in single dose vial
Duration	Initial and Continuation: 12 months

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy.

Drug/Indication	Criteria	Recommended Dosing

Lumizyme (Alglucosidase alfa)
 	
Indication: Pompe Disease
(FDA approval)
ICD10: E74.02
	Infantile Onset Pompe Disease
	• Enrollee is ≤ 1 year of age
	• Must be prescribed by, or in consultation with, a physician experienced in metabolic or neuromuscular disorders
	• Enrollee has enzymatically confirmed diagnosis of Infantile Onset Pompe Disease through at least one of the following:
	  o two confirmed GAA gene mutations
	  o acid alpha-glucosidase (GAA) enzyme deficiency of <1% normal demonstrated from either a blood or tissue sample (must be confirmed positive and not indeterminate)
	• Enrollee has hypertrophic cardiomyopathy on echocardiogram
	
	Late-Onset Pompe Disease
	• Must be prescribed by, or in consultation with, a physician experienced in metabolic or neuromuscular disorders AND
	• The patient must have confirmed late-onset Pompe disease (LOPD) demonstrated by:
	  o Acid alpha-glucosidase (GAA) enzyme activity <40% of the laboratory's normal reference value AND
	  o At least one of the following:
	  ▪ Demonstration of deficient GAA enzyme activity from a second validated tissue or blood source (e.g., purified lymphocytes, fibroblasts or muscle)
	  ▪ Molecular genetic testing confirming two pathogenic GAA variants AND
		• 20 mg per kg body weight administered every two weeks as an intravenous infusion

	• The patient must demonstrate objective evidence of symptomatic neuromuscular involvement consistent with LOPD, including all of the following:
	  o Baseline percent-predicted forced vital capacity (FVC) between 30% and 80% AND
	  o Ability to walk ≥40 meters on a 6-minute walk test (6MWT) AND
	  o Documented lower extremity muscle weakness confirmed by validated motor assessment or neurological examination
	• The following baseline clinical measurements must be obtained within 90 days of initiating treatment
	  o Percent-predicted FVC (upright or supine)
	  o 6-minute walk test (6MWT) distance
	  o Ventilation status
	  ▪ Patients requiring invasive mechanical ventilation are excluded from coverage
	  o Current body weight
	• Lumizyme will not be approved for concurrent use with other enzyme replacement therapies for Pompe disease, except for brief transition periods when medically necessary.	

Nexviazyme (avalglucosidase alfa)
 	
Indication: Late-Onset Pompe Disease
(FDA approval)
ICD10: E74.02
	• Enrollee is ≥ 1 year of age
	• Must be prescribed by, or in consultation with, a physician experienced in metabolic or neuromuscular disorders AND
	• The patient must have confirmed late-onset Pompe disease (LOPD) demonstrated by:
	  o Acid alpha-glucosidase (GAA) enzyme activity <40% of the laboratory's normal reference value AND
	  o At least one of the following:
	  ▪ Demonstration of deficient GAA enzyme activity from a second validated tissue or blood source (e.g., purified lymphocytes, fibroblasts or muscle)
	  ▪ Molecular genetic testing confirming two pathogenic GAA variants AND
	• The patient must demonstrate objective evidence of symptomatic neuromuscular involvement consistent with LOPD, including all of the following:
	  o Baseline percent-predicted forced vital capacity (FVC) between 30% and 80% AND
	  o Ability to walk ≥40 meters on a 6-minute walk test (6MWT) AND
	  o Documented lower extremity muscle weakness confirmed by validated motor assessment or neurological examination
	• The following baseline clinical measurements must be obtained within 90 days of initiating treatment
	  o Percent-predicted FVC (upright or supine)
	  o 6-minute walk test (6MWT) distance
	  o Ventilation status
	  ▪ Patients requiring invasive mechanical ventilation are excluded from coverage
	  o Current body weight
	• Nexviazyme will not be approved for concurrent use with other enzyme replacement therapies for Pompe disease, except for brief transition periods when medically necessary.
		• Intravenous infusion dosed every two weeks
		• Weight ≥ 30 kg, the recommended dosage is 20 mg/kg (of actual body weight) every two weeks.
		• Weight < 30 kg, the recommended dosage is 40 mg/kg (of actual body weight) every two weeks.
		• See FDA prescribing information for important administration considerations

Pombiliti (cipaglucosidase alfa-atga) and Opfolda (miglustat)
 	
Indication: Late-Onset Pompe Disease
(FDA approval)
ICD10: E74.02
	• Enrollee is 18 years of age or older and weighs ≥ 40 kg
	• Must be prescribed by, or in consultation with, a physician experienced in metabolic or neuromuscular disorders AND
	• The patient must have confirmed late-onset Pompe disease (LOPD) demonstrated by:
	  o Acid alpha-glucosidase (GAA) enzyme activity <40% of the laboratory's normal reference value AND
	  o At least one of the following:
	  ▪ Demonstration of deficient GAA enzyme activity from a second validated tissue or blood source (e.g., purified lymphocytes, fibroblasts or muscle)
	  ▪ Molecular genetic testing confirming two pathogenic GAA variants AND
	• The patient must demonstrate objective evidence of symptomatic neuromuscular involvement consistent with LOPD, including all of the following:
	  o Baseline percent-predicted forced vital capacity (FVC) between 30% and 80% AND
	  o Ability to walk ≥40 meters on a 6-minute walk test (6MWT) AND
	  o Documented lower extremity muscle weakness confirmed by validated motor assessment or neurological examination
	• The following baseline clinical measurements must be obtained within 90 days of initiating treatment
	  o Percent-predicted FVC (upright or supine)
	  o 6-minute walk test (6MWT) distance
	  o Ventilation status
	  ▪ Patients requiring invasive mechanical ventilation are excluded from coverage
	  o Current body weight
	• Must have an inadequate response to Lumizyme (alglucosidase alfa) or Nexviazyme (avalglucosidase alfa-ngpt)
	• Pombiliti must be used in combination with Opfolda (miglustat)
	• Pombiliti and Opfolda will not be approved for concurrent use with other enzyme replacement therapies for Pompe disease, except for brief transition periods when medically necessary.
		Opfolda:
		• Weight 40 kg to 50 kg: 195 mg
		• Weight ≥ 50 kg: 260 mg
		• Taken orally 1 hour before Pombiliti infusion
		
		Pombiliti:
		20 mg per kg body weight administered every two weeks as an intravenous infusion

Continuation Criteria

Continued coverage requirements

1. Continuation approvals will be for 1 year at a time
2. Improvement in at least one of the following relative to baseline:
   a. Improvement or stabilization in percent-predicted FVC (same position as baseline required) **OR**
   b. Improvement or stabilization of 6MWT distance
3. For patients who have received more than 24 months of therapy, consideration for continued coverage may include documentation demonstrating mild or slow decline in the absence of improvement or stabilization requirements described above. Mild or slow disease progression is defined as:
   a. A decline in percent-predicted FVC of less than 2% per year (same position as baseline required)
   b. A decline in 6MWT distance of less than 30 meters per year
   c. A decline in one domain (percent-predicted FVC or 6MWT) and stability in the other

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.

References

		Updated	Accessed
	Nexviazyme [package insert]. Cambridge, MA: Genzyme Corporation;	9/2023	11/2024
	Diaz-Manera J, Kishnani P, Kushlaf H, et al. Safety and efficacy of avalglucosidase alfa versus alglucosidase alfa in patients with late-onset Pompe disease (COMET): a phase 3, randomized, multicenter trial. The Lancet: Neurology. 2021;20(12)1012-1026. doi:10.1016/s1474-4422(21)00241-6	12/2021	12/2021
	Vanherpe P, Fieuws S, D'Hondt A, et al. Late-onset Pompe disease (LOPD) in Belgium: clinical characteristics and outcome measures. Orphanet J Rare Dis. 2020;15(83). doi:10.1186/s13023-020-01353-4	04/2020	11/2023
	Toscano A, Rodolico C, Musumeci O. Multisystem late onset Pompe disease (LOPD): an update on clinical aspects. Ann Transl Med. 2019;7(13)284. doi:10.21037/atm.2019.07.24	07/2019	11/2023
	Dhillon S. Avalglucosidase alfa: first approval. Drugs. 2021;81:1803-1809. doi:10.1007/s40265-021-01600-3	10/2021	11/2023
	Nexviaxyme Clinical Trial Information: https://clinicaltrials.gov/ct2/show/study/NCT02782741	09/2021	11/2023
	Nexviaxyme Clinical Trial Information: https://clinicaltrials.gov/ct2/show/study/NCT03019406	11/2021	11/2023
	LUMIZYME (alglucosidase alfa) [package insert]. Cambridge, MA: Genzyme Corporation; 2020	3/2024	11/2024
	POMBILITI (cipaglucosidase alfa-atga) [package insert]. Philadelphia, PA: Amicus Therapeutics, Inc.; 2023	7/2024	11/2024
	OPFOLDA (miglustat) [package insert]. Philadelphia, PA: Amicus Therapeutics, Inc.; 2003.	7/2024	11/2024
	Pombiliti (cipaglucosidase alfa-atga) and Opfolda (miglustat) New Drug Review [Internet]. IPD Analytics. Oct 2023 [cited 2023 Nov 1]. Available from: https://ipdanalytics.com [subscription required].		11/2023

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE CHOICES: Lumizyme, Nexviazyme, and Pombiliti: Subject to the terms and conditions noted in above policy for those medications listed as a medical benefit when administered and provided by physician office, coverage will be provided as a medical benefit. All other medications for Medicare Advantage with Part D members listed are subject to coverage under the current Part D benefit and Medicare Advantage Part D formulary.

Opfolda (miglustat): Not applicable.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.
Opfolda: Not applicable. Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program.

CDPHP Pharmacy Services 2/12/2026

New: 2/2022

Revised	Reviewed
2/24, 2/26	2/23, 2/25

Revision Date	Changes Made
2/24	Added inclusion/exclusion criteria for new drug combination Pombiliti and Opfolda, updated name of policy to "Pharmaceutical Management of Pompe Disease"
2/2026	Separated out criteria for Infantile Onset Pompe Disease for Lumizyme Revised criteria for consistency of FVC and ventilation status Added 6MWT

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Policy/Procedure Name: Pharmaceutical Treatment of Amyotrophic Lateral Sclerosis **Control Number: 1350/20.000475**

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Background

Amyotrophic Lateral Sclerosis (ALS) is a rapidly progressive, invariably fatal neurological disease that affects around 16,000 people in the United States. It is characterized by motor neuron degeneration in the motor cortex and spinal cord that leads to progressive muscle weakness. Onset of symptoms is gradual, and the rate of progression varies from person to person. Eventually, all muscles under voluntary control are affected and individuals lose their strength and their ability to mobilize and speak; when muscles in the diaphragm and chest wall fail, the ability to breath without ventilator support will be lost. Respiratory failure is the leading cause of death in patients with ALS, and in the majority of cases occurs within three to five years of symptom onset; however, in roughly 10% of cases, patients survive for greater than 10 years.

The severity of ALS is evaluated using the ALS Functional Rating Scale Revised (ALSFRS-R). It contains 12 items across four subdomains of bodily function (bulbar, fine motor, gross motor, and breathing). Each item is scored from 0 (total loss of function) to 4 (no loss of function). Total scores range from 0 to 48 with higher scores indicating better function. Regarding the clinical significance of changes in score, a survey of 65 members of the Northeast ALS Consortium (NEALS) showed that ninety percent believed a 20% change in slope was somewhat clinically significant; all surveyed believed that a 25% change or higher in score was at least somewhat clinically meaningful; and ninety-three percent believed that a 50% change in score is *very* clinically meaningful.

While there is no cure for ALS, current treatments seek to modulate the course of the disease. These therapies include riluzole (Rilutek, Exservan, Teglutik), edaravone (Radicava, Radicava ORS), and tofersen (Qalsody).

Radicava (edaravone) is a free-radical scavenger of peroxyl radicals and peroxynitrite that has been shown to inhibit motor neuron death by reducing oxidative stress in animal models. The exact mechanism is Radicava is unknown. FDA approval came following a six-month clinical trial conducted in Japanese patients with ALS who were living independently. At baseline, characteristics of the treatment arm (n=69) and placebo arm (n=68) were similar, and 90% of patients in the trial were being treated with riluzole. At week 24, there was a statistically significant difference between the decline in ALSFRS-R score in the treatment group compared with the placebo group. In May 2022, an oral formulation of edaravone was approved by the FDA based on a bioavailability study. It should be noted that for the oral formulation, timing is important in regards to both the fasting period prior to the dose, and subsequent feeding/nutrition administered after the dose.

Qalsody (tofersen) is indicated for the treatment of ALS in adults who have a mutation in the SOD1 gene. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain (NfL) observed in patients treated with Qalsody. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

The efficacy of Qalsody was evaluated in the 28-week, double-blind, placebo-controlled Phase 3 VALOR study involving patients with weakness attributable to ALS and confirmed SOD1 mutation. A total of 108 patients were randomized to receive treatment with either Qalsody 100 mg (n=72) or placebo (n=36) for 24 weeks (3 loading doses followed by 5 maintenance doses).[10]

The primary analysis population (n=60, mITT) had SVC > 65% of predicted value and met criteria for rapid disease progression, defined by their pre-randomization ALSFRS-R decline slope and SOD1 mutation type. The primary efficacy analysis was change from baseline to Week 28 in the ALSFRS-R total score. While Qalsody demonstrated less decline in the ALSFRS-R compared to placebo at Week 28, the results were not statistically significant. The secondary endpoints of change from baseline at Week 28 in plasma NfL and cerebrospinal fluid (CSF) SOD1 protein were nominally statistically significant.

After the completion of the 28-week VALOR study, patients had the option to enroll in an open-label extension study. At the 52-week interim analysis, patients previously receiving placebo who initiated Qalsody saw reductions in Nfl, similar to those treated with Qalsody in the placebo-controlled period. Earlier initiation of Qalsody was associated with a trend for reduction in ALSFRS-R decline but was not statistically significant. In addition, earlier initiation of Qalsody was associated with a trend toward a reduction in the risk of death or permanent ventilation but was not statistically significant. It is noted in the Qalsody prescribing information that these results should be interpreted with caution given the limitations of data collected outside a controlled trial.

Summary	
Effective Date of Policy:	8/13/2026
Indications	G12.21 Amyotrophic lateral sclerosis (ALS)
Availability	Radicava: 30 mg/100 mL solution for injection (J1301) Radicava ORS: 105 mg/5 mL oral suspension in a multi-dose amber glass bottle Qalsody: Injection 100 mg/15 mL (6.7 mg/mL) solution in a single-dose vial (J1304)
Duration	Six months

Required Criteria for Approval	
All of the following conditions for the requested indication must be met in order to approve therapy:	
Specific Drug	**Criteria**
Radicava Amyotrophic Lateral Sclerosis (FDA approval) ICD10: G12.21	1. Must be greater than 18 years of age AND 2. Must be prescribed by or in consultation with a neurologist, or provider that specializes in Amyotrophiclateral sclerosis (ALS) AND 3. According to the prescriber, the patient must have a diagnosis of ALS that meets one of the following: a. "Definite" or "Probable" ALS as determined by revised El Escorial criteria or Awaji criteria (See appendix for criteria) OR b. Diagnosis of ALS in accordance with the Gold Coast Criteria (See appendix for criteria) AND 4. Must not have tracheostomy (trach) OR 5. For patients who have a trach, the provider must attest that the trach is for prevention of aspiration only 6. Radicava and generic edaravone will not be covered for any other non-FDA approved indication 7. Initial and recertification requests will be for 6 months at a time. Recertification requires provider attestation that: a. The patient continues to benefit from therapy AND b. The patient is not dependent on invasive ventilation or tracheostomy (unless the trach is for prevention of aspiration only). 8. Recommended Dosing: a. IV: 60mg administered as an IV infusion over 60 minutes. b. Oral Suspension: 105 mg (5 mL) taken orally or via feeding tube in the morning after overnight fasting. Food should not be consumed for 1 hour after administration except water. i. Initial treatment cycle: daily dosing for 14 days followed by a 14-day drug-free period ii. Subsequent treatment cycles: daily dosing for 10 days out of 14-day periods 9. Quantity limits for oral suspension: a. 50 mL bottle: 1 per 28 days b. 70 mL bottle: 1 per 365 days
Qalsody Amyotrophic Lateral Sclerosis (FDA approval) ICD10: G12.21	**<u>For all lines of business except Medicare Part B and D-SNP:</u>** 1. Must be prescribed by or in consultation with a neurologist, or provider that specializes in Amyotrophic Lateral Sclerosis (ALS) **AND** 2. Must be 18 years of age or older **AND** 3. Must have diagnosis of ALS with confirmed SOD1 mutation **AND** 4. Provider must attest that the patient has weakness attributable to ALS **AND** 5. Must not have tracheostomy (trach) **OR** 6. For patients who have a trach, the provider must attest that the trach is for prevention of aspiration only **AND** 7. Qalsody will not be covered for any other non-FDA approved indication 8. The recommended dosage is 100 mg (15 mL) of Qalsody per administration. Initiate Qalsody treatment with three (3) loading doses administered at 14-day intervals. Administer a maintenance dose every 28 days thereafter. 9. Initial and recertification will be for 6 months at a time. Recertification requires provider attestation that: a. The patient continues to benefit from therapy **AND** b. The patient is not dependent on invasive ventilation or tracheostomy (unless the trach is for prevention of aspiration only) 10. This indication is approved under accelerated approval based on reduction in plasma neurofilament light chain observed in patients treated with Qalsody. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s) **<u>Medicare Part B, and D-SNP Plans:</u>** Medicare reviews are to follow the Local Coverage Determination (LCD) for Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394). The LCD can be found on the CMS website at: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33394

Considerations

- Patient must have prescription drug coverage administered by CDPHP for those agents fulfilled through the prescription benefit.
- Prior authorization is obtained through the CDPHP pharmacy department.

Table 1. SOD-1 Mutations Identifying Fast-Progressors

p.Ala5Val	p.Ala5Thr	p.Leu39Val
p.Gly42Ser	p.His44Arg	p.Leu85Val
p.Gly94Ala	p.Leu107Val	p.Val149Gly

References

		Updated	Accessed
1	National Institute of Neurological Disorders and Stroke. Amyotrophic Lateral Sclerosis (ALS) Fact Sheet. Retrieved from: https://www.ninds.nih.gov/Disorders/Patient-Caregiver-Education/Fact-Sheets/Amyotrophic-Lateral-Sclerosis-ALS-Fact-Sheet#267654842.	7/17	1/25
2	ALS symptoms and diagnosis. The ALS Association. https://www.als.org/understanding-als/symptoms-diagnosis		1/25
3	Cedarbaum JM, Stambler N, Malta E, Fuller C, Hilt D, Thurmond B, et al. The ALSFRS-R: a revised ALS functional rating scale that incorporates assessments of respiratory function. J Neurol Sci. 1999; 169(1): 13–21.	10/99	1/25
4	Brooks BR, Miller RG, Swash M, Munsat TL. World Federation of Neurology Research Group on Motor Neuron D. El Escorial revisited: revised criteria for the diagnosis of amyotrophic lateral sclerosis. Amyotroph Lateral Scler Other Motor Neuron Disord. 2000; 1:293–9.	12/17	1/25
5	Miller RG, et al. Practice Parameter update: The care of the patient with amyotrophic lateral sclerosis: Multidisciplinary care, symptom management, and cognitive/behavioral impairment (an evidence-based review). American Academy of Neurology. Neurology 2009; 73:1227-1233.	10/19	1/25
6	Castrillo-Viguera C, Grasso DL, Simpson E, Shefner J, Cudkowicz ME. Clinical significance in the change of decline in Alsfrs-R. Amyotrophic Lateral Sclerosis. 2010;11(1-2):178-180. doi:10.3109/17482960903093710	2/10	1/25
7	The Writing Group on behalf of the Edaravone (MCI-186) ALS 19 Study Group. Safety and efficacy of edaravone in well-defined patients with amyotrophic lateral sclerosis: a randomised, double-blind, placebo controlled trial. Lancet Neurol 2017; 16:505–12.	5/17	1/25
8	Prescribing Information: Radicava and Radicava ORS. MT Pharma American Inc., Jersey City, NJ, 2022.	11/22	1/25
9	Firman G. El Escorial criteria for the diagnosis of amyotrophic lateral sclerosis (ALS). MedicalCRITERIA.com. https://medicalcriteria.com/web/neuroals/	2/09	1/25
10	Combined FDA and Applicant Briefing Document NDA# 216660. FDA. https://www.fda.gov/media/157186/download.	3/22	1/25
11	Makam AN, Suh K, Nikitin D, Carlson JJ, Richardson M, Mohammed R, McKenna A, Pearson SD, Rind DM. AMX0035 and Oral Edaravone for ALS; Final Evidence Report. Institute for Clinical and Economic Review, September 13, 2022	9/22	1/25
12	Miller T, Cudkowicz M, Shaw PJ, Andersen PM, et. al Phase 1-2 Trial of Antisense Oligonucleotide Tofersen for *SOD1* ALS. N Engl J Med. 2020 Jul 9;383(2):109-119. doi: 10.1056/NEJMoa2003715. PMID: 32640130.	9/20	1/25
13	Miller TM, Cudkowicz ME, Genge et. al. VALOR and OLE Working Group. Trial of Antisense Oligonucleotide Tofersen for *SOD1* ALS. N Engl J Med. 2022 Sep 22;387(12):1099-1110. doi: 10.1056/NEJMoa2204705. PMID: 36129998.	9/22	1/25
14	Prescribing information: Qalsody. Biogen MA Inc., Cambridge, MA, 2023.	4/23	1/25

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE CHOICES:	For Radicava ORS: Not applicable For Radicava intravenous injection and Qalsody (tofersen): Subject to all terms and conditions noted in above application.
SELECT/HARP PLAN:	Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program. Subject to all terms and conditions noted in above application if administered under the medical benefit.

CDPHP Pharmacy Services 8/13/2026

New: 4/2023

Revised	Reviewed
4/2024, 4/2025, 2/2026	

Revision Date	Changes Made
4/2024	Qalsody section • Therapy is being requested by a neurologist who specializes in motor neuron diseases • Updated Qalsody dosing and administration details
4/2025	Removed all information pertaining to Relyvrio as it has been removed from the market
2/2026	Updated Qalsody to not be medically necessary for Commercial lines of business
8/2026	Criteria for Commercial changed from "not medically necessary" to align with clinical criteria for Medicaid Managed Care (MMC) and Child Health Plus Updated Radicava criteria

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Policy/Procedure Name: Pharmaceutical Treatment of Spinal Muscular Atrophy **Control Number: 1350/20.000303**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to healthcare practitioners how to provide appropriate healthcare to their patients. Healthcare practitioners shall exercise their own medical judgment when deciding the most appropriate care for enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing healthcare services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Spinal muscular atrophy (SMA) is a rare and irreversible neurodegenerative disease that affects the spinal cord, specifically the alpha motor neurons in the anterior horn.[6] As a result, SMA causes progressive proximal motor weakness and atrophy and in severe cases, often resulting in early mortality. Critical muscle functions lost include walking, speaking, swallowing, and breathing, and the primary cause of death results from respiratory muscle weakness leading to severe restrictive lung disease and progressive respiratory failure.[1] Prevalence is estimated at 1-2 per 100,000 persons and incidence around 1 in 10,000 live births.

SMA is linked to chromosome 5q and is recessive, caused by bi-allelic mutations in the survival motor neuron 1 (SMN1) gene, which produces the SMN protein that is essential for motor neuron development. Specifically, the mutations include the homozygous deletion or deletion and mutation of the alleles of the SMN1 gene on chromosome 5q.[6] The survival motor neuron 2 (SMN2) gene also produces SMN protein; however, only a small portion of the protein produced is functional. The number of SMN2 copies is important in determining the severity of SMA; however, those without SMN1 have an insufficient level of SMN protein regardless of the SMN2 copies. Characteristics of the different types of SMA are described in the chart below.

SMA Type	Age at Onset of Symptoms	Peak Motor Function Achieved	Lifespan	Copies of SMN2
Type 0	Prenatal onset	None	< 6 months	1 copy
Type 1	< 6 months	Sitting with support	< 2 years	1–3 copies
Type 2	6–18 months	May sit independently	> 2 years	2–3 copies
Type 3	> 18 months	May walk independently	Into adulthood	3–4 copies
Type 4	Adult onset	Will walk independently through adulthood	Death as an adult	≥ 4 copies

Spinraza (nusinersen) is an intrathecal agent used in the treatment of spinal muscular atrophy (SMA), and is currently FDA-approved for SMA types 1, 2, 3, or 4. Spinraza has been studied in clinical trials involving subjects with SMA types 1, 2, and 3 with an age of up to 12 years old. Spinraza works by increasing exon 7 inclusion in SMN2 (survival motor neuron-2) messenger RNA transcripts and producing full-length SMN proteins. This leads to an improvement in motor function in the studied population. The recommended dosage of Spinraza is 12 mg (5 mL) administered intrathecally. There are four loading doses (with 12 mg per dose); the first three doses are separated by 14-day intervals, and the fourth loading dose is given 30 days after the third dose. Maintenance doses are administered as 12 mg every four months.

Evrysdi (risdiplam) is an oral agent used for the treatment of SMA that is FDA approved for the treatment of SMA in pediatric and adult patients. FDA approval was based on the results of the open-label FIREFISH trial, where patients with SMA type 1 aged one to seven months were studied, and the placebo-controlled SUNFISH trial that enrolled patients with SMA type 2 or non-abmulatory SMA type 3 aged 2 to 25 years. Evrysdi is a first in class SMN2 mRNA splicing modifier that increases the amount of full-length SMN proteins prouced by the SMN2 gene.

Isembyld (apitegromab-mstn) is an intravenous infusion used in the treatment of spinal muscular atrophy (SMA), and is currently FDA-approved in adults and pediatric patients 2 years of age and older who are currently receiving a survival motor neuron 2 (SMN2)-targeted treatment. Isembyld is a fully human monoclonal IgG4 antibody that binds to promyostatin and latent myostatin and inhibits the activation of myostatin, blocking myostatin signaling, thus promoting increased muscle mass and strength. Approval was based on the phase 3 52-week randomized, double-blind, placebo-controlled SAPPHIRE trial. At 12 months, least squares mean difference in HFMSE change [KM7.1]from baseline was 1.8 [KM8.1](95% CI 0.30 to 3.32, p=0.019) points for participants aged 2-12 years receiving apitegromab versus placebo (least squares mean 0·6 vs -1.2). There is a warning therapy may increase the risk of fractures. The most common adverse reactions were upper respiratory tract infections, vomiting, cough, other viral infections, headache, gastroenteritis, pharyngitis, and hypersensitivity.

Summary	
Effective date of policy:	10/8/2026
Indications	Spinal muscular atrophy
ICD10 diagnosis codes	G12.9
Availability	Spinraza: Single-use vials (12mg/5mL, 28 mg/5 mL, 50 mg/5 mL) Evrysdi: 0.75 mg/mL oral solution when reconstituted, 5 mg tablets Isembyld: 150 mg/3 mL (50 mg/mL) single-dose glass vial
Limitations	CDPHP administers benefits to enrollees for Spinraza (nusinersen) and Isembyld (apitegromab-mstn) only if the enrollee has a medical benefit CDPHP administers benefits to enrollees for Evrysdi (risdiplam) only if the enrollee has a pharmacy benefit

Required Criteria for Approval	
All of the following conditions for the requested indication must be met in order to approve therapy:	
Indication	Criteria for Approval
Spinraza (nusinersen) **Spinal muscular atrophy** (FDA approval) ICD10: G12.9 *Medical benefit* HCPCS: J2326	**For Commercial/Essential/ Child Health Plus/Medicare Advantage:** **1.** Must be prescribed by or in consultation with a provider who specializes in the treatment of Spinal Muscular Atrophy (SMA) and/or neuromuscular disorders **AND** 2. Must have a diagnosis of Type I, II, or III Spinal Muscular Atrophy a. Confirmed by targeted mutation analysis i. Homozygous deletions of SMN1 gene **OR** ii. Homozygous mutation in the SMN1 gene (e.g., biallelic mutations of exon 7) **OR** iii. Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 and mutation of SMN1) **AND** **3.** Must have genetic testing confirming 1, 2, 3, or 4 copies of the SMN2 gene **a.** If genetic testing confirms 4 copies of the SMN2 gene, Spinraza will only be approved if the patient is symptomatic **AND** **4.** The patient must not have advanced disease (e.g., complete limb paralysis or permanent ventilator dependence **AND** 5. Progress notes containing results of at least one of the following baseline exams must be submitted to establish baseline motor ability: a. Hammersmith Infant Neurological Exam (HINE) **OR** b. Hammersmith Functional Motor Scale Expanded (HFMSE) **OR** c. Upper Limb Module (ULM) Test/Revised Upper Limb Module Test (RULM) **OR** **d.** Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP- INTEND) **AND** **6.** There must be a proven contraindication to Evrysdi **a.** This requirement does not apply to Medicare Advantage **AND** **7.** Spinraza will not be approved for use in patients that have previously been treated with Zolgensma or Itvisma or in combination with Evrysdi or any other experimental therapy for spinal muscular atrophy **AND** **8.** Administration and Dose **a.** Spinraza must be administered in accordance with the current FDA-approved prescribing information. **b.** Low-Dose Spinraza will be required for all patients unless they meet the coverage criteria described in Spinraza High-Dose Criteria section below **c.** Both Low-Dose (12 mg) and High-Dose (28 mg maintenance) regimens must follow the labeled dosing schedule and monitoring requirements **AND** 9. Approval Timeframe and Recertification Requirements a. Approval Timeframe: 12-months b. Recertification Requirements i. Initial (12-months from treatment initiation), there must be documentation of ONE of the following: 1. Clinically meaningful response from pre-treatment baseline on at least one validated, age-appropriate SMA motor function scale: a. CHOP-INTEND: ≥ 4-point improvement from baseline b. HINE-2: Improvement in ≥ 1 motor milestone category without worsening

in any category
- c. HFMSE: ≥ 3-point improvement from baseline
- d. ULM/RULM: ≥ 2-point improvement from baseline **OR**

2. The patient has achieved or maintained a motor milestone not expected based on natural history (e.g., independent sitting, standing, ambulation, head control) **OR**
3. For patients with advanced disease at baseline (HFMSE ≤ 10 or CHOP-INTEND ≤ 20), there must be documentation of stabilization of motor function **AND** at least ONE of the following: respiratory stabilization (no new requirement for permanent ventilation), bulbar stabilization (no new requirement for enteral feeding), or preservation of a functionally meaningful motor ability as attested by the treating specialist.

ii. Continued (every 12-months after initial response has been established), there must be documentation of ongoing clinically meaningful therapeutic benefit, defined as meeting at least ONE of the following:
1. No decline exceeding the minimal clinically important difference (MCID) threshold for clinically meaningful deterioration on the primary motor scale used for monitoring (HFMSE: > 3-point decline; CHOP-INTEND: > 4-point decline; RULM: > 2-point decline), OR no loss of a previously achieved motor milestone.
2. Further improvement on a validated motor scale from the most recent assessment.
3. Documentation that the patient's disease course is meaningfully altered relative to the expected natural history for their SMA type, SMN2 copy number, and disease duration. This may include but is not limited to:
- a. Preservation of respiratory function (stable ventilatory support requirements; no progression to permanent invasive ventilation)
- b. Preservation of bulbar function (stable nutritional support requirements)
- c. Maintenance of functional independence in activities of daily living
- d. Slowed rate of motor decline relative to published natural history data

<u>For Medicaid/HARP:</u>

1. Must be prescribed by or in consultation with a provider who specializes in the treatment of Spinal Muscular Atrophy (SMA) and/or neuromuscular disorders AND
2. Must have a diagnosis of Type I, II, or III Spinal Muscular Atrophy
   - a. Confirmed by targeted mutation analysis
     - i. Homozygous deletions of SMN1 gene OR
     - ii. Homozygous mutation in the SMN1 gene (e.g., biallelic mutations of exon 7) OR
     - iii. Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 and mutation of SMN1) AND
3. The patient must not have advanced disease (e.g., complete limb paralysis or permanent ventilator dependence AND
4. Progress notes containing results of at least one of the following baseline exams must be submitted to establish baseline motor ability:
   - a. Hammersmith Infant Neurological Exam (HINE) OR
   - b. Hammersmith Functional Motor Scale Expanded (HFMSE) OR
   - c. Upper Limb Module (ULM) Test/Revised Upper Limb Module Test (RULM) OR
   - d. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP- INTEND) AND
5. Spinraza will not be approved for use in patients that have previously been treated with Zolgensma or Itvisma or in combination with Evrysdi or any other experimental therapy for spinal muscular atrophy AND
6. Administration and Dose
   - a. Spinraza must be administered in accordance with the current FDA-approved prescribing information.
   - b. Low-Dose Spinraza will be required for all patients unless they meet the coverage criteria described in Spinraza High-Dose Criteria section below
   - c. Both Low-Dose (12 mg) and High-Dose (28 mg maintenance) regimens must follow the labeled dosing schedule and monitoring requirements AND
7. Approval Timeframe and Recertification Requirements
   - a. Approval Timeframe: 12-months

	b. Recertification Requirements i. Initial (12-months from treatment initiation), there must be documentation of ONE of the following: 1. Clinically meaningful response from pre-treatment baseline on at least one validated, age-appropriate SMA motor function scale: a. CHOP-INTEND: ≥ 4-point improvement from baseline b. HINE-2: Improvement in ≥ 1 motor milestone category without worsening in any category c. HFMSE: ≥ 3-point improvement from baseline d. ULM/RULM: ≥ 2-point improvement from baseline OR 2. The patient has achieved or maintained a motor milestone not expected based on natural history (e.g., independent sitting, standing, ambulation, head control) OR 3. For patients with advanced disease at baseline (HFMSE ≤ 10 or CHOP-INTEND ≤ 20), there must be documentation of stabilization of motor function AND at least ONE of the following: respiratory stabilization (no new requirement for permanent ventilation), bulbar stabilization (no new requirement for enteral feeding), or preservation of a functionally meaningful motor ability as attested by the treating specialist. ii. Continued (every 12-months after initial response has been established), there must be documentation of ongoing clinically meaningful therapeutic benefit, defined as meeting at least ONE of the following: 1. No decline exceeding the minimal clinically important difference (MCID) threshold for clinically meaningful deterioration on the primary motor scale used for monitoring (HFMSE: > 3-point decline; CHOP-INTEND: > 4-point decline; RULM: > 2-point decline), OR no loss of a previously achieved motor milestone. 2. Further improvement on a validated motor scale from the most recent assessment. 3. Documentation that the patient's disease course is meaningfully altered relative to the expected natural history for their SMA type, SMN2 copy number, and disease duration. This may include but is not limited to: a. Preservation of respiratory function (stable ventilatory support requirements; no progression to permanent invasive ventilation) b. Preservation of bulbar function (stable nutritional support requirements) c. Maintenance of functional independence in activities of daily living d. Slowed rate of motor decline relative to published natural history data
Spinraza (nusinersen) High-Dose **Spinal muscular atrophy** (FDA approval) ICD10: G12.9 *Medical benefit* HCPCS: J2326	Criteria Applies to all LOB. The patient must meet **ONE** of the following (1, 2, or 3): 1. The patient must have severe Type 1 disease (defined as symptom onset ≤ 6 months or ≤ 2 SMN2 copies) **OR** 2. The patient is currently receiving the Low Dose Regimen for Spinraza for an adequate trial period (≥ 12 months) with documentation of plateau or declining function a. Plateau or declining function on the Low Dose Regimen is defined as any of the following: i. Failure to achieve meaningful improvement from pre-treatment baseline, defined as (1) < 4-point improvement on CHOP-INTEND (2) < 3-point improvement on HFMSE (3) < 2-point improvement on ULM/RULM ii. Clinically meaningful decline exceeding expected natural disease progression assessed over a 12-month time period, defined as: (1) ≥ 4 points decline on CHOP-INTEND (2) ≥ 3 points on HFMSE (3) ≥ 2 points on ULM/RULM (4) Loss of a previously achieved motor milestone (per HINE-2 criteria) iii. New requirement for respiratory support (BiPAP, CPAP, or mechanical ventilation) not present at treatment initiation iv. New requirement for nutritional support (G-tube or NG tube) not present at treatment

	initiation 3. For patients currently receiving the Low Dose Regimen for ≥ 12 months who are clinically stable (i.e., does not meet for coverage for plateau or declining function), coverage requires at least **ONE** of the following features considered high-risk for rapidly progressive disease: a. The patient has bulbar dysfunction as evidenced by dysphagia, weak suck/swallow, aspiration risk, feeding difficulty, or need for NG/G-tube nutritional support b. The patient has respiratory insufficiency as evidenced by need for BiPAP, CPAP, invasive ventilation, cough-assist dependence, recurrent respiratory decompensation, or clinically significant decline in pulmonary status attributable to SMA 4. The following patients do not qualify for coverage of the High Dose Regimen: a. Patients that are clinically stable on Low Dose Regimen for > 12 months **AND** do not have a high-risk feature for rapidly progressive disease 5. Approval Timeframe and Recertification Requirements a. For patients initiating treatment directly on the High-Dose Regimen (e.g., treatment naïve severe Type I disease) should follow the Approval Timeframe and Recertification Requirements described in the Spinraza Coverage Criteria section. b. For patients transitioning from the Low-Dose Regimen to the High-Dose Regimen after prior Spinraza exposure, recertification following the first 12 months of High-Dose therapy requires documentation of at least ONE of the following: i. Improvement on a validated motor function scale relative to status at High-Dose initiation ii. Stabilization of previously declining motor function relative to the period immediately preceding High-Dose initiation iii. Preservation of previously achieved motor milestones iv. Preservation or stabilization of respiratory function (e.g., no progression in ventilatory support requirements) v. Preservation or stabilization of bulbar function (e.g., no progression in nutritional support requirements) vi. Documentation from the treating specialist that the patient's disease trajectory has been meaningfully altered relative to the clinical course observed prior to High-Dose initiation vii. Following establishment of response to the High-Dose Regimen, patients should meet the Continued Recertification Requirements described in the Spinraza Coverage Criteria section.
Evrysdi (risdiplam) **Spinal muscular atrophy** (FDA approval) ICD10: G12.9 *Rx Benefit*	1. Must be prescribed by or in consultation with a provider who specializes in the treatment of Spinal Muscular Atrophy (SMA) and/or neuromuscular disorders AND 2. Must have a diagnosis of Type I, II, or III Spinal Muscular Atrophy a. Confirmed by targeted mutation analysis i. Homozygous deletions of SMN1 gene OR ii. Homozygous mutation in the SMN1 gene (e.g., biallelic mutations of exon 7) OR iii. Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 and mutation of SMN1) AND 3. Must have genetic testing confirming 1, 2, 3, or 4 copies of the SMN2 gene a. If genetic testing confirms 4 copies of the SMN2 gene, Evrysdi will only be approved if the patient is symptomatic AND 4. The patient must not have advanced disease (e.g., complete limb paralysis or permanent ventilator dependence) AND 5. Progress notes containing results of at least one of the following baseline exams must be submitted to establish baseline motor ability: a. Hammersmith Infant Neurological Exam (HINE) OR b. Hammersmith Functional Motor Scale Expanded (HFMSE) OR c. Upper Limb Module (ULM) Test/Revised Upper Limb Module Test (RULM) OR d. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP- INTEND) OR

e. Motor Function Measure 32 (MFM32) OR
f. Bayley Scales of Infant and Toddler Development- Third Edition gross motor scale (BSID-III) (For Infantile-Onset disease only) AND

6. Evrysdi will not be approved for use in patients that have previously been treated with Zolgensma or Itvisma and will not be approved in combination with Spinraza or any other experimental therapy for spinal muscular atrophy **AND**
7. Approved Daily Dosing
    a. Less than 2 months of age: 0.15 mg/kg of Evrysdi Oral Solution
    b. 2 months to less than 2 years of age: 0.20 mg/kg of Evrysdi Oral Solution
    c. 2 years of age and older weighing less than 20 kg: 0.25 mg/kg of Evrysdi Oral Solution
    d. 2 years of age and older weighing 20 kg or more: 5 mg of Evrysdi Oral Solution or Evrysdi Tablet
8. Quantity Limit
    a. Oral Solution: 80 mL per 30 days
        i. The allowed quantity will be reviewed at each authorization request in accordance with the FDA-approved weight-based dosing regimen. Coverage will be limited to the minimum number of 80 mL (60 mg) bottles necessary to deliver the patient's prescribed daily dose for the approved supply period, accounting for the 64-day in-use expiration of the constituted oral solution.
        ii. To accommodate anticipated pediatric weight gain between reviews, a volume buffer may be applied to the calculated quantity based on the patient's age:
            1. Infants < 2 months: 25%
            2. Infants/Toddlers 2 months to < 2 years: 15%
            3. Children ≥ 2 years and < 20 kg: 10%
            4. Patients ≥ 20 kg: no volume buffer required due to fixed 5 mg/day dose
    b. Tablet: 30 tablets per 30 days
9. Initial and continued approval will be at 12-month intervals. Subsequent approval will require documentation of positive response to therapy from pretreatment baseline status as evidenced by at least one of the following exams:
    a. HINE milestones:
        i. One of the following:
            1. Improvement or maintenance of previous improvement of at least 2 points (or maximal score) increase in ability to kick **OR**
            2. Improvement or maintenance of previous improvement of at least 1-point increase in any other HINE milestone (e.g., head control, rolling, sitting, crawling, etc.)
    b. HFMSE:
        i. One of the following:
            1. Improvement or maintenance of previous improvement of at least a 3- point increase in score from pretreatment baseline **OR**
            2. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to doso
    c. ULM/RULM:
        i. One of the following:
            1. Improvement or maintenance of previous improvement of at least a 2- point increase in score from pretreatment baseline **OR**
            2. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to doso
    d. CHOP-INTEND
        i. One of the following:
            1. Improvement or maintenance of previous improvement of at least a 4- point increase in score from pretreatment baseline **OR**
            2. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to doso
    e. MFM32
        i. One of the following:
            1. Improvement or maintenance of previous improvement of at least a 3-point or greater change from pretreatment baseline **OR**

	2. Patient has achieved and maintained any new motor milestone from pretreatment baseline when they would otherwise be unexpected to doso f. BSID-III i. Infantile-onset disease **AND** ability to sit without support for at least 5 seconds (BSID-III, Item 22)
Isembyld (apitegromab-mstn) **Spinal muscular atrophy** (FDA approval) ICD10: G12.9 *Medical benefit*	**Isembyld (apitegromab-mstn) for Commercial/Exchange/Essential Plan/Child Health Plus:** Based on a review of the available peer-reviewed evidence, Isembyld (apitegromab-mstn) is considered not medically necessary for the treatment of Spinal Muscular Atrophy (SMA). Apitegromab was studied in the multicenter phase 2 (NCT03921528) TOPAZ trial in patients with Type 2 or 3 SMA on nusinersen or no SMA therapy. This trial demonstrated the lack of efficacy in ambulatory patients and older non-ambulatory patients aged 5-21 based on the mean change from baseline in the Revised Hammersmith Scale (RHS) of -0.3 points in the ambulatory cohort (±2 points representing minimal detectable change) and Hammersmith Functional Motor Scale Expanded of 0.6 points in the older non-ambulatory cohort (approximately 3-4 point change represents clinically meaningful change). The Phase 3, 52-week double-blind, placebo-controlled SAPPHIRE trial (NCT05156320) studied apitegromab at 10 mg/kg and 20 mg/kg dosing in non-ambulatory patients age 2-21 with types 2 or 3 SMA on background nusinersen or risdiplam therapy. At 12 months, the primary endpoint least squares mean difference in HFMSE change from baseline was 1.8 (95% CI 0.30 to 3.32, p=0.019) points for participants aged 2-12 years receiving apitegromab versus placebo (least squares mean 0·6 vs -1.2). This does not meet the 3-4 point range that represents a clinically meaningful change. The secondary endpoint of least squares mean difference in HFMSE change from baseline in the 10 mg/kg group was 2.2 (95% CI 0.49 to 3.95); however, subgroup analyses had mixed results depending on nusinersen vs. risdiplam use, age, and region. Spinal Muscular Atrophy is a rare, progressive neuromuscular disorder with both pharmacologic as well as gene therapies available. Therefore, disease rarity, unique mechanism, and unmet needs were not considered sufficient to resolve the uncertainty regarding the clinical meaningfulness of the demonstrated incremental benefit. <u>Reconsiderations of Medical Necessity</u> This determination will be reevaluated when new evidence materially addresses the uncertainty regarding the clinical meaningfulness of apitegromab's treatment-attributable benefit. Evidence that may support reconsideration includes: • Replication or confirmation of clinically meaningful responder benefit in an additional adequately designed study • Demonstration of sustained benefit beyond the currently established 52-week controlled treatment period • Comparative or add-on evidence demonstrating clinically meaningful incremental benefit relative to established therapies **Isembyld (apitegromab-mstn) for Medicare Advantage/Medicaid Managed Care (MMC)/Health and Recovery Plans (HARP):** 1. Must be prescribed by or in consultation with a provider who specializes in the treatment of Spinal Muscular Atrophy (SMA) and/or neuromuscular disorders 2. Must be ≥ 2 years of age 3. Must have a diagnosis of Type II, or III Spinal Muscular Atrophy a. Confirmed by targeted mutation analysis i. Homozygous deletions of SMN1 gene OR ii. Homozygous mutation in the SMN1 gene (e.g., biallelic mutations of exon 7) OR iii. Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 and mutation of SMN1) 4. Must have genetic testing confirming 2, 3, or 4 copies of the SMN2 gene, consistent with Type II or III SMA 5. The patient must not have advanced disease (e.g., complete limb paralysis or permanent ventilator dependence)

6. Progress notes containing results of at least one of the following baseline exams must be submitted to establish baseline motor ability:
    a. Hammersmith Infant Neurological Exam (HINE) OR
    b. Hammersmith Functional Motor Scale Expanded (HFMSE) OR
    c. Upper Limb Module (ULM) Test/Revised Upper Limb Module Test (RULM) OR
    d. Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP-INTEND) OR
    e. Motor Function Measure 32 (MFM32)
7. Must be non-ambulatory (Non-ambulatory patients must be able to sit independently (sits up straight with head erect for at least 10 seconds; does not use arms or hands to balance body or support position) per World Health Organization (WHO) motor milestones definition)
8. Must be on one background therapy for SMA (i.e., either nusinersen or risdiplam)
    a. If on Spinraza (nusinersen), patient must be currently receiving Spinraza for an adequate trial period (≥ 12 months)
        i. If patient was escalated to high dose Spinraza (nusinersen), patient must be currently receiving high dose Spinraza for an adequate trial period (≥ 12 months)
    b. If on Evrysdi (risdiplam), patient must be currently receiving Evrysdi for an adequate trial period (≥ 12 months)
9. Isembyld must be administered in accordance with the current FDA-approved prescribing information at a dose of 10 mg/kg.
10. Isembyld will not be authorized for any non-FDA approved indication
11. Isembyld will not be approved for use in patients that have previously been treated with Zolgensma or Itvisma
12. Approval Timeframe and Recertification Requirements
    a. Approval Timeframe: 12-months
    b. Recertification Requirements
        i. Initial (12-months from treatment initiation), there must be documentation of ONE of the following:
            1. Clinically meaningful response from pre-treatment baseline on at least one validated, age-appropriate SMA motor function scale:
                a. CHOP-INTEND: ≥ 4-point improvement from baseline
                b. HINE-2: Improvement in ≥ 1 motor milestone category without worsening in any category
                c. HFMSE or MFM32: ≥ 3-point improvement from baseline
                d. ULM/RULM: ≥ 2-point improvement from baseline
            2. The patient has achieved or maintained a motor milestone not expected based on natural history (e.g., independent sitting, standing, ambulation, head control) OR
            3. For patients with advanced disease at baseline (HFMSE ≤ 10 or CHOP-INTEND ≤ 20), there must be documentation of stabilization of motor function AND at least ONE of the following: respiratory stabilization (no new requirement for permanent ventilation), bulbar stabilization (no new requirement for enteral feeding), or preservation of a functionally meaningful motor ability as attested by the treating specialist.
        ii. Continued (every 12-months after initial response has been established), there must be documentation of ongoing clinically meaningful therapeutic benefit, defined as meeting at least ONE of the following:
            1. No decline exceeding the minimal clinically important difference (MCID) threshold for clinically meaningful deterioration on the primary motor scale used for monitoring (HFMSE or MFM32: > 3-point decline; CHOP-INTEND: > 4-point decline; RULM: > 2-point decline), OR no loss of a previously achieved motor milestone.
            2. Further improvement on a validated motor scale from the most recent assessment.
            3. Documentation that the patient's disease course is meaningfully altered

		relative to the expected natural history for their SMA type, SMN2 copy number, and disease duration. This may include but is not limited to: a. Preservation of respiratory function (stable ventilatory support requirements; no progression to permanent invasive ventilation) b. Preservation of bulbar function (stable nutritional support requirements) c. Maintenance of functional independence in activities of daily living d. Slowed rate of motor decline relative to published natural history data

Considerations

- CDPHP reserves the right to make decisions based on clinical judgment on a case-by-case basis.
- In clinical studies, prior use (at any time in the participants lives) and/or anticipated need for quinolones (chloroquine and hydroxychloroquine), thioridazine, vigabatrin, retigabine, or any other drug known to cause retinal toxicity, was part of the exclusion criteria.

Policy guidelines:

1. Utilization Management are contract dependent. Refer to specific contract/benefit language for exclusions.
    a. Coverage criteria may be dependent on the contract renewal date.
    b. Coverage of drugs listed in this policy are contract dependent.
    c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit
    d. Not all contracts/benefits cover all medical infusible drugs
2. This policy is applicable to drugs that are included on a specific drug formulary (Pharmacy benefit only). If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for review guidelines.
3. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging, and other objective or subjective measures of clinical benefit. For recertification, continued approval requires documentation demonstrating that the requested product is providing ongoing benefit to the patient, evidenced by improvement or stability in the disease state or condition, and that continued use remains medically necessary. Ongoing use of the requested product must continue to align with the current policy's preferred formulary. Recertification reviews may result in a requirement to trial more cost-effective treatment alternatives as they become available (e.g., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must remain consistent with FDA-approved or off-label/guideline-supported dosing recommendations.
4. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
5. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
6. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
7. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy.

8. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
9. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
10. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.
11. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may require prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.

References

		Updated	Accessed
1	Spinraza [prescribing information]. Cambridge, MA; Biogen. April 2024.	4/24	7/24
2	Finkel RS, Chiriboga CA, Vajsar J, et al. Treatment of infantile-onset spinal muscular atrophy with nusinersen: a phase 2, open-label, dose-escalation study. Lancet. 2016 Dec 17; 388(10063):3017-3026.	12/16	3/23
3	Finkel RS, Mercuri E, Darras BT, et al. Nusinersen versus Sham Control in Infantile-Onset Spinal Muscular Atrophy. N Engl J Med 2017; 377:1723-32.	11/17	3/23
4	Mercuri E, Darras BT, Chiriboga CA, et al. Nusinersen versus Sham Control in Later-Onset Spinal Muscular Atrophy. N Engl J Med 2018; 378:625-635.	2/18	3/23
5	ICER. Sprinaza® and Zolgensma® for Spinal Muscular Atrophy: Effectiveness and Value. Final Evidence Report. 2019 Apr 3.	5/19	3/23
6	Verhaart IEC, et al. Prevalence, incidence and carrier frequency of 5qlinked spinal muscular atrophy - a literature review. Orphanet J Rare Dis. 2017; 12(1):124.	7/17	3/23
7	Evrysdi[prescribing information]. South San Francisco, CA; Genentech/Roche. February 2024.	2/24	7/24
8	Crawford TO, Swoboda KJ, De Vivo DC, et al. NURTURE Study Group. Continued benefit of nusinersen initiated in the presymptomatic stage of spinal muscular atrophy: 5-year update of the NURTURE study. Muscle Nerve. 2023 Aug;68(2):157-170. doi: 10.1002/mus.27853. Epub 2023 Jul 6. PMID: 37409780	7/23	7/23

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application.

SELECT PLAN/HARP: Subject to all terms and conditions noted in above application for Spinraza. Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program.

CDPHP Pharmacy Services 10/8/2026

New: 06/17

Revised	Reviewed
09/18, 6/20, 6/25, 5/26, 6/26, 10/26	6/21, 6/22, 6/23, 9/23, 9/24

Revision Date	Changes Made
6/25	Criteria regarding SMN2 copies adjusted to include 4 copies for symptomatic patients with SMA type 3
5/26	Updated Spinraza for Commercial vs. Medicaid criteria, Updated Evrysdi formatting, updated approval lengths to 12 months, added Spinraza HD, updated Evrysdi how supplied
6/26	Updated dosing and quantity for Evrysdi Updated Spinraza high dose criteria and made it its own section in the policy Updated clinical response criteria and recertification Added policy guidelines to considerations
10/26	Added Isembyld

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Policy/Procedure Name: Pharmaceutical Treatment of Transthyretin-Mediated (ATTR) Amyloidosis **Control Number: 1350/20.000341**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care for enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Transthyretin-mediated (ATTR) amyloidosis is a rare, progressive, and fatal multisystem illness caused by deposits of misfolded proteins produced by the liver called transthyretin (TTR). These proteins accumulate in the peripheral nerves, heart, kidney, and gastrointestinal tract resulting in polyneuropathy and cardiomyopathy. The amyloid deposits cause significant neurologic problems, functional limitations, and disability. The type of precursor protein, tissue distribution, and amount of amyloid deposition largely determines the clinical manifestations experienced. Musculoskeletal involvement can result in bilateral carpal tunnel syndrome, spinal stenosis, bicep tendon rupture, or arthropathies due to amyloid deposition in joints and surrounding structures. Gastrointestinal symptoms vary widely and include nausea, constipation, diarrhea, and weight loss. Specific neurologic symptoms include but are not limited to peripheral neuropathy, orthostatic hypotension, and gait and balance disorders (with subsequent evidence of amyloidosis). Cardiac manifestations may include but are not limited to heart failure with a preserved ejection fraction (HFpEF), heart failure with a reduced ejection fraction (HFrEF), conduction abnormalities (bundle branch or atrioventricular blocks, sinoatrial disease, atrial fibrillation), low-flow, low-gradient aortic stenosis (AS), as well as discordance between voltage on EKG and left ventricular hypertrophy (LVH) on ECHO or MRI. It is estimated that 13 to 17 percent of older patients with HFpEF (EF > 50%) may be on the basis of amyloid. Average survival after onset of neuropathy is two to 15 years; two to five years among patients presenting with cardiomyopathy.

Onpattro™ (patisiran) is a double-stranded small interfering ribonucleic acid (siRNA) that causes degradation of mutant and wild-type transthyretin (TTR) messenger RNA through RNA interference, which results in a reduction of serum TTR protein and TTR protein deposits in tissues. Onpattro is indicated for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults. It carries a warning for infusion-related reactions and reduced vitamin A levels. Onpattro was studied in a randomized, double-blind, placebo-controlled phase III trial. This APOLLO NT trial established that Onpattro every three weeks was superior to placebo at 18 months in improving neuropathy, as demonstrated by a decrease from baseline in mNIS+7 and improvement in quality of life as demonstrated by a decrease in Norfolk QOL-DN score.

Amvuttra™ (vutrisiran) is a double-stranded siRNA-GalNAc conjugate that causes degradation of mutant and wild-type TTR mRNA through RNA interference which results in a reduction of serum TTR protein and TTR protein deposits in tissues. Amvuttra is indicated for the treatment of polyneuropathy associated with hereditary transthyretin-mediated amyloidosis in adults. Efficacy was evaluated in a randomized, open-label, phase III clinical trial (HELIOS-A) in which 164 adult participants were randomized 3:1 to receive either Amvuttra 25mg subcutaneous injection every three months or Onpattro 0.3 mg/kg intravenous infusion every three weeks. The placebo arm of the APPOLLO study was used as an external comparator since the participants were composed of a comparable adult population to the HELIOS-A study. The primary endpoint of the study was the change from baseline to month nine in the modified neuropathy impairment score +7 (mNIS+7). The clinical meaningfulness of the effects on the mNIS+7 score was assessed by the change from baseline to month nine in the Norfolk Quality of Life-Diabetic Neuropathy (QoL-DN) total score. Additional endpoints were gait speed as measured by the 10-minute walk test (10MWT) and modified body mass index (mBMI). Treatment with Amvuttra resulted in statistically significant improvements in the mNIS+7, Norfolk QoL-DN total score, and the 10MWT at month nine compared to placebo in the external study.

The FDA has set a PDUFA date of March 23, 2025, for the supplemental New Drug Application to expand Amvuttra's label to ATTR-CM. Efficacy was evaluated in a double-blind, randomized trial (HELIOS-B), where 655 assigned patients with ATTR-CM in a 1:1 ratio to receive vutrisiran (25 mg) or placebo every 12 weeks for up to 36 months. Vutrisiran treatment led to a lower risk of death from any cause and recurrent cardiovascular events than placebo (HR overall population, 0.72; 95% CI, 0.56 to 0.93; P=0.01; HR in the monotherapy population, 0.67; 95% CI, 0.49 to 0.93; P=0.02) and a lower risk of death from any cause through 42 months (HR in the overall population, 0.65; 95% CI, 0.46 to 0.90; P=0.01). In the overall population, treatment with vutrisiran resulted in less of a decline in the distance covered on the 6-minute walk test than placebo (least-squares mean difference, 26.5 m; 95% CI, 13.4 to 39.6; P<0.001) and less of a decline in the KCCQ-OS score (least-squares mean difference, 5.8 points; 95% CI, 2.4 to 9.2; P < 0.001).

Wainua™ (eplontersen) is an antisense oligonucleotide GaINAc conjugate that causes degradation of mutant and wild-type TTR mRNA, reducing protein deposits in tissues. Wainua is indicated for the treatment of polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults. In the NEURO-TTRanform trial, a reduction in mNIS+7 score and Norfolk QoL-DN score were seen at week 66.

Vyndaqel and Vyndamax are both oral formulations of tafamidis. These formulations are both FDA-approved for the treatment of cardiovascular TTR amyloid. The ATTR-ACT trial demonstrated that tafamidis (pooled treatment with both formulations) compared to placebo had a lower rate of all-cause mortality and cardiovascular-related hospitalizations (combined). Secondary analysis identified that tafamidis had a lower rate of all-cause mortality compared to placebo (29.5% vs 42.9%; HR 0.7, 95% CI 0.51-0.96) as well as lower rate of cardiovascular-related hospitalization (RRR 0.68 - 0.48/year vs. 0.7/year; 95% CI 0.56-0.81).[6] Survival curves diverged only after 18 months of treatment.[6] Additional secondary endpoints included the six-minute walk test (6MWT), which assesses functional capacity. Tafamidis reduced the decline of the 6MWT by 75 meters at month 30.[6]

Attruby™ (acoramidis) is a selective stabilizer of transthyretin (TTR) that binds to TTR at thyroxine binding sites and slows dissociation of the TTR tetramer into its constituent monomers, which is the rate-limiting step in amyloidogenesis. In the ATTRibute-CM trial, all-cause mortality was reported as 19.3% in the acoramidis group compared to 25.7% in the placebo group, with a hazard ratio (HR) of 0.77 (95% CI 0.54-1.10; p = 0.15). There was a significant adjusted mean factor change in NT-proBNP from baseline of 0.529 (95% CI 0.46-0.60; p < 0.05), indicating better cardiac function preservation. Participants receiving acoramidis demonstrated an improvement in the 6-minute walk distance by 39.6 meters (95% CI 21.1-58.2; p < 0.001) from baseline, along with a reduction in cardiovascular-related hospitalizations to 26.7% compared to 42.6% in the placebo group (p < 0.0001). Additionally, the least means square change in the Kansas City Cardiomyopathy Questionnaire Overall Summary (KCCQ-OS) score was a significant 9.94 points (95% CI 5.97-13.91; p < 0.001), highlighting improvements in quality of life and functional status.

Summary	
Effective date of policy:	2/12/2026
Indications	See specific agents listed below
ICD10 diagnosis codes	See specific agents listed below
Availability	Onpattro™(patisiran): available as a 10 mg/5 mL single-dose vial Amvuttra (vutrisiran): available as a 25 mg/0.5mL single-dose prefilled syringe Wainua (eplontersen): available as 45 mg/0.8 mL single-dose autoinjector Vyndaqel™ (tafamidis meglumine): available as a 20 mg capsule Vyndamax (tafamidis): available as a 61 mg capsule Attruby (acoramidis): available as 356 mg tablets
Duration	Per product

Required Criteria for Approval

__All__ of the following conditions for the requested indication must be met in order to approve either ATTR or hATTR therapy separated below:

Indication	Inclusion	Recommended Dosing

Onpattro (patisiran)
 	
Indication
Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR)
(FDA approval)
 	
ICD10: E85.1
 	
HCPCS: J0222
	• The enrollee is ≥ 18 years of age
	• Prescribed by specialist experienced in the diagnosis of hATTR amyloidosis such as hematologist-oncologist, neurologist, gastroenterologist, geneticist, or nephrologist
	• The enrollee has a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis confirmed by:
	  o Documentation of a pathologic mutation in the transthyretin (TTR) gene (via genetic testing/DNA sequencing) **and**
	  o Documented amyloid deposits determined by biopsy
	  ▪ Biopsy not necessary if enrollee has positive ^{99m}Tc-PYP along with positive genetics and known neuropathy
	• A baseline for one of the following diagnostic tests has been established (see below):
	  o Polyneuropathy disability (PND) score of IIIb or lower; OR
	  o Documentation of baseline functional ambulation performance (FAP) stage of 1 or 2
	• Must also have symptoms consistent with polyneuropathy attributed to hATTR and other causes of neuropathy have been excluded:
	  o Peripheral sensorimotor polyneuropathy symptoms, such as: tingling or increased pain in the hands/feet/arms, loss of feeling in the hands/feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature or pain, difficulty with
		Adults ≥ 18 years of age:
		• Less than 100 kg: 0.3 mg/kg once every three weeks
		• ≥ 100 kg: 30 mg once every three weeks
		• **Maximum Dosing: 30 mg IV every three weeks**

	fine motor skills, weakness/numbness/pain in the legs, difficulty walking, seizures, headaches, inability to perform activities of daily living (ADLs) o Autonomic neuropathy symptoms such as: orthostasis, abnormal sweating, sexual dysfunction, recurrent urinary tract infection, dysautonomic symptoms of constipation, diarrhea, nausea, vomiting, anorexia, and early satiety • Must be administered by a healthcare professional • Onpattro must be used as monotherapy and will NOT be covered in combination with Tegsedi (inotersen) or any other polyneuropathy of hereditary transthyretin mediated amyloidosis (hATTR) disease specific therapy. o Please note: Prior approval for any other polyneuropathy of hereditary transthyretin mediated amyloidosis (hATTR) specific treatment will be terminated upon approval of Onpattro • Current body weight and requested dose regimen must be submitted for initial review and each recertification request. • Onpattro will not be approved for ATTR cardiomyopathy • Initial approval for Onpattro will be for one year • Continued approval beyond on year and recertification every two years will require: o Documentation of improvement OR stability of disease and symptoms with Onpattro (via lab reports, progress notes, neurologic exam, PND or FAP score)	
Amvuttra (vutrisiran) **Indication Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR)** (FDA approval) ICD10: E85.1 HCPCS: J0225	• The prior authorization is obtained by a neurologist o Prior authorization may be obtained by cardiologist if member has both hATTR cardiomyopathy and neuropathy • The enrollee is ≥ 18 years of age • The enrollee has a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis confirmed by: o Genetic testing documenting a pathogenic variant in *TTR (e.g., V30M)* **and** o Documented amyloid deposits determined by biopsy ▪ Biopsy not necessary if enrollee has positive ^{99m}Tc-PYP along with positive genetics and known neuropathy • A baseline Polyneuropathy disability (PND) score of IIIb or lower AND • Must also have symptoms consistent with polyneuropathy attributed to hATTR: o Peripheral sensorimotor polyneuropathy symptoms, such as: tingling or increased pain in the hands/feet/arms, loss of feeling in the hands/feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature or pain, difficulty with fine motor skills, weakness/numbness/pain in the legs, difficulty walking, seizures, headaches, inability to perform activities of daily living (ADLs) o Autonomic neuropathy symptoms such as: orthostasis, abnormal sweating, sexual dysfunction, recurrent urinary tract infection, dysautonomic symptoms of constipation, diarrhea, nausea, vomiting, anorexia, and early satiety AND • Comprehensive neurological examination has ruled out other causes of sensorimotor/autonomic neuropathy besides hereditary transthyretin-mediated amyloidosis (hATTR) o E.g., chronic inflammatory demyelinating polyneuropathy; diabetic neuropathy in the setting of uncontrolled diabetes • Must be administered by a healthcare professional	• Adults ≥ 18 years of age: 25 mg subcutaneously once every three months

	• Amvuttra must be used as monotherapy and will NOT be covered in combination with Tegsedi (inotersen), Onpattro (patisiran), Wainua (eplontersen) or any other polyneuropathy of hereditary transthyretin mediated amyloidosis (hATTR) disease specific therapy. Please note: Prior approval for any other polyneuropathy of hereditary transthyretin mediated amyloidosis (hATTR) specific treatment will be terminated upon approval of Amvuttra
	  o Amvuttra will not be approved for use in combination with tafamidis (Vyndamax/Vyndaqel) or acoramidis (Attruby)
	• Initial approval for Amvuttra will be for one year.
	• Approval will be for 1 year at a time
	  o Continued approval beyond on year and recertification every two years will require:
	  ▪ Documentation of improvement OR stability of disease and symptoms with Amvuttra (via lab reports, progress notes, neurologic exam, PND)
	• Quantity Limit: 1 syringe per 84 days	

Amvuttra (vutrisiran)
 	
Indication: Treatment of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) (pending FDA approval)
 	
HCPCS: J0225
	• Prior authorization is obtained by or in consultation with a cardiologist
	• The enrollee is ≥ 18 years of age
	• Documented diagnosis of ATTR amyloidosis with cardiomyopathy, classified as either hATTR amyloidosis with cardiomyopathy to wtATTR amyloidosis with cardiomyopathy.
	  o The diagnosis must be confirmed by one the following:
	  ▪ 99mTechnetium-labeled pyrophosphate cardiac imaging (nuclear scintigraphy) positive for transthyretin (TTR) amyloid OR
	  ▪ Amyloid deposits identified on cardiac biopsy AND presence of a variant TTR genotype and/or TTR precursor protein identification by molecular genetic testing (i.e., immunohistochemistry, scintigraphy, or mass spectrometry) or next-generation sequencing (NGS)
	• Enrollee has documented echocardiogram (ECHO) including wall thickness and function and ideally strain imaging
	  o Strain imaging typically shows apical sparing/apical preservation
	• Classification of NYHA class I or class II/III heart failure with ≥ 1 hospitalizations for heart failure or clinical evidence of HF without prior hospitalization for HF (such as shortness of breath, peripheral edema, ascites, elevated jugular pressure, etc. requiring treatment with a diuretic for improvement)
	• The patient must have had a trial of tafamidis (Vyndamax/Vyndaqel) or acoramidis (Attruby) for at least 6 months, unless contraindicated or not clinically appropriate.
	  o The trial must provide evidence that treatment with tafamidis (Vyndamax/Vyndaqel) or acoramidis (Attruby) is no longer sufficient to control disease progression as demonstrated by at least one of the following (i, ii, iii, OR iv):
	  ▪ i. Sustained elevation of cardiac biomarkers (e.g., NT-proNBP or Troponin)
		• Adults ≥ 18 years of age: 25mg subcutaneously once every three months

	▪ ii. Worsening of cardiac function (e.g., decline in left ventricular ejection fraction or increased left ventricular wall thickness on imaging) ▪ iii. Clinical deterioration indicated by a decrease in 6-Minute Walk Test performance ▪ iv. Increasing amyloid burden on bone scintigraphy or cardiac MRI • To effectively monitor treatment process and clinical improvement, documentation of the following clinical parameters is required prior to initiating therapy: o Cardiac Biomarkers (NT-proBNP or troponin) o TTR Protein Level (i.e., serum TTR) o 6-Minute Walk Test • Amvuttra must be used as monotherapy o Amvuttra will not be covered for use in combination with tafamidis (Vyndamax) or acoramidis (Attruby) for the treatment of ATTR-CM ▪ The concurrent use of transthyretin (TTR) stabilizers (e.g., tafamidis [Vyndamax] or acoramidis [Attruby]) and TTR silencers (e.g., vutrisiran [Amvuttra])) is considered not medically necessary due to the absence of clinical evidence demonstrating additional therapeutic benefit (e.g., additional reduction in mortality or hospitalization) and safety • Initial approval for Amvuttra will be for one year • Recertification requirements o First recertification (after initial approval) will require documentation of the following: ▪ A reduction in cardiac stress or damage, or improving function as evidenced by a decrease in NT-proBNP or troponin from baseline ▪ A reduction in TTR production as evidenced by a decrease in serum TTR from baseline ▪ Improvement or stabilization of the 6-Minute Walk test compared to baseline values o Subsequent recertifications (after first recertification) will require documentation of the following: ▪ Continued reduction or stabilization of NT-proBNP or troponin (no increase in biomarker) ▪ Continued suppression of TTR production (no increase in serum TTR) ▪ Continued improvement or stabilization of the 6-Minute Walk test compared to baseline values • Quantity Limit: 1 syringe per 84 days	
Wainua (eplontersen) **Indication** **Polyneuropathy of hereditary transthyretin-mediated amyloidosis (hATTR)** (FDA approval)	• The prior authorization is obtained by a neurologist. o Prior authorization may be obtained by cardiologist if member has both hATTR cardiomyopathy and neuropathy • The enrollee is ≥ 18 years of age. • The enrollee has a diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis confirmed by: o Genetic testing documenting a pathogenic variant in *TTR (e.g., V30M)* **and**	• Adults ≥ 18 years of age: 45 mg by subcutaneous injection once monthly

ICD10: E85.1	○ Documented amyloid deposits determined by biopsy ▪ Biopsy not necessary if enrollee has positive ^{99m}Tc-PYP along with positive genetics and known neuropathy • A baseline Polyneuropathy disability (PND) score of IIIb or lower • Must also have symptoms consistent with polyneuropathy attributed to hATTR: ○ Peripheral sensorimotor polyneuropathy symptoms, such as: tingling or increased pain in the hands/feet/arms, loss of feeling in the hands/feet, numbness or tingling in the wrists, carpal tunnel syndrome, loss of ability to sense temperature or pain, difficulty with fine motor skills, weakness/numbness/pain in the legs, difficulty walking, seizures, headaches, inability to perform activities of daily living (ADLs) ○ Autonomic neuropathy symptoms such as: orthostasis, abnormal sweating, sexual dysfunction, recurrent urinary tract infection, dysautonomic symptoms of constipation, diarrhea, nausea, vomiting, anorexia, and early satiety AND • Comprehensive neurological examination has ruled out other causes of sensorimotor/autonomic neuropathy besides hereditary transthyretin-mediated amyloidosis (hATTR) ○ E.g., chronic inflammatory demyelinating polyneuropathy; diabetic neuropathy in the setting of uncontrolled diabetes • Wainua must be used as monotherapy and will NOT be covered in combination with Amvuttra (vutrisiran), Tegsedi (inotersen), Onpattro (patisiran) or any other polyneuropathy of hereditary transthyretin mediated amyloidosis (hATTR) disease specific therapy. Please note: Prior approval for any other polyneuropathy of hereditary transthyretin mediated amyloidosis (hATTR) specific treatment will be terminated upon approval of Wainua, AND • Initial approval for Wainua will be for one year. • Continued approval beyond on year and recertification every two years will require: ○ Documentation of improvement OR stability of disease and symptoms with Wainua (via lab reports, progress notes, neurologic exam, PND) • Quantity Limit: 1 pen per 30 days	
Vyndamax (tafamidis) **Indication: Treatment of cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization** (FDA Approval) ICD10: E85.4	• The medication must be prescribed by or in consultation with a physician who specializes in the treatment of amyloidosis, such as a cardiologist • The enrollee is ≥ 18 years of age • AL amyloid ruled out via free light chain assay SPEP/UPEP with immunoelectrophoresis • Diagnosis of ATTR-CM confirmed through a positive ^{99m}Tc-PYP **or** Amyloid deposits identified on cardiac biopsy AND presence of a variant TTR genotype and/or TTR precursor protein identification by molecular genetic testing (i.e., immunohistochemistry, scintigraphy, or mass spectrometry) or next-generation sequencing (NGS) • Enrollee has documented echocardiogram (ECHO) including wall thickness and function and ideally strain imaging ○ Strain imaging typically shows apical sparing/apical preservation • Classification of NYHA class I or class II/III heart failure with ≥ 1 hospitalizations for heart failure OR in the absence of prior hospitalization must have clinical evidence of heart failure with signs/symptoms (such as shortness of breath, peripheral edema, ascites, elevated jugular pressure, etc.) requiring treatment with a diuretic for improvement	Vyndamax: 61 mg orally once daily

	• To effectively monitor treatment process and clinical improvement, documentation of the following clinical parameters is required prior to initiating therapy:
	  o Cardiac Biomarkers (NT-proBNP or troponin)
	  o TTR Protein Level (i.e., serum TTR)
	  o 6-Minute Walk Test
	• Vyndamax must be used as monotherapy
	  o Vyndamax will NOT be covered for use in combination with acoramidis (Attruby) or vutrisiran (Amvuttra) for the treatment of ATTR-CM i. The concurrent use of transthyretin (TTR) stabilizers (e.g., tafamidis [Vyndamax] or acoramidis [Attruby]) and TTR silencers (e.g., vutrisiran [Amvuttra])) is considered not medically necessary due to the absence of clinical evidence demonstrating additional therapeutic benefit (e.g., additional reduction in mortality or hospitalization) and safety.
	• Initial approval: 1 year
	• Recertification: 1 year
	  o First recertification (after initial approval) will require documentation of the following:
	  ▪ A reduction in cardiac stress or damage, or improving function as evidenced by a decrease in NT-proBNP or troponin from baseline
	  ▪ Improvement or stabilization of the 6-Minute Walk test compared to baseline values
	  o Subsequent recertifications (after first recertification) will require documentation of the following:
	  ▪ Continued reduction or stabilization of NT-proBNP or troponin (no increase in biomarker)
	  ▪ Continued improvement or stabilization of the 6-Minute Walk test compared to baseline values
	• Quantity limit: 30 capsules per 30 days	

Attruby (acoramidis) **Indication: Treatment of the cardiomyopathy of wild-type or variant transthyretin-mediated amyloidosis (ATTR-CM) in adults to reduce cardiovascular death and cardiovascular-related hospitalization.** (FDA Approval) ICD10: E85.4	• The medication must be prescribed by or in consultation with a physician who specializes in the treatment of amyloidosis, such as a cardiologist • The enrollee is ≥ 18 years of age • Diagnosis of ATTR-CM confirmed through a positive ^{99m}Tc-PYP **or** Amyloid deposits identified on cardiac biopsy AND presence of a variant TTR genotype and/or TTR precursor protein identification by molecular genetic testing (i.e., immunohistochemistry, scintigraphy, or mass spectrometry) or next-generation sequencing (NGS) • Enrollee has documented echocardiogram (ECHO) including wall thickness and function and ideally strain imaging o Strain imaging typically shows apical sparing/apical preservation • Classification of NYHA class I or class II/III heart failure with ≥ 1 hospitalizations for heart failure **OR** in the absence of prior hospitalization must have clinical evidence of heart failure with signs/symptoms (such as shortness of breath, peripheral edema, ascites, elevated jugular pressure, etc.) requiring treatment with a diuretic for improvement • To effectively monitor treatment process and clinical improvement, documentation of the following clinical parameters is required prior to initiating therapy:	• Adults ≥ 18 years of age: Recommended dose of Attruby is **712 mg** given as two-356 mg tablets orally twice daily, with or without food.

- Cardiac Biomarkers (NT-proBNP or troponin)
- TTR Protein Level (i.e., serum TTR)
- 6-Minute Walk Test

- Attruby must be used as monotherapy
  - Attruby will not be covered for use in combination with tafamidis (Vyndamax) or vutrisiran (Amvuttra) for the treatment of ATTR-CM
    - The concurrent use of transthyretin (TTR) stabilizers (e.g., tafamidis [Vyndamax] or acoramidis [Attruby]) and TTR silencers (e.g., vutrisiran [Amvuttra])) is considered not medically necessary due to the absence of clinical evidence demonstrating additional therapeutic benefit (e.g., additional reduction in mortality or hospitalization) and safety.
- Initial approval: 1 year
- Recertification: 1 year
  - First recertification (after initial approval) will require documentation of the following:
    - A reduction in cardiac stress or damage, or improving function as evidenced by a decrease in NT-proBNP or troponin from baseline
    - Improvement or stabilization of the 6-Minute Walk test compared to baseline values
  - Subsequent recertifications (after first recertification) will require documentation of the following:
    - Continued reduction or stabilization of NT-proBNP or troponin (no increase in biomarker)
    - Continued improvement or stabilization of the 6-Minute Walk test compared to baseline values
- Quantity limit: 120 tablets/30 days

Exclusion Criteria

Concomitant treatment with more than one of the above agents will not be covered.

Therapy for patisiran (Onpattro), vutrisiran (Amvuttra), eplontersen (Wainua), tafamidis (Vyndamax), and acoramidis (Attruby) will not be authorized if **any** of the following criteria are met:

- Previous liver transplantation or liver transplantation while receiving therapy for hATTR
- New York Heart Association class of IV heart failure as determined by cardiology consult
- Presence of primary (light chain) amyloidosis, secondary (AA) amyloidosis or any other nonATTR amyloidosis
- Use in combination with each other

Considerations

- Patient must have medical drug benefit coverage administered by CDPHP for patisiran or vutrisiran and pharmacy drug benefit coverage through CDPHP for inotersen, eplontersen, Vyndaqel, Vyndamax or acoramidis.
- Prior authorization is obtained through the CDPHP pharmacy department.

References

		Updated	Accessed
1.	Adams D, Gonzalez-Duarte A, O'Riordan WD, et al. Patisiran, an RNAi Therapeutic, for Hereditary Transthyretin Amyloidosis. N Engl J Med. 2018;379(1):11-21.	2018	11/22
2.	Alnylam Pharmaceuticals, Inc. Onpattro (patisiran) lipid complex injection, for intravenous use. Prescribing Information. Cambridge, MA: Alynlam Pharmaceuticals; revised February 2020.	1/23	10/23

3.	Benson MD, Waddington-Cruz M, Berk JL, et al. Inotersen treatment for patients with hereditary transthyretin amyloidosis. N Engl J Med. 2018;379(1):22-31.	8/2018	11/22
4.	Institute for Clinical and Economic Review (ICER). Inotersen and Patisiran for Hereditary Transthyretin Amyloidosis: Effectiveness and Value. Final Evidence Report. 2018 Oct 4.	8/2018	11/22
5.	Maurer MS, Schwartz JH, Gundapaneni B, et al. Tafamidis Treatment for Patients with Transthyretin Amyloid Cardiomyopathy. N Engl J Med. 2018; 379(11):1007-1016.	9/2018	11/22
6.	Gillmore JD, Maurer MS, Falk RH, et al. Nonbiopsy Diagnosis of Cardiac Transthyretin Amyloidosis. Circulation. 2016;133:2404-2412.	2016	11/22
7.	Pfizer Inc., Vyndaqel (tafamidis meglumine) capsules, for oral administration and Vyndamax (tafamidis) capsules, for oral administration. Prescribing Information. New York, NY: Pfizer Labs Division of Pfizer Inc., revised April 2020.	4/23	10/23
8	APOLLO-B: A Study to Evaluate Patisiran in Participants With Transthyretin Amyloidosis With Cardiomyopathy (ATTR Amyloidosis With Cardiomyopathy) (NCT03997383) Available at: https://www.clinicaltrials.gov/study/NCT03997383	6/22	10/23
9.	Coelho T, Marques W Jr, Dasgupta NR, et al.; NEURO-TTRansform Investigators. Eplontersen for Hereditary Transthyretin Amyloidosis With Polyneuropathy. JAMA. 2023 Oct 17;330(15):1448-1458. doi: 10.1001/jama.2023.18688. PMID: 37768671; PMCID: PMC10540057.	10/23	3/24
10.	Wainua (Prescribing information). Wilmington, DE; AstraZeneca Pharmaceuticals LP; 2023	12/23	3/24
11.	Gillmore JD, Judge DP, Cappelli F, et al. Efficacy and safety of acoramidis in transthyretin amyloid cardiomyopathy. N Engl J Med. 2024;390(2):132-142.		1/25
12.	Fontana M, Berk JL, Gillmore JD, et al. Vutrisiran in Patients with Transthyretin Amyloidosis with Cardiomyopathy. N Engl J Med. August 2024.		1/25

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Onpattro (patisiran) and Amvuttra (vutrisiran): Subject to the terms and conditions noted in above policy for those medications listed as a medical benefit when administered and provided by physician office, coverage will be provided as a medical benefit. All other medications for Medicare Advantage with Part D members listed are subject to coverage under the current Part D benefit and Medicare Advantage Part D formulary.

Wainua (eplontersen): Not applicable.
Vyndaqel and Vyndamax: Not applicable.
Attruby: Not applicable

SELECT/HARP PLAN: Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program.

CDPHP Pharmacy Services 2/12/2026

New: 4/2019

Date	Notes
04/19	New Policy
04/21, 04/22	Reviewed with no changes
06/19, 04/20	Revised
12/22	Revised – added background information for Amvuttra, added inclusion criteria for Amvuttra, added trial of Onpattro for both Tegsedi and Amvuttra, removed subjective polyneuropathy scales for Onpattro and Tegsedi.
12/23	Added criteria for Onpattro that non-FDA approved uses would not be covered considering 10/8/23 FDA decision not to approve for ATTR-CM
4/24	Addition of Wainua with coverage criteria following FDA approval
9/24	Removal of Tegsedi following discontinuation of product
2/25	Addition of Amvuttra criteria for ATTR-CM Addition of Attruby criteria following FDA approval for ATTR-CM
2/26	Updated criteria – clarified clinical evidence of HF, documentation baseline clinical parameters, PND score for polyneuropathy agents

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	Removed AL amyloidosis rule out for Amvuttra Removed lab criteria Removed Vyndqel as discontinued by manufacturer

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Policy/Procedure Name: Pharmacy Care Management (RxC/M) **Control Number: 1350/20.000358**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care for enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Summary

Effective Date of Policy: 6/11/2025

Description and Criteria of Pharmacy Care Management Model

Pharmacists within the managed care setting are perfectly positioned to provide a unique model of care for members that are on select high-impact Specialty agents. This collaborative effort places the Pharmacy Care Management Pharmacists (Rx C/M RPh) centrally, where they can effectively coordinate communication and care among the member, provider, and pharmacy to provide efficient, value-based care around these high impact Specialty agents. It is also the goal of this model to ensure delivery of evidence-based care in a way that supports the relationship between our members and their providers.

This enhanced management model applies to the agents listed in the table below (Table A) as well as new market entrants that are deemed high impact. The list contained within Table A is subject to change at any time, and may be without notice. These agents will be managed at an appropriate cadence to ensure delivery of pharmaceutical care in an efficacious, safe, and efficient manner, which is consistent with clinical evidence. Specific details of the interactions include the following:

Member: The Rx C/M RPh engages with the member telephonically and electronically upon initiation of therapy, and intermittently thereafter as determined by the medication regimen to ensure appropriate utilization, tolerability, and access to therapy.
Provider/Provider Representative: The Rx C/M RPh will obtain a direct contact at the Provider Office and will engage with that person to ensure CDPHP has access to requested laboratory follow up and pertinent clinical information, and that the Provider is aware of the status of the members therapy (i.e., Adherence, clinical benefit, tolerability).
Other Internal/External Care Management Teams: The Rx C/M RPh will collaborate with other identified care managers for each member to ensure coordination of care and to identify any unforeseen barriers to being successful with therapy.
Pharmacy/Infusion Company: The Rx C/M RPh will engage with a direct contact at the entity and will be telephonically or electronically authorizing all fills for the selected therapy. This authorization includes the initial fill, refill, or infusion of any of the agents listed in Table A.

The authorization for refills/subsequent infusions will be done by the Rx C/M RPh after a thorough review has been performed by the above parties to ensure an accurate, safe, effective, and efficient supply of the medication is provided.

Table A - Medications

Abecma (idecabtagene vicleucel)	Ilaris (canakinumab)	Saphnelo (anifrolumab)
Actemra (tocilizumab)	Ilumya (tildrakizumab-asmn)	Scenesse (afamelanotide)
Acthar (corticotropin)	Inbrija (levodopa oral inhalation)	Siklos (hydroxyurea)
Adakveo (crizanlizumab)	Infliximab Biosimilar Products	Siliq (brodalumab)
Adalimumab Biosimilar Products	Iqirvo (elafibranor)	Simponi (golimumab)
Adstiladrin (nadofaragen firadenovec)	Izervay (avacincaptad pegol)	Simponi Aria (golimumab)
Aduhelm (aducanumab)	Joenja (leniolisib)	Skyclarys (omaveloxolone)
Adzynma (ADAMTS13, recombinant-krhn)	Juxtapid (lomitapide)	Skyrizi (risankizumab-rzaa)
Agamree (vamorolone)	Kebilidi (eladocagene exuparvovec-tneq)	Skysona (elivaldogene autotemcel)
Alhemo (concizumab-mtci)	Kevzara (sarilumab)	Sohonos (palovarotene)
Alyftrek (vanzacaftor/tezacaftor/deutivacaftor)	Kineret (anakinra)	Soliris (eculizumab)
Amondys 45 (casimersen)	Kisunla (donanemab-azbt)	Spinraza (nusinersen)
Amtagvi (lifileucel)	Korlym (mifepristone)	Stelara (ustekinumab)
Amvuttra (vutrisiran)	Kymriah (tisagenlecleucel)	Stelara SC (ustekinumab)
Anktiva (nogapendekin alfa inbakicept-pmln)	Kuvan (sapropterin)	Sublocade (buprenorphine extended release) injection
Antihemophilic Factors (i.e., Advate, Adynovate, Altuviiio, Eloctate, Humate P, Jivi, Kogenate FS, Recombinate, SevenFact)	Lamzede (velmanase alfa)	Sucraid (sacrosidase)
Aqneursa (levacetylleucine)	Leqembi (lecanemab)	Syfovre (Pegcetacoplan)
Arcalyst (rilonacept)	Lenmeldy (atidarsagene autotemcel)	Synagis (Palivizumab)
Attruby (acoramidis)	Livmarli (maralixibat)	Taltz (Ixekizumab)
Aucatzyl (obecabtagene autoleucel)	Lumizyme (alglucosidase alfa)	Talvey (talquetamab)
Benlysta (belimumab)	Lunsumio (mosunetuzumab)	Tecartus (brexucabtagene autoleucel)
Beqvez (fidanacogene elaparvovec-dzkt)	Lupkynis (voclosporin)	Tecelra (afamitresgene autoleucel)
Beyfortus (nirsevimab-alip)	Lyfgenia (lovotibeglogene autotemcel)	Tecvayli (teclistamab)
Blincyto (blinatumomab)	Mavenclad (cladribine)	Tegsedi (Inotersen)
Breyanzi (lisocabtagene maraleucel)	Mayzent (siponimod)	Tepezza (teprotumumab)
Bylvay (odevixibat)	Mulpleta (lusutrombopag)	Tezspire (Tezepelumab)
Camzyos (mavacamten)	Nexviazyme (avalglucosidase alfa)	Tremfya (Guselkumab)
Carvykti (ciltacabtagene autoleucel)	Nucala (mepolizumab)	Tryngolza (olezarsen)
Casgevy (exagamglogene autotemcel)	Ofev (nintedanib)	Tysabri (Natalizumab)
Cimzia (certolizumab pegol)	Ogsiveo (nirogacestat)	Tzield (teplizumab-mzwv)
Columvi (glofitamab)	Ojemda (tovorafenib)	Ultomiris (ravicizumab)
Cosentyx (secukinumab)	Olpruva (sodium phenylbutyrate)	Uplizna (inebilizumab)
Crenessity (crinecerfont)	Olumiant (baricitinib)	Veopoz (pozelimab)
Crysvita (burosumab)	Onpattro (patisiran)	Vijoice (Alpelisib)
Daybue (trofinetide)	Opsynvi (macitentan and tadalafil)	Viltepso (vitolarsen)
Doptelet (avatrombopag)	Orencia (abatacept)	Vimizim (Elosulfase alfa)
Dupixent (dupilumab)	Orfadin (nitisinone)	Voranigo (vorasidenib)
Duvyzat (givinostat)	Otezla (apremilast)	Voydeya (danicopan)
Elfabrio (pegunigalsidase alfa)	Oxbryta (voxelotor)	Vyalev (foscarbidopa/foslevodopa)
Elevidys (delandistrogene moxeparvovec)	Oxervate (cenegermin-bkbj)	Vyjuvek (beremagene geperpavec)
Elrexfio (elranatamab)	Oxlumo (lumasiran)	Vyndamax (Tafamidis)
Emflaza (deflazacort)	Palforzia (peanut allergen powder)	Vyndaqel (Tafamidis meglumine)
Empaveli (pegcetacoplan)	Palynziq (pegvaliase)	Vyondys 53 (golodirsen)
Enbrel (Etanercept)	PiaSky (crovalimab)	Vyvgart (efgartigimod alfa)
Endari (L-glutamine)	Pombiliti (cipaglucosidase alfa) and Opfolda (miglustat)	Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)
Enjaymo (Sutimlimab)	Pyrukynd (mitapivat)	Wainua (eplontersen)
Enspryng (satralizumab)	Qalsody (tofersen)	Winrevair (sotatercept-csrk)
Entyvio IV (vedolizumab)	Radicava (edaravone)	Xeljanz (Tofacitinib Citrate)
Entyvio SC (vedolizumab)	Ravicti (glycerol phenylbutyrate)	Xeljanz XR (Tofacitinib Citrate)
Epkinly (epcoritamab-bysp)	Remicade (infliximab)	Xenpozyme (Olipudase alfa)
Esbriet (pirfenidone)	Revuforj (revumenib)	Xolair (Omalizumab)
Etanercept Biosimilar Products	Rezdiffra (resmetirom)	Xolremdi (mavorixafor)
	Rinvoq (upadacitinib)	Xpovio (selinexor)
	Rituxan (rituximab)	Yescarta (axicabtagene ciloleucel)
	Rituximab Biosimilar Products	

Evkeeza (evinacumab-dgnb) Evrysdi (risdiplam) Exonodys 51 (eteplirsen) Fabhalta (iptacopan) Fabrazyme (agalsidase beta) Fasenra (benralizumab) Filsuvez (birch triterpenes) Fintepla (fenfluramine) Hemlibra (emicizumab) Hemgenix (etranacogene dezaparvovec) Humira (adalimumab) Hympavzi (marstacimab-hncq)	Rivfloza (nedosiran) Roctavian (valocotgene roxaparvovec) Rybrevant (amivantamab) Ryplazim (plasminogen, human) Rystiggo (rozanolixizumab) Rytelo (imetelstat)	Yorvipath (palopegteriparatide) Zilbrysq (zilucoplan) Zolgensma (onasemnogene abeparvovec) Zynteglo (betibeglogene autotemcel) Ztalmy (ganaxolone)

Considerations

- Patient must have drug coverage administered by CDPHP for the drugs in Table A.
- Prior authorization is obtained through the CDPHP pharmacy department pursuant to existing coverage criteria in applicable policies for each medication listed within Table A.

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program

CDPHP Pharmacy Services 8/13/2026

New: 6/2019

Revised	Reviewed
9/2019, 9/2020, 4/2021, 4/2022, 4/2023, 6/2023, 6/2024, 6/2025	8/2026

Revision Date	Changes Made
4/2021	Added medications to Table A including: Amondys 45, Evrysdi, Esbriet, Evkeeza, Juxtapid, Ofev, Pegcetacoplan, Vimizim, Vyondys 53
4/2022	Added medications to Table A including: Aduhelm, Bylvay, Empaveli, Livmarli, Lumizyme, Lupkynis, Nexviazyme Oxlumo, Ryplazim, Saphnelo, Vyvgart
4/2023	Added medications to Table A including: Camzyos (Mavacamten), Enjaymo (sutimlimab), Pyrukynd (mitapivat), Radicava (edaravone), Soliris (Eculizumab), Spinraza (Nusinersen), Synagis (Palivizumab), Tezspire (tezepelumab), Vijoice (alpelisib), Xenpozyme (Olipudase alfa)
6/2023	Added medications to Table A including: Daybue (Trofinetide) and Skyclarys (Omaveloxolone)
6/2024	Added several medications to Table A
6/2025	Added several medications to Table A

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MEDICAL POLICY

Medical Policy Title	**Photodynamic Therapy for Malignant Disease**
Policy Number	**8.01.06**
Current Effective Date	**November 1, 2026**
Next Review Date	**February 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.

(Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Photodynamic therapy (PDT) with Photofrin is considered **medically appropriate** for **ANY** of the following indications:

   A. Treatment of early-stage non-small-cell lung cancer (NSCLC) in patients who are ineligible for surgery and radiation therapy;

   B. Reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial lesions;

   C. Palliative treatment of obstructing esophageal cancer;

   D. Treatment of Barrett's high-grade dysplasia (HGD) in patients who:

      1. are considered at high risk for adverse outcomes (morbidity and mortality) during prophylactic esophagectomy surgery; **and**

      2. decide on this treatment method, based on shared decision-making with their physician and understanding the actual risks and benefits of various treatment options;

   E. Palliative treatment of unresectable cholangiocarcinoma as an adjunct to stenting.

II. PDT with 5-aminolevulinic acid (5-ALA) topical preparation is considered **medically appropriate** for **EITHER** of the following indications:

   A. Superficial and nodular basal cell skin cancer, only when surgery or radiation is contraindicated;

   B. Bowen's disease (cutaneous squamous cell carcinoma in situ), only when surgery or radiation is contraindicated.

III. PDT is considered **investigational** in the treatment of other types of malignancies, including but not limited to colon, rectal, pancreas, hepatocellular, mesothelioma, prostate, bladder, brain, head and neck cancers, soft tissue sarcoma and Barrett's esophagus (other than HGD, as stated above).

IV. PDT with porfimer sodium (Photofrin) is contraindicated in patients with **ANY** of the following:

A. Known bone marrow suppression;

B. Porphyria or known allergies to porphyrins;

C. Existing tracheoesophageal or broncho-esophageal fistula;

D. Tumors eroding into a major vessel;

E. Esophageal or gastric varices or esophageal ulcers greater than one (1) cm in diameter.

RELATED POLICIES

Corporate Medical Policy

7.01.01 Focal Therapies for Prostate Cancer Treatment

8.01.21 Light and Laser Therapies for Dermatological Conditions

11.01.03 Experimental or Investigational Services

11.01.10 Clinical Trials

POLICY GUIDELINE(S)

I. A second laser treatment (with no additional Photofrin) can be given 96-120 hours after the first injection, preceded by debridement (via endoscopy) 48 hours after the initial light application.

II. Patients may receive a second course of PDT (with Photofrin) a minimum of 30 days after the initial therapy. Up to three (3) courses of PDT (every 30 days) can be given.

III. As pathologists do not always agree on differentiating between low- and high-grade dysplasia and between high-grade dysplasia and carcinoma in situ, in many cases, high-grade Barrett's dysplasia is confirmed by two pathologists with expertise in gastrointestinal pathology.

DESCRIPTION

PDT is a cancer treatment method using intravenous injection of a photosensitizing agent (e.g., porfimer sodium, Photofrin) and exposure of tumor cells to a laser light source to cause cellular damage. The clearance of porfimer sodium occurs over a period of time (40-72 hours) in normal tissue; however, tumor cells retain porfimer for a longer period. Treatment of the tumor is the result of selective retention of porfimer and selective delivery of light.

PDT with Photofrin is a two-stage process. The first stage is the intravenous injection of Photofrin. Illumination with 630-nm wavelength laser light constitutes the second stage of therapy. The laser treatment induces a photochemical, not a thermal, effect. The photochemical reaction results in the release of toxic, singlet oxygen that causes tumor necrosis.

PDT should not be confused with extracorporeal photopheresis, which is the treatment of certain skin malignancies through the use of ultraviolet light irradiation of the patient's blood.

SUPPORTIVE LITERATURE

Published studies have shown that PDT with Photofrin improves the quality of life (e.g., relief of dysphagia, improvement in dyspnea) and relieves obstruction by reducing tumor mass for those patients with obstructing tumors of the esophagus or endobronchial tree. For those patients with microinvasive NSCLC, not amenable to surgery or radiation, who were treated with PDT, reported tumor response rates (50-84%) and disease-free survival rates (2.7-4.1 years) are favorable. Studies investigating the Nd:YAG laser and PDT found that survival rates were comparable, and that PDT was technically easier to perform, more comfortable for patients, and caused fewer side effects (e.g., perforation).

In a systematic review and meta-analysis, investigators examined the effectiveness of PDT in the treatment of Bowen disease (BD) and cutaneous squamous cell carcinoma (cSCC) for clearance rate (CR) after 1 year. A total of 43 studies were included, enrolling 1,943 BD lesions and 282 SCC lesions. Pooled CRs for BD and SCC were 76 % (95 % CI: 71 % to 80%; I2 = 78.9 %) and 51 % (95 % CI: 35 % to 66 %; I2 = 85.7 %), respectively. The authors concluded that these findings supported the selective use of PDT for BD; however, patients should be advised of potential for recurrence. Moreover, these researchers stated that although PDT can be used for certain cases of cSCC, the high rate of treatment failure necessitates close surveillance for residual or recurrent disease; further studies are needed to justify the usage of PDT in the treatment of BD and cSCC (Yongpisarn 2022).

PDT has also been evaluated as an adjunct to stenting and drainage as a palliative treatment for unresectable bile duct cancer. Two pivotal yet small RCTs have demonstrated improvements in survival.

Ortner et al (2003) conducted a prospective, open-label, randomized multicenter study that aimed to compare PDT in addition to stenting with stenting alone in patients with NCC. A total of 39 patients with non-resectable cholangiocarcinoma were randomized to either PDT plus stenting (Group A, n =20) or stenting alone (Group B, n = 19). Investigators reported that the median survival was 493 days (95% CI, 276–710) in group A and 98 days (95% CI, 87–107) in group B ($P < 0.0001$). The investigators noted that PDT also improved biliary drainage and quality of life.

Zoepf et al (2005) conducted a randomized controlled study that investigated the influence of PDT on survival time in advanced bile duct cancer (BDC). A total of 32 patients with non-resectable cholangiocarcinoma were randomized. Light activation was performed in the patients assigned to PDT 48 hours after intravenous application of 2 mg/kg body weight of Photosan-3, an oligomer of hematoporphyrin that has been approved for use in the European Union but is not approved by the FDA. In the control group, patients were treated with stenting and drainage without PDT. The investigators stated that the PDT group and the control group were comparable due to age, gender, performance status, bilirubin level, and bile duct cancer stage. The investigators reported that the median survival time after randomization was 7 months for the control group and 21 months for the PDT group ($p = 0.0109$). The investigators noted that, in 50% of the initially percutaneously treated patients, they were able to change from percutaneous to transpapillary drainage after PDT.

Li et al (2023) stated that PDT is a promising treatment for non-muscle-invasive bladder cancer (NMIBC). In a systematic review, investigators examined the safety and effectiveness of PDT for the

treatment of NMIBC. A total of 28 single-arm studies were included in the meta-analysis. For unresectable NMIBC, therapeutic PDT achieved CR in 68 % (95 % CI: 59 % to 77 %) of patients. Among these CR cases, 71 % (95 % CI: 56 % to 85 %) and 38 % (95 % CI: 12 % to 64 %) had a RFS longer than 12 and 24 months, respectively. For Tis patients, the CR rate was 68 % (95 % CI: 56 % to 80 %), and 84 % (95 % CI: 48 % to 100 %) and 13 % (95 % CI: 1 % to 32 %) had a RFS longer than 12 and 24 months. For patients with resectable tumors, post-resection adjuvant PDT could provide a 12 and 24 months RFS in 81 % (95 % CI: 76 % to 87 %) and 56 % (95 % CI: 41 % to 71 %) of them. The complications were mostly mild and transient, including lower urinary tract symptoms and photosensitivity. The authors noted that although high-level evidence is still lacking, current studies suggested that both therapeutic and adjuvant PDT provided satisfying safety and effectiveness. Moreover, these researchers stated that as a promising option for NMIBC, PDT deserves further examination by future high-quality research.

Although PDT (using porfimer sodium or other photosensitizing agents) has been used in treatment of other cancers, all are either in Phase I or Phase II studies and have not yet been proven outside an investigational setting.

PROFESSIONAL GUIDELINE(S)

The 2026 National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology state that in patients with superficial basal cell carcinoma or squamous cell carcinoma in situ, therapies such as topical imiquimod, topical 5-fluorouracil (5-FU), or photodynamic therapy (PDT) may be considered, although cure rates are approximately 10% lower than for surgical treatment modalities. These options are also recommended for patients where surgery or radiation therapy is contraindicated or impractical.

Additionally, the NCCN Clinical Practice Guidelines (V.2.2025) Biliary Tract Cancers states, "Photodynamic therapy (PDT) is an ablative therapy that involves intravenous injection of a photosensitizing drug followed by selective irradiation with light of a specific wavelength to initiate localized drug activation and has been used for palliation in patients with extrahepatic cholangiocarcinoma (CCA). The combination of PDT with biliary stenting was reported to be associated with prolonged overall survival (OS) in patients with unresectable CCA in two small RCTs."

REGULATORY STATUS

Photofrin (porfimer sodium) is the only photosensitizing agent with specific indications for use that has been approved by the U.S. Food and Drug Administration (FDA). It was approved in 2003.

The U.S. Food and Drug Administration (FDA) is responsible for ensuring the safety, efficacy, and quality of drugs sold in the United States. This includes both prescription and over-the-counter medications. Refer to the FDA Drug website. Available from: https://www.fda.gov/drugs [accessed 2025 Jan 12]

The FDA maintains information for consumers and health professionals on new drug warnings and other safety information, drug label changes, and shortages of medically necessary drug products. Available from: Drug Safety and Availability | FDA [accessed 2025 Jan 12]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
96570	Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drugs(s); first 30 minutes (List separately in addition to code for endoscopy or bronchoscopy procedures of lung and gastrointestinal tract)
96571	Each additional 15 minutes

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HCPCS Codes

Code	Description
J9600	Drug; porfimer sodium, 75 mg

ICD10 Codes

Code	Description
C15.3 - C15.9	Malignant neoplasm esophagus (code range)
C34.00 - C34.92	Malignant neoplasm bronchus and lung (code range)
C78.00 - C78.02	Secondary malignant neoplasm of lung (code range)
C78.80 - C78.89	Secondary malignant neoplasm of other and unspecified digestive organs (code range)
D00.1	Carcinoma in situ of esophagus
D02.20 - D02.22	Carcinoma in situ of bronchus and lung (code range)
K22.70 - K22.719	Barrett's esophagus (code range)

REFERENCES

American Society for Gastrointestinal Endoscopy (ASGE). Technology status evaluation report. Photodynamic therapy for gastrointestinal disease. Gastrointest Endosc. 2006;63(7):927-32.

American Gastroenterological Association (AGA). Medical position statement on the management of Barrett's oesophagus. Gastroenterol. 2011 Mar;140(3):1084-91.

Li H, et al. Efficacy and safety of photodynamic therapy for non-muscle-invasive bladder cancer: a systematic review and meta-analysis. Front Oncol. 2023 Oct 4:13:1255632.

National Comprehensive Cancer Network (NCCN) [Internet]. Basal cell skin cancers. NCCN Clinical Practice Guidelines in Oncology. Version 1.2026;2025 Sept 2 [Accessed 2026 Jan 914] Available from: http://www.nccn.org/professionals/physician_gls/PDF/nmsc.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Squamous cell skin cancers. NCCN Clinical Practice Guidelines in Oncology. Version 1.2026;2025 Sept 2 [accessed 2025 Jan 14] Available from: http://www.nccn.org/professionals/physician_gls/pdf/squamous.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Biliary Tract Cancers. NCCN Clinical Practice Guidelines in Oncology. Version 2.2025;2025 Jul 2 [Accessed 2026 Jan 14] Available from: https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Esophageal and Esophagogastric Junction Cancers. NCCN Clinical Practice Guidelines in Oncology. Version 1.2026;2025 Dec 10. [Accessed 2026 Jan 14] Available from: https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf

National Institute for Health and Clinical Excellence (NICE) [Internet]. Interstitial photodynamic therapy for malignant parotid tumours. 2008 Apr [Accessed 2026 Jan 14] Available from: https://www.nice.org.uk/Guidance/IPG259

National Institute for Health and Clinical Excellence (NICE) [Internet]. Photodynamic therapy for Barrett's oesophagus. IPG 350. 2010 Jun [Accessed 2026 Jan 14] Available from:https: https://www.nice.org.uk/Guidance/IPG350

National Institute for Health and Clinical Excellence (NICE) [Internet]. Barrett's oesophagus and stage 1 oesophageal adenocarcinoma: monitoring and management. 2023 Feb 08 [accessed 2025 Jan 14]. Available from: https://www.nice.org.uk/guidance/ng231

National Institute for Health and Clinical Excellence (NICE) [Internet]. Photodynamic therapy for brain tumours. 2009 Mar 25 [Accessed2026 Jan 14] Available from: https://www.nice.org.uk/guidance/ipg290

Ortner ME, et al. Successful photodynamic therapy for unresectable cholangiocarcinoma. Gastroenterol. 2003 Nov;125(5):1355-63.

Penetra M, et al. Trial watch: an update of clinical advances in photodynamic therapy and its immunoadjuvant properties for cancer treatment. Oncoimmunology. 2023;12(1):2226535.

Yongpisarn T, et al. Durable clearance rate of photodynamic therapy for Bowen disease and cutaneous squamous cell carcinoma: a systematic review and meta-analysis. Dermatol Surg. 2022

Apr 1;48(4):395-400.

Zoepf T, et al. Palliation of nonresectable bile duct cancer: improved survival after photodynamic therapy. Am J Gastroenterol. 2005 Nov;100(11):2426-30.

SEARCH TERMS

Blue light therapy

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Photodynamic therapy for malignant conditions is not specifically addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 7/26

Revised:

Reviewed:

Date	Summary of Changes
11/1/2026	• New

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: PHYSICAL THERAPY

POLICY EFFECTIVE DATE:	3/1/2025
Policy Control #:	1370/20.000057
Next Annual Review:	March, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

Evaluation: 97161, 97162, 97163, 97164
Modalities: 97010-97039, G0281, G0283, G0329
Therapeutic Procedures: 97110-97546
Tests & Measurements: 97750, 97755
Orthotic & Prosthetic Management: 97760, 97761, 97763

DESCRIPTIONS

Physical therapy is the evaluation, treatment, or prevention of disability, injury, disease, or other condition of health using physical, chemical, and mechanical means, including but not limited to heat, cold, light, air, water, sound, electricity, massage, mobilization, and therapeutic exercises, with or without assistive devices; and the performance and interpretation of tests and measurements to assess pathophysiological, pathomechanical, and developmental deficits of human systems to determine treatment and assist in diagnosis and prognosis.

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Physical therapy services must be considered to be specific, effective, and reasonable treatment for the patient's diagnosis and physical condition relative to information gathered on the care plan/progress note. Services must be performed to achieve a specific diagnosis-related goal for a patient who has reasonable expectation of achieving measurable improvement in a reasonable time. These services must require the judgment, knowledge, and skills of a qualified provider because of the complexity and sophistication of the therapy and the physical condition of the patient.

Physical therapy services may be habilitative or rehabilitative in nature.

- Rehabilitation services are health care services that help a person keep, get back, or improve skills and functioning for daily living that have been lost or impaired because a person was sick, hurt, or disabled.

- Habilitation Services are health care services that help a person keep, learn, or improve skills and functioning for daily living. They include the management of limitations and disabilities, including services or programs that help maintain or prevent deterioration in physical, cognitive, or behavioral function.
    - Refer to specific member contracts for availability of benefits, if any, relating to habilitative services.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

- Chiropractic Care, 10.01.02
- Durable Medical Equipment, Prosthetics/Orthotics & Medical Supplies, 1370/20.000509
- Home Health Care, 1370/20.000048.
- Neuromuscular/Functional Electric Stimulation, 1370/20.000073.
- Occupational Therapy, 1370/20.000104.
- Speech Language/ Pathology Services, 1370/20.000056

Payment Policies:

- Chiropractic Services, 1550/20.000167

POSITION STATEMENT

CDPHP administers benefits for medically necessary physical therapy services as outlined below.

POLICY NAME: PHYSICAL THERAPY

Outpatient Physical Therapy

CDPHP administers benefits for medically necessary physical therapy services when all of the following conditions are met:

1. Physical therapy services are medically necessary, are recommended by the ordering practitioner, and are related to the treatment or diagnosis of a physical illness or injury (includes medically diagnosed congenital defect of a covered child).

2. Services are ordered by a primary care physician, neurologist, pediatric neurologist, neurosurgeon, orthopedic surgeon, physiatrist, rheumatologist, podiatrist, hand surgeon, vascular surgeon, or pulmonologist.

3. A plan to ensure the successful transition to a home exercise program will be initiated early in the course of therapy.

4. Services are provided by a qualified practitioner (e.g., physical therapist, physiatrist) who is performing within the scope of their license.

5. The goal of the program is to develop and train the patient to independently participate in a home exercise program to achieve maximum expected benefit.

6. Physical therapy services are subject to all applicable contract limitations.

Autism Spectrum Disorder

Benefits are provided for covered therapeutic services, to include those for habilitative services, necessary to develop, maintain, or restore, to the greatest extent practicable, functioning of an individual when such services are provided by a licensed physical therapist for the treatment of autism spectrum disorder. Such benefits will apply only to those plans to which the mandate applies.

Vestibular Rehabilitation Therapy

Benefits may be provided for vestibular rehabilitation therapy for enrollees who meet the following criteria:

- Documentation of vestibular hypofunction with continuous presenting symptoms for at least two months and;

POLICY NAME: PHYSICAL THERAPY

- Unresponsive to conventional therapy.

POLICY CONSIDERATIONS

Benefits for physical therapy services are subject to all contract limitations and appropriate visit cost-share as stated in the enrollee's contract.

CDPHP will reimburse physical therapy services as a global payment based upon first service billed, per date of service, per practitioner, per contractual agreement.

A physical therapy session is defined as treatment, and/or evaluation, on any given day. Sessions include a combination of modalities and procedures.

Certain physical therapy services may be billed by selected practitioners who are performing within their scope of practice.

All patients participating in physical therapy are expected to actively participate in a daily home exercise program, outlined by the physical therapist, to meet expected goals.

Benefits are provided for medically necessary physical therapy services in the home setting as follows:

- Services are rendered by a participating home health agency and;
- Required criteria for home health care services are met in accordance with resource coordination policy, Home Health Care.

Coverage is provided for establishment/re-evaluation of home self-management maintenance programs, up to a maximum of six visits per calendar year. No coverage will be provided for the continuation of maintenance programs (activities that preserve the patient's present level of function, or when no additional functional progress is apparent or expected to occur).

CDPHP does not provide benefits for massage therapy as a stand-alone treatment. Massage therapy (97124) is considered an acceptable treatment when it is part of a comprehensive treatment plan consisting of a combination of other covered procedures and modalities, and performed by a practitioner who is licensed and who is performing within the scope of the license.

Appending modifier 59 on the evaluation (97161-97163) does not provide additional reimbursement.

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Medically necessary physical therapy conducted on two non-adjacent body parts (e.g., lumbosacral and cervical spine or a shoulder and wrist) will be reimbursed at one and a half times standard therapy when billed using modifier 59.

Medically necessary physical therapy conducted on two or more co-linear and adjacent body parts (e.g., cervical and thoracic spine or a shoulder, elbow, and wrist) will be reimbursed as a single standard therapy.

In a physical therapy session, it is expected there be a maximum ratio of up to three patients to one physical therapist (3:1 or 2:1 or 1:1) for all treatment modalities, regardless of treatment location (e.g., pool or land).
Gait training must be skilled in nature (i.e., designed to restore functional abilities).

- Benefits will be provided for covered durable medical equipment required as a part of a home program when in compliance with the requirements outlined in the CDPHP resource coordination policy, Durable Medical Equipment, Prosthetics/Orthotics & Medical Supplies, 1370/20.000509.

When a service or procedure that may be either habilitative or rehabilitative in nature is provided for habilitative purposes, the use of modifier 96 is required to indicate that the service or procedure provided was a habilitative service.

Services or procedures provided for rehabilitative purposes do not require the use of a modifier.

All physical therapy services are subject to retrospective review for medical necessity as defined by this policy and for compliance with the enrollee's contract.

- Providers who demonstrate unexpected variations in utilization outcomes over a period of time may be subject to focused review.

Coverage will no longer be provided once the allowable maximum benefit is exhausted, even if the medical necessity criteria stated above is met.

EXCLUSIONS

Physical therapy that duplicates services being provided as part of another therapy program through another therapy discipline (i.e., occupational therapy). When multiple therapies are used, each must have separate written treatment plans and must provide significantly different treatments.

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Physical therapy that duplicates services being provided by a federal or state governmental agency (i.e., Early Intervention Program), by a school district (Individualized Educational Program) or by a developmental learning center that are sufficient in meeting the needs of an individual.

Chronic conditions which will require maintenance therapy (S8990) to prevent regression.

Any treatment relating to temporomandibular joint disease when it is dental in nature.

Iontophoresis (97033), used for administration of non-steroidal anti-inflammatory drugs or corticosteroids for treating musculoskeletal disorders, as scientific evidence does not support the use of this procedure as an effective physical therapy modality.

Infrared therapy (97026), used for the treatment of diabetic and/or non-diabetic peripheral sensory neuropathy, wound healing, or pain management (e.g., Anodyne Therapy System) as scientific evidence does not support the use of this procedure as an effective physical therapy modality.

Hippotherapy (S8940), as scientific evidence is insufficient to determine the effects of this technology on health outcomes for any indication, including autism spectrum disorder, cerebral palsy, or other motor dysfunctions.

Prolotherapy (M0076), for the treatment of joint or ligament instability, as scientific evidence does not support the use of this procedure as an effective physical therapy modality.

Orthotic and prosthetic training, fitting, and checkout (97760, 97761, 97763) are considered global to the dispensing of the device.

Services for the purpose of athletic training evaluation (97169, 97170, 97171, 97172), enhancing athletic performance or for recreation.

Sensory integrative techniques (97533), as scientific evidence does not support the use of these services as a physical therapy modality.

Self-care/home management training, community/work reintegration training, physical performance test or measurement, and assistive technology assessment (97535, 97537, 97750, 97755).

POLICY NAME: PHYSICAL THERAPY

Work hardening programs (97545, 97546), as such programs are not considered medically necessary, but rather a requirement of employment.

Benefits are not provided when a session consists of modalities alone (i.e., hot packs, whirlpool, paraffin baths, Hubbard Tank, cold packs/ice packs, and contrast baths). These alone are not considered a skilled level of treatment.

Functional rehabilitation programs when goals of increasing functional strength have been achieved and the patient no longer requires skilled physical therapy intervention to continue rehabilitative therapeutic exercises.

Gait training rendered for assistive walking, when the patient is walking repetitiously and merely improving distance or endurance, whether assistive or non-assistive.

Concurrent treatment for the same condition by both a chiropractor and physical therapist is not allowed.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy. • Benefits are provided for a condition amenable to significant clinical improvement within a period of 60 days or less from the date of the initial treatment.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy. Benefits for unlimited medically necessary physical therapy visits. Includes therapy that would otherwise be covered as an inpatient and is provided under the care of a physician pursuant to a written plan of treatment. The following physical therapy codes are covered: • Evaluation: 97161, 97162, 97163, 97164 • Modalities: 97010-97032, 97033-97039, G0281, G0283, G0329 (97026 is non-covered). G0281 and G0329 are only covered for chronic stage III and stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of

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	conventional care as part of a therapy plan of care. • Therapeutic procedures: 97110-97130, 97139-97542, 97750, 97755, 97760-97763 (97545, 97546 are non-covered)
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy. Benefit coverage includes unlimited medically necessary physical therapy visits. Benefits for functional electrical stimulation (97014, 97032) used as a treatment modality for spinal cord and head injury, cerebral palsy, and upper motor neuron disease are not provided. Coverage remains available for functional electrical stimulation for indications other than those listed above when medically necessary.
SMALL GROUP/ COMMERCIAL INDIVIDUAL:	Rehabilitative physical therapy services are covered only when: • Therapy is related to the treatment or diagnosis of a physical illness or injury (in the case of a covered child, this includes a medically diagnosed congenital defect); **and** • Therapy is ordered by a physician; **and** • The enrollee has been hospitalized or has undergone surgery for such illness or injury. Covered physical therapy services must begin within six months of the later to occur: • The date of the injury or illness that caused the need for the therapy; • The date of discharged from the hospital where the surgical treatment was rendered; **or** • The date outpatient surgical care is rendered. Habilitation services consisting of physical therapy are covered in the outpatient department of a facility or in a health care professional's office.

SOURCES

1. Black, Angel, Pesznecker, Gianna, "Outcome Analysis of Individualized Vestibular Rehabilitation Protocols The American Journal of Otology," 21:543:551, 2000.
2. Capital District Physicians' Health Plan, Inc. Participating Adjunct Provider Agreement.
3. Member contract language
4. Empire Medicare Services, Medical Policy Bulletin Licensed Physical Therapy (Y-4E), revised 9/8/98, www.empiremedicare.com
5. Helen Cohen, EdD, "Vestibular Rehabilitation Reduces Functional Disability," Otolaryngol Head Neck Therapy 107:638, 1992.
6. National Government Services Local Coverage Determination: Outpatient Physical and Occupational Therapy Services (L33631), effective 10/1/18: https://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/home-lob/pages/medical-policy-center/mpc-search-detail/lcd%20for%20outpatient%20physical%20and%20occupational%20therapy%20services%20(l33631)/!ut/p/z1/pVJdb4IwFP0r2w8gt3xJfaygyJcgU5G-mA4KkgkYNJjt168uy0x0m1nWl-benp5zenqBwhpow_qqZMeqbdhO1CkdbDTijGXZRF5oyQYinhah6SJEtm7AClIHUuW0thoCyT00Fcfoh0UQuPcAwo7SBWZQAt2z41aqmqKFdVMeap5XGeu4sEA_SC4m1BAjok1GljWPVHukfAJ-UUnFM4wLAzY9ExHTj4LZxERobkDSV_wEy6btapHR05lxn1U5pIWuaFjjTOK5kktagbCEDZxJQx1nWoFZritDmN4oXAXlf6uQmMFmvhzH4u6B9Txr25eKn5myHWfdpfTDEaQR644PYo_HthPORPtvFq8TWMQiAS_wV0sHq8j-bwLu1RfdzEnifs0UlWFfN68SfR7E-LQotmVNSDSTUrd_88jjO7ebTAk!/dz/d5/L2dBISEvZ0FBIS9nQSEh/?clearcookie=&savecookie=&LOB=Part%20B&REGION=
7. Neil Shepard,Ph.D./Steven Telian, M.D., "Programmatic Vestibular Rehabilitation," Otolarngol Head Neck Surgery",112: 173-82, 1995.
8. New York State Medicaid Redesign Team: Medicaid Managed Care Benefit Changes, 2011-2012, www.health.ny.gov
9. New York State Medicaid Update: Limitation for Coverage for Functional Electrical Stimulation (FES), Volume 29, No. 10, September 2013, http://www.health.ny.gov/health_care/medicaid/program/update/2013/2013-09.htm
10. Nordin, M; Campello, M. Lower Back Pain: Physical Therapy, Exercise and the Modalities: When, What and Why? Neurologic Clinics, Vol. 17:1, Feb. 1999.
11. Other Payers.
12. Rene, Shubert,Balkany, "Visual-Vestibular Habituation and Balance Training for Motion Sickness," Physical Therapy, Vol. 79:10, Oct. 1999.
13. Steven Telian, MD, "Habituation Therapy for Chronic Vestibular Dysfunction: Preliminary Results," Otolaryngol Head Neck Surgery, 103:89,1990.
14. Susan Whitney, PhD.,PT, Maureen Rossi, PhD, PT, "Practical issues in the Management of the Dizzy and Balanced Disorder Patient. Efficiency of Vestibular Rehabilitation,"

POLICY NAME: PHYSICAL THERAPY

Otolaryngologic Clinics of North America Vol. 33:3, June 2000.

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POLICY APPROVAL DATES

New:	11/89
Revised:	05/93, 05/94, 05/95, 04/96, 12/96, 08/98, 07/99, 01/00, 03/00, 11/00 01/01, 01/02, 09/02, 03/03, 01/04, 08/04, 05/05, 02/06, 05/06, 05/07, 11/07, 03/08, 05/08. 03/09, 11/09, 03/10, 05/10, 03/11, 09/11, 11/11, 03/12, 07/12, 09/12, 03/13, 09/13, 11/13, 03/16, 09/16, 01/17, 01/18, 03/18, 07/18, 09/18, 11/18, 03/19, 11/20, 3/22, 3/23, 5/23, 5/24, 3/25, 5/25
Reviewed:	03/14, 03/15, 03/17, 3/20, 3/21, 3/24, 3/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
3/1/2025 *No change to effective date of policy	Under Medicare section, removed information on iontophoresis for hyperhidrosis as this listed in the Non-Covered Technologies policy with an exception for Medicare Advantage.
3/1/2025	Removed Pneumatic cervical traction devices (E0856) from Exclusions as it is addressed in the Durable Medical Equipment, Orthotics/Prosthetics and Medical Supplies policy.
9/1/2024	Under Policy Considerations added the following statement: Appending modifier 59 on the evaluation (97161-97163) does not provide additional reimbursement.
6/1/2023	Removed specific diagnoses from the exclusion section.
4/1/2022 *No change to policy effective date	Clarified coverage in Medicare section and removed deleted codes 97005 and 97006. Removed visit limitations under product variations as contracts are the best source for identifying limits.

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4/1/22	Added coverage criteria for 97033 in Medicare Advantage section.
1/1/21	Updated the Select Plan/Harp section as coverage now includes unlimited medically necessary physical therapy visits.

This Resource Coordination Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI) and Capital District Physicians' Healthcare Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

MEDICAL POLICY

Medical Policy Title	**Platelet Rich Plasma and Growth Factor Treatments**
Policy Number	**2.01.24**
Current Effective Date	**January 1, 2027**
Next Review Date	**January 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Platelet-Rich Plasma (PRP) and autologous platelet-derived preparations (i.e., Basic Fibroblast Growth Factor (BFGF), Epidermal Growth Factor (EGF), Placental Angiogenic Growth Factors (PGFs) are considered **investigational** for **ALL** indications.

RELATED POLICIES

Corporate Medical Policy

7.01.35 Bioengineered Tissue Products for Wound Treatment and Surgical Interventions

8.01.10 Prolotherapy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Growth factors are polypeptides produced by cells during development and in response to injury. Owing to their effects on cell proliferation, growth factors have undergone extensive analyses, to determine their usefulness as wound healing agents.

Examples of growth factors used in wound healing are:

I. Basic Fibroblast Growth Factor (BFGF);

II. Epidermal Growth Factor (EGF);

III. Placental Angiogenic Growth Factors (PGFs); and

IV. Platelet-Derived Growth Factor (PDGF).

Platelet-rich plasma (PRP) preparations, which contain growth factors, have been proposed as a primary treatment of miscellaneous conditions such as arthritis, Dupuytren's contracture, epicondylitis, plantar fasciitis, and tendinopathy.

SUPPORTIVE LITERATURE

Platini et al (2024) conducted a systematic review and meta-analysis to assess the efficacy and safety of autologous PRP gel for managing diabetic foot ulcers in older adults (N=598) across eight randomized controlled trials (RCTs). Compared with standard care, autologous PRP gel significantly improved wound healing rates (Relative Risk [RR]=1.32; 95% CI: 1.22 to 1.57; p<.0001; I2=23%) and reduced the time to complete healing (MD= -16.97 days; 95% CI: -32.64 to -1.29; p<.0001; I2=93%). PRP also shortened hospital stays (MD=-20.11 days; 95% CI: -38.02 to -2.20; p=.03) and decreased the amputation rate (RR=0.36; 95% CI: 0.16 to 0.84; p=.02; I2=0%) when compared to conventional treatments. The authors also noted its infection prevention efficacy during early treatment was significant at one week (RR=0.56; 95% CI: 0.34 to 0.91; p=.02) and two weeks (p=.01), but when assessed from week 4 to 12, no significant differences were observed. No improvements in the reduction of wound surface area were noted in the included studies. Heterogeneity across outcomes varied but was particularly high in healing duration outcomes. Funnel plot analyses revealed minimal publication bias. Limitations included non-standardized dosages of PRP, high heterogeneity for some pooled estimates, and insufficient reporting of some clinical outcomes.

Li et al (2025) conducted a RCT to evaluate tendon healing after arthroscopic extensor carpi radialis brevis (ECRB) repair in recalcitrant lateral epicondylitis (RLE) combined with PRP compared to surgery repair alone. Individuals (n=73) were randomized to the PRP group (n=35) and the control group (n=38). Tendon healing was assessed by MRI at follow up intervals (3, 6, and 12 months). No significant differences were found in magnetic resonance imaging classification and functional scores between groups at preoperative and follow-up periods. However, the PRP group showed a significant improvement in grip and wrist extension muscle strength at 6 weeks postoperatively (P = .008 and P < .001, respectively), whereas the control group did not (P = .583 and .056). No complications were associated with PRP injection. The authors concluded this RCT showed PRP used as an adjuvant to ECRB repair did not show a difference in tendon healing and functional outcomes compared with ECRB repair alone for RLE at 12-month follow-up.

Bains et al (2025) published results from a single center, double blind, RCT comparing PRP injections to corticosteroid (CS) injections in patients (n=52) with mild to moderate symptomatic knee osteoarthritis. Follow up at 6 weeks and 3 months conducted outcome measurements in pain scores, including Visual Analog Scale (VAS) and Numeric Pain Rating Scale (NPRS); and functional scores, including Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Knee Injury and Osteoarthritis Outcome Score (KOOS). Patients were randomized to receive treatment with an intra-articular injection of CS (n = 26) or PRP (n = 26). At six weeks, CS patients had significantly greater reductions from baseline in VAS (-24.26 versus -7.38, P = 0.033) and NPRS (-2.24 versus -0.92, P = 0.042). At three months, CS and PRP patients experienced similar improvements in VAS (-18.27 versus 13.27, P = 0.610) and NPRS (-1.81 versus -0.65, P = 0.798), respectively. Both groups experienced similar improvements in KOOS and WOMAC. The authors concluded this RCT showed treatment of mild to moderate knee osteoarthritis with CS injections demonstrated greater pain reduction at six weeks. Based on these findings, expectations regarding the clinical utility of PRP should be tempered. Limitations of the study include only mild to moderate knee osteoarthritis patients were recruited, patient report of pain and functional scores are subjective, and a lack of

long-term follow up.

PROFESSIONAL GUIDELINE(S)

The American Academy of Orthopaedic Surgeons clinical practice guidelines for the management of osteoarthritis of the hip (AAOS 2017), glenohumeral joint (AAOS 2020), and rotator cuff (AAOS 2025) do not recommend the use of PRP for management of these conditions.

The AAOS clinical practice guidelines for the management of osteoarthritis of the knee (AAOS 2021) made the following recommendations regarding PRP:

- "Platelet-rich plasma (PRP) may reduce pain and improve function in patients with symptomatic osteoarthritis of the knee. (Strength of Recommendation: Limited, downgrade)"

The National Institute for Health and Care Excellence (NICE) published interventional procedure guidance for PRP for knee osteoarthritis (NICE 2019) and state the evidence on efficacy is limited in quality.

The Agency for Healthcare Research and Quality (AHRQ) (2020) published a Technology Assessment on Platelet-Rich Plasma for Wound Care in the Medicare Population. This Technology Assessment was requested by the Centers for Medicare & Medicaid Services to inform reconsideration of a National Coverage Decision on autologous blood-derived products for chronic non-healing wounds. This Technology Assessment evaluates evidence in lower extremity diabetic ulcers, lower extremity venous ulcers and pressure ulcers. Their findings are as follows:

- "We are moderately confident that autologous platelet-rich plasma increases complete wound closure or healing (moderate strength of evidence [SOE]) in individuals with lower extremity diabetic ulcers. We have low confidence that autologous platelet-rich plasma may shorten time to wound closure (low SOE) and reduce wound size (low SOE). Evidence is insufficient to make conclusions about other important outcomes such as hospitalization, amputations, and wound recurrence.
- Evidence is insufficient to make conclusions about the effect of autologous platelet-rich plasma on wound healing in individuals with lower extremity venous ulcers.
- Evidence is insufficient to make conclusions about the effect of autologous platelet-rich plasma on wound healing in individuals with pressure ulcers.
- There is no statistically significant difference in adverse events and serious adverse events between autologous platelet-rich plasma and management without autologous platelet-rich plasma, though the available literature does not evaluate and report adverse events consistently.
- The available literature suffers from important limitations, such as inadequate description of offloading and wound care procedures, wound characteristics, platelet-rich plasma formulation techniques, concentration and volume; inadequate length of follow up and lack of stratification by comorbidities and other patient characteristics such as diabetes control, vascular perfusion and under representation of older adults."

REGULATORY STATUS

The FDA regulates human cells and tissues intended for implantation, transplantation, or infusion

through the Center for Biologics Evaluation and Research, under Code of Federal Regulation, Title 21, parts 1270 and1271. Under these regulations, certain products including blood products such as PRP are exempt and therefore, do not follow the traditional FDA regulatory pathway. To date, the FDA has not attempted to regulate activated PRP.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0232T (E/I)	Injection(s), platelet rich plasma, any site, including image guidance, harvesting and preparation when performed

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HCPCS Codes

Code	Description
G0460 (E/I)	Autologous platelet rich plasma (PRP) or other blood-derived product for nondiabetic chronic wounds/ulcers (includes, as applicable: administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)
G0465 (E/I)	Autologous platelet rich plasma (PRP) or other blood-derived product for diabetic chronic wounds/ulcers, using an FDA-cleared device for this indication, (includes, as applicable: administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)
P9020 (E/I)	Platelet rich plasma, each unit
S9055 (E/I)	Procuren or other growth factor preparation to promote wound healing

ICD10 Codes

Code	Description
E08.621	Diabetes mellitus due to underlying condition with foot ulcer
E08.622	Diabetes mellitus due to underlying condition with other skin ulcer
E09.621	Drug or chemical induced diabetes mellitus with foot ulcer
E09.622	Drug or chemical induced diabetes mellitus with other skin ulcer

Code	Description
E10.621	Type 1 diabetes mellitus with foot ulcer
E10.622	Type 1 diabetes mellitus with other skin ulcer
E11.621	Type 2 diabetes mellitus with foot ulcer
E11.622	Type 2 diabetes mellitus with other skin ulcer
E13.621	Other specified diabetes mellitus with foot ulcer
E13.622	Other specified diabetes mellitus with other skin ulcer

REFERENCES

Agency for Healthcare Research and Quality. Pressure ulcer treatment strategies: comparative effectiveness. AHRQ Pub [Internet]. 2013 May [accessed 2026 Jan 22] No. 13-EHC003-1-EF. Available from: https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/pressure-ulcer-treatment_executive.pdf

American Academy of Orthopedic Surgeons: Management of glenohumeral joint osteoarthritis evidence-based clinical practice guideline [Internet]. 2020 March 23 [accessed 2026 Jan 22]. Available from: https://www.aaos.org/globalassets/quality-and-practice-resources/glenohumeral/gjo-cpg.pdf

American Academy of Orthopedic Surgeons: Management of Osteoarthritis of the Hip Evidence-based Clinical Practice Guideline [Internet]. 2017 Mar 13 [accessed 2026 Jan 22]. Available from: https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-hip/oa-hip-cpg_6-11-19.pdf

American Academy of Orthopedic Surgeons: Management of Osteoarthritis of the knee Evidence-based Clinical Practice Guideline [Internet]. 2021 Aug 31 [accessed 2026 Jan 22]. Available from: https://www.aaos.org/globalassets/quality-and-practice-resources/osteoarthritis-of-the-knee/oak3cpg.pdf

American Academy of Orthopedic Surgeons: Management of Rotator Cuff Injuries Evidence-based clinical practice guideline [Internet]. 2025 Aug 18 [accessed 2026 Jan 22]. Available from: https://www.aaos.org/globalassets/quality-and-practice-resources/rotator-cuff/rotator-cuff-2025/rotator-cuff-cpg.pdf

Bains SS, et al. Platelet-rich plasma injections are inferior to corticosteroid injections for short-term pain relief: a prospective, double-blinded, randomized controlled trial. J Arthroplasty. 2025 Jul;40(7S1):S59-S64.

Boesen AP, et al. Effect of platelet-rich plasma on nonsurgically treated acute Achilles tendon ruptures: a randomized, double-blinded prospective study. Am J Sports Med. 2020 Jul;48(9):2268-2276.

Catapano M, et al. Effectiveness of platelet rich plasma injections for non-surgical management of carpal tunnel syndrome: a systematic review and meta-analysis of randomized controlled trials. Arch Phys Med Rehabil. 2020 May;101(5):897-906.

Chen X, et al. Use of platelet-rich plasma for the improvement of pain and function in rotator cuff tears: a systematic review and meta-analysis with bias assessment. Am J Sports Med. 2020 Jul;48(8):2028-2041.

Chen Z, et al. Platelet-rich plasma versus hyaluronic acid in the treatment of knee osteoarthritis: a meta-analysis. Medicine (Baltimore). 2020 Mar;99(11):e19388.

Dai J, et al. Autologous platelet-rick plasma treatment for patients with diabetic foot ulcers: a meta-analysis of randomized studies. Journal of Diabetes and Its Complications. 2020; 34:1-7.

Davey MS, et al. Anterior cruciate ligament reconstruction with platelet-rich plasma: a systematic review of randomized control trials. Arthroscopy. 2020 Apr;36(4):1204-1210.

Haunschild ED, et al. Platelet-rich plasma augmentation in meniscal repair surgery: a systematic review of comparative studies. Arthroscopy. 2020 Jun;36(6):1765-1774.

Hossam EM, et al. Autologous platelet rich plasma promotes the healing of non-ischemic diabetic foot ulcers. a randomized controlled trial. Ann Vasc Surg. 2022 May;82:165-171.

Huang K, et al. Platelet-rich plasma versus corticosteroid injections in the management of elbow epicondylitis and plantar fasciitis: an updated systematic review and meta-analysis. Am J Sports Med. 2020 Aug;48(10):2572-2585.

Ji-jun H, et al. Efficacy of using platelet-rich plasma in spinal fusion surgery-a preferred reporting items for systematic reviews and meta-analyses-compliant meta-analysis. World Neurosurg. 2020 Jul;139:e517-e525.

Li S, et al. Use of adjunctive platelet-rich plasma for healing during arthroscopic release and repair for recalcitrant lateral epicondylitis: a prospective, double-blind, randomized controlled trial. Am J Sports Med. 2025 Jul;53(8):1817-1825.

Li F, et al. Effect of platelet-rich plasma injections on pain reduction in patients with temporomandibular joint osteoarthrosis: a meta-analysis of randomized controlled trials. J Oral Facial Pain Headache. 2020 Spring;34(2):149-156.

Luo P, et al. How to choose platelet-rich plasma or hyaluronic acid for the treatment of knee osteoarthritis in overweight or obese patients: a meta-analysis. Pain Res Manag. 2020 Mar 10;2020:7587936.

Martí-Carvajal AJ, et al. Growth factors for treating diabetic foot ulcers. Cochrane Database of Systematic Reviews. 2015 Oct;10:CD008548.

Mohammadi Tofigh A and Tajik M. Comparing the standard surgical dressing with dehydrated amnion and platelet-derived growth factor dressings in the healing rate of diabetic foot ulcer: A randomized clinical trial. Diabetes Res Clin Pract. 2022 Mar;185:109775.

National Institute for Health and Care Excellence [Internet]. Interventional procedures guidance: platelet-rich plasma for knee osteoarthritis (IPG637). 2019 Jan 23 [accessed 2026 Jan 22]. Available

from: https://www.nice.org.uk/guidance/ipg637

Nolan GS, et al. Histological analysis of fat grafting with platelet-rich plasma for diabetic foot ulcers-A randomized controlled trial. Int Wound J. 2022 Feb;19(2):389-398.

Platini H, et al. The Potential of autologous platelet-rich plasma gel for diabetic foot ulcer care among older adults: a systematic review and meta-analysis. Ther Clin Risk Manag. 2024 Jan 25;20:21-37.

Qu W, et al. Platelet-rich plasma for wound care in the Medicare population. Technology assessment program project ID 040-353-492. Rockville, MD: Agency for Healthcare Research and Quality [Internet]. 2020 Sep. [accessed 2026 Jan 22]. Available from: https://archive.ahrq.gov/research/findings/ta/prp/prp-wound-care.pdf

Smith OJ, et al., Fat grafting and platelet-rich plasma for the treatment of diabetic foot ulcers: A feasibility-randomized controlled trial. Int Wound J. 2020 Dec; 17(6): 1578-1594.

Wu Q, et al. Platelet-rich plasma versus hyaluronic acid in knee osteoarthritis: a meta-analysis with the consistent ratio of injection. J Orthop Surg (Hong Kong). Jan-Apr 2020;28(1):2309499019887660.

Xie J, et al. Autologous platelet-rich gel for the treatment of diabetic sinus tract wounds: a clinical study. J Surg Res. 2020 Mar;247:271-279.

Yilmaz G and Tanrikulu Y. Short-term results of platelet-rich plasma in the treatment of chronic anal fissure: randomized controlled clinical study. Dis Colon Rectum. 2021; 64(6): 714-723.

Zhao Z, et al. Different intra-articular injections as therapy for hip osteoarthritis: a systematic review and network meta-analysis. Arthroscopy. 2020 May;36(5):1452-1464.e2.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Blood-Derived Products for Chronic Non-Healing Wounds (NCD 270.3) [accessed 2026 Jan 22]

Platelet Rich Plasma (LCD L38937) [accessed 2026 Jan 22]

Billing and Coding: Platelet Rich Plasma (Article A58609) [accessed 2026 Jan 22]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates	
01/01/27	
Date	Summary of Changes
01/01/27	• Original effective date

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: POSTERIOR TIBIAL NERVE STIMULATION FOR URINARY DYSFUNCTION

POLICY EFFECTIVE DATE:	1/1/2026
Policy Control #:	1370/20.000483
Next Annual Review:	November, 2025

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

64566, 0587T-0590T, E0737, A4545, 0988T, 0989T

DESCRIPTION

Posterior tibial nerve stimulation (PTNS), also known as percutaneous tibial nerve stimulation, is a technique of electrical neuromodulation for the treatment of overactive bladder (OAB) and the associated symptoms of urinary urgency, urinary frequency, and urge incontinence in patients who have failed behavioral and/or pharmacologic therapies. PTNS treatment consists of a series of short-term insertions of a percutaneous needle electrode for approximately 30 minutes, with intermittent neuromodulation while the needle electrodes remain in place. The neurostimulator includes a lead set with surface electrodes and a needle electrode, which produces an electrical pulse that travels to the sacral nerve plexus via the tibial nerve. The sacral nerve plexus then regulates the bladder and the pelvic floor functionality.

POSITION STATEMENT

CDPHP administers benefits for PTNS for enrollees with overactive bladder syndrome as a less invasive third-line treatment in accordance with criteria outlined below.

PTNS is considered medically necessary when all of the following criteria are met:

POLICY NAME: POSTERIOR TIBIAL NERVE STIMULATION FOR URINARY DYSFUNCTION

- The enrollee has experienced OAB with associated symptoms of urinary urgency, urinary frequency, and urge incontinence for at least 12 months and the condition has resulted in significant disability (frequency and severity of leakages are limiting the enrollee's ability to participate in daily activities).
- An evaluation has been performed by an appropriate specialist (i.e., urologist or urogynecologist) and determined the individual is a candidate for PTNS
- The medical record demonstrates the following documentation:
    - The enrollee has been compliant with and failed a trial of symptom-appropriate behavioral therapy (e.g., pelvic floor exercise, biofeedback, timed voids, and fluid management), of sufficient length to evaluate potential efficacy.
    - The enrollee has been compliant with and has failed or been unable to tolerate a trial of at least two appropriate medications administered for four to eight weeks.
    - Voiding diary shows continued findings of OAB.
    - The enrollee demonstrates a willingness to attend in-office treatment sessions, to comply with the behavioral therapies, and to continue to keep voiding diaries including documentation of behavioral therapy compliance.

POLICY CONSIDERATIONS

Treatment will consist of an initial course of one 30-minute session per week for 12 weeks. If an enrollee fails to demonstrate improvement after twelve PTNS treatments, continued treatment is considered not medically necessary.

Treatments for maintenance therapy will be allowed only for those patients who achieved a >50% decrease in overactive bladder symptoms with the initial treatment and will be authorized for one 30-minute session per month. The expectation is that the maintenance treatments continue to demonstrate improvement as documented in the enrollee diary. Continued maintenance treatments are considered not medically necessary if improvement of symptoms subside. Prior authorization will be required following the initial 12-week course of PTNS and then yearly to document continued improvement of symptoms for ongoing maintenance treatments to be considered medically necessary.

Treatments for relapse shall only be allowed for those patients who achieved a > 50% decrease in overactive bladder syndrome symptoms with the initial treatment and then relapse. Treatments for relapse will consist of one 30-minute session per week for 12 weeks. If an enrollee fails to demonstrate improvement after these twelve PTNS treatments, further treatment is considered not medically necessary. Prior authorization will be required for PTNS treatments due to relapse.

EXCLUSIONS

CDPHP considers posterior tibial nerve stimulation experimental/investigational when criteria

above are not met. This would include but not be limited to:

- Posterior tibial nerve stimulation for fecal incontinence
- Implantable posterior tibial nerve stimulator (0587T-0590T)
- Transcutaneous tibial nerve stimulator, controlled by phone application (E0737, A4545 (supplies))
- Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (e.g., array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous and subfascial (0988T
- Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous and subfascial (0989T)

PTNS treatment is contraindicated for the following circumstances:

- Individual with pacemakers or implantable defibrillators
- Individual prone to excessive bleeding,
- Individual with nerve damage that could impact either percutaneous tibial nerve or pelvic floor function
- Women who are pregnant or planning to become pregnant during the duration of the treatment.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. Blue Cross/Blue Shield Association (BCBSA), Technology Evaluation Center (TEC). Percutaneous Tibial Nerve Stimulation for the Treatment of Voiding Dysfunction. May, 2014. http://www.bcbs.com/blueresources/tec/vols/28/percutaneous-tibial-nerve.html
2. American Urological Association Clinical Guideline: Overactive Bladder Diagnosis and

Treatment of Overactive bladder in Adults, 2014, http://www.auanet.org/education/guidelines/overactive-bladder.cfm
3. Hayes Inc., Medical Directory Report: Percutaneous Tibial Nerve Stimulation for the Treatment of Lower Urinary Tract Dysfunction, December 9, 2014
4. National Government Services, Medicare Local Coverage Determination (LCD): Posterior Tibial Nerve Stimulation for Voiding Dysfunction (L31391), effective 9/1/2014. http://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/home-lob/pages/medical-policy-center/mpc-search-detail/l31391/!ut/p/a1/xVNNU8IwEP0rvXDsZEsCqcdQsCAtBQShvTAhrRht0wod_Pj1psAM6Iyo4zjmlJe8vN19u0ERmqNI8a1c8VLmiqcVjpoLwnody3KgH7QtCqxPhtCdBOA2KJqhCEUbvk1Enj_IpEIiTfj6CMcdtxcMdheqLMo7FKrVJktiKfhav1JlokqVPNXg5HiHizyV4qUGqYg3BlexsT8w-LqUOsbGMI2sEMZBQvOwhS-sKlAhZIxCAg2wY4FNjJvUJPTCNpccqCmAkjqJ-ZIvScX2ghYKh1rVaOl6Q10vfLIYfMuOdxQc2MDIZavdHg2x26ofCGdChDoHelSwnb4DzPGG_uDSARhRdP3DGs8LNslecOb4i9G0M9bsk35qdNpPDQ_91LtT436V0QcfPfrvGdmTsfao73s3056Nwf256VdfjYoetfrad_yVluXlnSnVbY7mhyHWl_L-8TFi-tdU8_1covnffpsiexi7Ns7MOdw3iu3rhLFuthj4jCVLG3Aj3XrsDSMFIGY!/dl5/d5/L2dBISEvZ0FBIS9nQSEh/?clearcookie=&savecookie=&REGION=&LOB=Part%20B
5. National Institute for Health and Care Excellence (NICE) Guidance (IPG362), Percutaneous posterior Tibial nerve Stimulation for Overactive Bladder Syndrome, October, 2010, http://www.nice.org.uk/guidance/IPG362/chapter/1-Guidance
6. U.S. Food and Drug Administration (FDA), Center for Devices and Radiologic Health (CDRH). Urgent PC Neurostimulation System. Summary of Safety and Effectiveness Data. 510(k) No. K052025. Rockville, MD: FDA; October 17, 2005.

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POLICY APPROVAL DATES

New: 01/15

Revised: 11/22, 5/23, 11/24, 3/26

Reviewed: 01/16, 11/16, 11/17, 11/18, 11/19, 11/20, 11/21, 11/23, 11/25

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: POSTERIOR TIBIAL NERVE STIMULATION FOR URINARY DYSFUNCTION

Effective Date	Update
1/1/2026	Under exclusions added new codes effective 1/1/2026: 0988T and 0989T.
10/1/2024	Added new code E0737 and A4545 to exclusions.
7/1/2023	Added criteria for maintenance PTNS treatments and clarified treatment allowance for relapse.
3/1/2023	Added the following to the exclusions: • Posterior tibial nerve stimulation for fecal incontinence • Implantable posterior tibial nerve stimulator (0587T-0590T)

This Resource Coordination Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI) and Capital District Physicians' Healthcare Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

MEDICAL POLICY

Medical Policy Title	**Powered Compression Devices/Lymphedema Pumps**
Policy Number	**1.01.17**
Current Effective Date	**November 1, 2026**
Next Review Date	**December 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Standard pneumatic compression devices without calibrated gradient pressure (HCPCS codes E0650, E0651) and associated appliances are considered **medically appropriate** for home use when **ALL** of the following criteria are met:

   A. When used for the treatment of proven intractable lymphedema, regardless of body part;

   B. Documented failure of a 4-week trial of conservative therapy which consists of **ALL** of the following:

      1. Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression;

      2. Regular exercise; **and**

      3. Elevation of the affected body part;

   C. The patient has undergone a supervised training program and is able to show proficiency in using the device.

II. Advanced pneumatic compression devices with calibrated gradient pressure (HCPCS code E0652) and associated appliances are considered **medically appropriate** for home use when **ALL** of the following criteria are met:

   A. The individual is otherwise eligible for a standard pneumatic compression pump, meeting the criteria in Policy Statement I;

   B. The individual meets **EITHER** of the following:

      1. Documented failure of a standard pneumatic compression device without calibrated gradient pressure; **or**

      2. Documentation of unique characteristics (e.g., significant scarring) that prevent satisfactory pneumatic compression with a standard compression device without calibrated gradient pressure.

III. Compression devices are considered **investigational** for **ALL** other indications, including but not limited to:

   A. Venous statis ulcers;

B. Peripheral artery disease (e.g., intermittent claudication, ischemia, arterial insufficiency) (HCPCS code E0675);

C. Non-pneumatic compression pump or non-pneumatic sequential compression garment for **any** indication (e.g., Koya Dayspring, VenoWave) (HCPCS codes E0680, E0681, E0682, E0677, E0678, E0679, E0683).

IV. Durable Medical Equipment (DME) Repair

A. Repair of a medically necessary compression device or components not under warranty will be considered **medically appropriate** when the following criteria are met:

1. Physician documentation includes **ALL** the following:

a. Date of compression device initiation;

b. Manufacturer warranty information, if applicable;

c. Attestation that the patient has been compliant with the use of the compression device and will continue to benefit from the use of the compression device;

2. The compression device is no longer functioning adequately; and **BOTH** of the following criteria are met:

a. Inadequate function interferes with activities of daily living; **and**

b. Repair is expected to make the equipment fully functional (as defined by manufacturer).

B. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

V. DME Replacement

A. Replacement of a medically necessary compression device or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

1. The compression device is no longer functioning adequately and has been determined to be non-repairable or the cost of the repair is in excess of the replacement cost;

2. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

B. The replacement of a properly functioning compression device, its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or to make the compression device more aesthetically pleasing;

C. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto,

liability insurance, etc.) is **ineligible for coverage**.

D. Accessories or components for compression devices that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

10.01.01 Breast Reconstruction Surgery and Prophylactic Breast Cancer Risk-Reducing Mastectomy

1370/20.000509 Durable Medical Equipment, Prosthetics/Orthotics & Medical Supplies

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. The Federal Women's Health and Cancer Right Act (WHRCA) of 1998, as well as the New York Insurance Law, mandates coverage of all stages of reconstructive surgery (including surgery and reconstruction of other breast to produce symmetrical appearance, chest wall reconstruction, prosthesis and treatment of physical complication following mastectomy such as lymphedema) for all group health plans, whether insured or self-funded, that provide medical and surgical benefits including mastectomies. Federal laws do not require a diagnosis of breast cancer (preventive mastectomies are also covered).

II. According to the New York State Insurance Laws for prostheses and physical complications of all stages of the mastectomy, including lymphedemas, while an issuer may perform a medical necessity review of these items or services, the issuer should use appropriate written clinical criteria and the most recent medical literature to determine medical necessity.

III. Medical documentation of all of the following criteria is required for consideration of a powered compression device/ lymphedema pump:

A. The lymphedema is intractable (has been difficult to manage and nonresponsive to decongestive treatment). Documentation should include etiology, symptoms and objective findings, measurements establishing the severity of the condition, and the extent to which the lymphedema impairs function of the extremity causing pain and gross distention.

B. Conservative treatments have been tried and found inadequate (e.g., leg/arm elevation, custom fabricated gradient pressure stockings or sleeves, and exercise).

C. Appropriate oversight (e.g., instruction in the operation of the machine, amount of pressure to be used, frequency and duration of use, and ongoing monitoring of use and response to treatment) has been provided.

IV. Per the manufacturer's user guide (Tactile Medical, Minneapolis, MN), the Flexitouch and Flexitouch plus pneumatic compression devices have a two-year warranty for the controller and a five-year warranty for the garments and garment accessories. The average expected controller

lifetime is five years.

DESCRIPTION

Lymphedema is the abnormal accumulation of lymph fluid in the subcutaneous tissues, most commonly affecting the limbs, but it may also involve the chest, head and neck, or genitals. It is classified as either primary, due to a genetic malformation of the lymphatic system, or secondary, resulting from damage caused by surgery, radiation, or trauma. Although lymphedema is considered incurable, early-stage cases may be reversible. Without appropriate treatment, the condition typically progresses.

Management focuses on nonsurgical therapies to reduce limb volume and maintain size, including compression garments, exercise, and pharmacologic support. The standard of care for stage II lymphedema is Complete Decongestive Therapy (CDT), which consists of skin care, manual lymphatic drainage (MLD) or self-administered MLD (SMLD), and compression bandaging. MLD, performed by trained therapists, is a key component of CDT but is not recommended as a standalone treatment for volume reduction.

Compression therapy devices, commonly referred to as lymphedema pumps, are used to promote lymphatic and venous fluid movement from the extremities toward central drainage areas. These devices help prevent complications associated with unmanaged lymphedema and are being investigated as adjunctive therapy for chronic venous insufficiency and venous stasis ulcers. By mimicking the natural pumping action of the calf muscles, they enhance circulation, reduce swelling, and support ulcer healing.

Compression devices are generally categorized into four types:

- Standard non-segmental compression pumps are single-chamber, non-programmable devices that apply uniform pressure across the entire limb during inflation. These basic pumps do not allow for pressure variation between limb regions. Examples include the KCI Extremity Pump 7000 and Huntleigh Flowpress.
- Standard segmental compression pumps feature multiple chambers that inflate sequentially, delivering fixed pressure either equally or following a preset gradient. These non-programmable devices offer more targeted compression than non-segmental models. Examples include the Flowtron Hydroven FPR, KCI Extremity Pump 7500, Lympha Press, Petite Basic 701A, and BioCompression Pump Model 2004.
- Advanced pneumatic compression devices (APCDs) are programmable segmental pumps that deliver calibrated gradient pressure, higher distally and lower proximally, to promote central lymphatic and venous flow. Each chamber's pressure can be individually adjusted, allowing for customized therapy, especially beneficial for patients with localized sensitivity, scarring, or pain. Examples include the Flexitouch System, which features a two-phase treatment cycle, and the ACTitouch System, a wearable device offering both intermittent and sustained compression for venous ulcer management.
- Non-pneumatic compression devices utilize mechanisms other than air pressure to promote

lymphatic drainage and improve circulation. These portable devices are designed for mobility during treatment, making them suitable for daily activities. Examples include the Koya Dayspring and Dayspring Lite, which use shape-memory flex frames embedded in wearable garments to provide sequential calibrated gradient pressure. Another example is the Venowave VW5, a battery-operated device worn below the knee that uses peristaltic motion to promote upward fluid displacement in the lower limbs.

SUPPORTIVE LITERATURE

Lymphedema- Pneumatic Compression Applied to Extremities

Multiple moderate-to-high quality randomized controlled trials (RCTs) and systematic reviews have demonstrated significant improvements in lymphedema outcomes with the use of pneumatic compression pumps compared to conservative care alone.

Hou et al (2024) conducted a systematic review and meta-analysis of 12 studies (identified through March 2024) to assess the efficacy of intermittent pneumatic compression (IPC) as an adjunct to complete decongestive therapy (CDT) for treatment of breast cancer-related upper limb lymphedema. The results indicated that adding IPC to CDT enhanced lymphedema reduction during the initial 4 weeks of treatment. However, this benefit diminished over time, with reduced effectiveness observed approximately 9.4 ± 2.6 weeks after discontinuation of physical therapy. To sustain the synergistic effects of CDT and IPC in promoting lymphatic drainage and symptom relief, the authors recommend periodic and ongoing treatment. Treatment durations across the included studies ranged from 4 to 12 weeks, which may introduce potential bias.

Yao et al (2024) performed a systematic review and meta-analysis of nine RCTs comparing decongestive lymphatic therapy (DLT) with and without IPC in managing upper limb lymphedema following breast cancer surgery. The pooled standardized mean difference for percentage volume reduction was 0.63, indicating no statistically significant difference between the two groups ($p = .15$). Pain and heaviness scores were also similar. However, a significant improvement in external rotation joint mobility was observed in the DLT plus IPC group. These findings suggest that while DLT with IPC is as effective as DLT alone in reducing lymphedema volume and symptoms, it may offer additional benefits in improving joint mobility.

Zaleska and Krzesniak (2025) investigated the effects of a single 45-minute IPC session on fluid movement in patients with stage II and III breast cancer-related lymphedema (BCRL). The study included 25 patients and utilized indocyanine green imaging to assess lymphatic flow before and after treatment. Post-treatment, 92% of patients showed fluid movement in the upper arm, with newly identified drainage pathways directed toward the ipsilateral supraclavicular lymph node (30%), ipsilateral axilla (22%), and axilla, chest, and scapula (26%). Fluorescent intensity changes revealed decreased signal in the hand and forearm, increased signal in the arm (64%), and overall reduction along some or all limb segments (36%). Additionally, skin, and subcutaneous tissue stiffness decreased at all limb levels, with statistically significant reductions in the middle forearm (36.4%) and elbow (33.4%). The authors concluded that IPC effectively promotes proximal fluid movement, facilitates compensatory lymphatic drainage pathways, and reduces tissue stiffness. Early application

of IPC was recommended to prevent limb enlargement and secondary tissue changes.

Lymphedema - Pneumatic Compression Applied to Chest or Trunk

There is limited evidence in the peer-reviewed literature that pneumatic compression pumps applied to the chest and/or trunk provides incremental improvement beyond that provided by pumps treating the affected limb only.

Ridner et al (2012) conducted a RCT to evaluate the effectiveness of advanced pneumatic compression therapy applied to the trunk, chest, and arm (experimental group; n=21) versus treatment of the arm alone (control group; n=21) in patients with stage II breast cancer-related lymphedema. The Flexitouch System was used for both groups at home for 30 days. Statistically significant reductions in bioelectrical impedance and arm circumference were observed within each group; however, no statistically significant difference was found between the two groups. These findings suggest that while both treatments are effective in reducing lymphedema symptoms, there may be no added benefit to pneumatic treatment of the trunk and/ or chest for arm lymphedema. The authors recommend further research with a larger sample size to confirm these findings.

Fife et al (2012) conducted a randomized trial comparing the Flexitouch advanced pneumatic compression device (APCD) with a standard pneumatic compression device (SPCD), the Bio Compression Systems Sequential Circulator, in 36 women across three centers. All participants had at least 5% upper extremity edema volume and were randomized to use either device for one hour daily over 12 weeks (n=18 per group). The SPCD treated only the arm, while the APCD used three garments to treat the arm, chest, and truncal quadrant. Outcome assessments were performed by experienced lymphedema therapists, although blinding procedures were not reported. Edema outcomes were available for all participants, while local tissue water data were available for 28 (78%). At 12 weeks, two of the four primary outcomes showed statistically significant improvements favoring the APCD: percent edema volume reduction ($p = .047$) and tissue water content ($p = .049$). No significant differences were observed in absolute arm volume ($p = .141$) or edema volume in milliliters ($p = .050$). Study limitations include the small sample size, missing data, and lack of clarity regarding assessor blinding. The authors concluded that the observed improvements with APCD use warrant further, more comprehensive research.

Lymphedema - Pneumatic Compression Applied to the Head and Neck

The current literature on the use of the Flexitouch system for head and neck lymphedema (HNL) is limited and primarily consists of a few industry-sponsored randomized controlled trials (RCTs). These studies suggest that the device may offer modest reductions in HNL.

Mayrovitz et al (2017) conducted a functional usability study involving 44 patients with HNL. Participants reported the devices was comfortable and subjective improvement after a single treatment. However, the study was limited by its single-arm, single-treatment design and did not assess long-term home use. A secondary objective assessed safety and acute changes in edema using facial and neck measurements. Statistically significant reductions were observed in composite facial (82.5 ± 4.3 cm to 80.9 ± 4.1 cm; $p < .001$) and neck (120.4 ± 12.2 cm to 119.2 ± 12.1 cm; p

< .001) measurements, with no adverse events reported. Despite its limitations, the study suggests potential short-term benefits of the device.

Gutierrez et al (2019) evaluated the effects of advanced pneumatic compression device APCD treatment in ten head and neck cancer (HNC) survivors who underwent facial composite measurements and near-infrared fluorescence lymphatic imaging (NIRFLI) before and after (APCD) treatments. After a single pneumatic compression treatment, NIRFLI showed enhanced lymphatic uptake and drainage in all subjects. After two weeks of daily use, dermal backflow was reduced or resolved in six of the eight participants with baseline backflow. The authors noted that reductions in facial measurements generally aligned with imaging improvements and patient-reported outcomes. However, they emphasized the need for longer-term studies to determine sustained efficacy and the potential of APCD to reverse dermal backflow in HNL.

Gutierrez et al (2020) conducted an observational study to assess self-reported outcomes and satisfaction among 205 HNC survivors using the Flexitouch APCD for HNL. After at least 25 days of home use, participants completed pre- and post-treatment assessments evaluating efficacy, function, and symptom relief. Statistically significant improvements were observed across all symptom and function domains ($p < 0.00001$), based on the Wilcoxon Signed Rank test. Compliant use for a minimum of 30 minutes per day was high, with 71% reporting daily use and 87% expressing overall satisfaction. These findings support the device's potential for improving quality of life in HNL patients, though the study relied on self-reported data and lacked a control group.

Ridner et al (2021) conducted a randomized, wait-list controlled trial involving 49 patients (control group, n=24; intervention group, n=19). A total of 43 patients completed the study. All participants were assessed at 1, 4, and 8 weeks. The intervention group reported significant improvement in perceived ability to control lymphedema ($p=0.003$) and visible external swelling (front view $p < 0.001$, right view $p = 0.004$, left $p = 0.005$). However, there was no statistically significant differences were found in functional outcomes ($p=0.312$ - $p=0.615$) or in inflammatory biomarker levels ($p>0.10$) between groups from baseline to 8 weeks. Compliance was low, with only one participant using the device the prescribed. The authors concluded that the device appears safe and feasible for HNL management, but acknowledge the need for larger, more diverse RCTs.

Shires et al (2022) conducted a non-industry-sponsored retrospective cohort study evaluating patient-reported outcomes following prolonged home use of the Flexitouch APCD for HNL. Of the 35 patients approved for home-based therapy, the average time from cancer treatment completion to therapy initiation was 9 months. Common symptoms included stiffness (n=31), pain (n=29), dysphagia (n=20), and swelling (n=9). Compliance was high: 33 patients used the device daily, one used it twice daily, and one was non-compliant. The average duration of use was 4.4 months. Patients reported improvements in fibrosis, daily functioning, and overall satisfaction, supporting the potential value of home-based APCD therapy.

Tritter et al (2022) conducted a small pilot study to investigate anecdotal reports of improved dysphagia and dysphonia following pneumatic compression garment therapy (PCGT) in patients with cervical lymphedema post-radiation for head and neck cancer (HNC). Seven patients who had used PCGT for at least six months were surveyed. While 85% reported subjective improvement, objective

laryngoscopic assessments showed no significant change in laryngeal edema scores (p = .975). The authors noted that low inter-rater reliability may have affected the results. Despite the lack of objective findings, the authors concluded that the strong patient-reported benefits suggest the need for further formal investigation.

Cheng et al (2023) performed a systematic review and meta-analysis of 23 studies (n=2147 participants) published through January 2023 evaluating rehabilitation interventions for HNL. Interventions were categorized as standard lymphedema therapy (e.g., standard or modified CDT, early manual lymphatic drainage, focused exercise) and adjunct therapies (e.g., APCDs, kinesio taping, photobiomodulation, acupuncture Six studies (n=399) specifically assessed the Flexitouch APCD, including one RCT and five observational studies. Intervention durations ranged from a single session to six months. Most studies involved participants who had completed or were undergoing CDT, though one study noted no CDT use among its participants. Four studies (80%) were industry-funded or had author affiliations with the manufacture. While reported outcomes were generally positive, the studies were rated as low quality due to high risk of bias. The authors concluded that APCDs may be beneficial and appear safe, but higher-quality research is needed to inform treatment guidelines.

Gregor et al (2025) conducted a proof-of-concept study to evaluate the immediate effects of external advanced pneumatic compression (APC) on pharyngeal and laryngeal head and neck cancer-related lymphedema (HNCRL) using fluoroscopic imaging. Thirty patients underwent imaging before and after a single APC session. All participants demonstrated significant reductions in both external and internal lymphedema. The authors concluded that fluoroscopy is a clinically valuable tool for detecting and quantifying internal HNL and may complement clinical assessment for detecting, monitoring, and quantifying internal HNCRL.

Pneumatic Compression for Venous Insufficiency with Venous Statis Ulcer(s)

There is insufficient evidence in the peer-reviewed literature to establish that intermittent pneumatic compression (IPC) improves outcomes in patients with chronic venous insufficiency (CVI) or venous stasis ulcers.

A Cochrane review updated by Nelson et al (2014) examined whether IPC improves the healing outcomes in patients with of venous leg ulcers. In a meta-analysis of three of the five trials the added benefit of IPC over continuous compression therapy alone, combined treatment was associated with a significantly higher healing rate. However, two of the three trials included in the meta-analysis were judged to have a high risk of bias due to issues such as lack of blinding and unclear allocation or concealment methods. Additionally, there was substantial heterogeneity among the studies, and results from other randomized controlled trials (RCTs) were not pooled. Notably, two trials comparing IPC with continuous compression (stockings or bandages) did not find statistically significant differences in healing rates between groups.

A RCT by Dolibog et al (2014), published after the Cochrane review's literature search cutoff, compared five types of compression therapy for venous leg ulcers. The study evaluated changes in ulcer surface area, volume, linear dimensions, and healing rates. The treatment modalities included: intermittent pneumatic compression (IPC) using a 12-chamber Flowtron device, compression

stockings, multilayer bandages, two-layer bandages, and Unna boots. A total of 147 patients with unilateral venous leg ulcers were randomized into one of the five treatment groups. After two months, the highest healing rates were observed in the IPC group (57%; 16/28 patients), the ulcer stocking system group (56%; 17/30), and the multilayer bandage group (58%; 17/29). In contrast, significantly lower healing rates were reported in the two-layer bandage group (16%; 5/30) and the Unna boot group (20%; 6/30).

Alvarez et al (2020) conducted a small RCT involving patients (n= 52) with large chronic venous leg ulcers (>20 cm^2). The study compared intermittent pneumatic compression (IPC) plus standard compression therapy (n=27) to standard compression therapy alone (n=25), which consisted of multilayer compression bandages. IPC was administered for one hour, twice daily. At nine months, the median time to complete wound closure was significantly shorter in the IPC group compared to the control group (141 days vs. 211 days; p=.03). Additionally, greater pain relief was reported in the IPC group during the first three weeks of treatment, although pain levels were similar between groups at later time points.

A meta-analysis by Xu and Li (2023) was retracted in August 2024 due to findings that the peer review and publishing process for the article were found to be manipulated.

Pneumatic Compression for Arterial Insufficiency

There is insufficient evidence in the peer-reviewed literature to establish that intermittent pneumatic compression (IPC) improves outcomes in patients with chronic arterial insufficiency. Preliminary studies have proposed that IPC improves exercise tolerance in a model of peripheral arterial insufficiency, in part, by enhancing blood flow to collateral-dependent tissues but further research is needed to validate use for these indications.

Moran et al (2015) conducted a systematic review on the use of intermittent pneumatic compression (IPC) for patients with critical limb ischemia (CLI) who were not candidates for revascularization. The review included two controlled before-and-after (CBA) studies and six case series; no randomized controlled trials were identified. One retrospective CBA study using calf compression reported improved limb salvage and wound healing ($p < .01$). Another prospective CBA study using sequential compression of the foot and calf showed statistically significant improvements in claudication distance and quality of life. All included studies had a high risk of bias. The authors concluded that while IPC may be associated with improvements in limb salvage, wound healing, and pain management, the treatment remains unproven due to the lack of well-designed analytical studies.

Zaki et al (2016) performed a retrospective analysis involving 187 patients with critical limb ischemia, comparing outcomes between those who used a specific sequential pneumatic compression device and those who did not receive IPC therapy. The primary endpoint was limb salvage, with secondary endpoints including amputation-free survival and improvements in toe pressure. Among device users, amputation-free survival rates were 98% at 6 months and 96% at 12 months, compared to 90% and 84%, respectively, in the non-user group. Although the difference in limb salvage was not statistically significant ($p = .714$), significant improvements were observed in rest pain ($p < .0001$), reduction in minor amputations ($p = .023$), and overall amputation-free survival (p-value not fully reported).

Non-Pneumatic Compression

There are a few manufacturer-sponsored trials published in 2022. Rockson et al (2022a) conducted an open-label pilot study to the safety, efficacy, and impact on quality of life (QoL) of a novel wearable compression device, Dayspring, for the treatment of upper extremity lymphedema secondary to breast cancer. The study enrolled 40 participants, who used the device for 28 days. Participants in the intervention group received intermittent pneumatic compression therapy for approximately 44 minutes per day, with an adherence rate of 98%. At the end of the study period, participants experienced a statistically significant 18% improvement in overall QoL, as measured by the Lymphedema Quality-of-Life Questionnaire ($p < 0.001$). Additionally, there was a statistically significant reduction in limb volume (mean decrease of 2%; range: 1–12%; $p = 0.042$). The contralateral (non-study) arm showed a negligible, non-significant volume increase of 0.4% ($p = 0.042$). The authors concluded that the Dayspring device appears to be safe, well-tolerated, and effective in improving both limb volume and quality of life in patients with breast cancer-related lymphedema. They recommended further research to validate these findings in larger, controlled trials.

Rockson et al (2022b) conducted a non-randomized, open-label study to evaluate the safety and effectiveness of the Koya Dayspring device for lower limb lymphedema. The study enrolled 24 participants who used the Dayspring lower leg garment for one hour daily over a 12-week period. Participants were encouraged to remain active while wearing the device. The primary outcomes included changes in quality of life (QoL) and lower limb volume. Only 18 participants completed the study. Results showed an 8% improvement in QoL and a 39.4% reduction in lower limb edema compared to baseline, during which no compression pump had been used. Despite these promising findings, the study was limited by its small sample size and lack of a control group. The authors concluded that while the results are encouraging, larger, well-designed, and long-term studies are needed to establish the role of nonpneumatic compression therapy in standard lymphedema treatment protocols.

Rockson et al (2022c) reported findings from the NILE study, a multicenter randomized crossover head-to-head trial comparing the novel nonpneumatic Koya Dayspring to the APCD, the Flexitouch, in 50 adult women with unilateral breast cancer-related upper extremity lymphedema. Participants were randomized to use either the nonpneumatic compression device (NPCD) or the APCD for 28 days, followed by a 4-week washout period, and then crossed over to the alternate device for another 28 days. Compared to the APCD, NPCD resulted in a significantly greater mean reduction in limb edema volume (64.6% vs. 27.7%; $p < .001$), greater improvements in QoL scores, higher adherence (95.6% vs. 49.8%; $p < .001$), and greater patient satisfaction (90% vs. 14%; $p < .001$). Participants also reported that the NPCD facilitated exercise and was more convenient for travel. No adverse events were reported. No adverse events were reported. There was a significant difference in reported compliance between groups, with 95.6% of Dayspring subjects complying with the 60-minute per day therapy and only 49.8% of the control group subjects complying. The authors concluded that the NPCD was noninferior to the APCD in reducing edema volume and offered superior outcomes in symptom relief, adherence, and patient satisfaction.

Barfield et al (2025) conducted the TEAYS study, a randomized, prospective, multicenter, crossover

head-to-head trial designed to evaluate the safety and efficacy of a novel NPCD compared to an APCD for treating lower extremity lymphedema. Following a 30-day washout period without pneumatic therapy, 71 patients (108 affected limbs) were randomized to receive either NPCD or APCD treatment for 90 consecutive days. After this initial phase, participants underwent another 30-day washout period before crossing over to the alternate device for an additional 90 days. Outcome measurements were assessed at baseline and at the end of each 90-day treatment period, with patient-reported outcomes collected at the conclusion of the study. The NPCD group demonstrated a significantly greater mean reduction in limb edema volume compared to the APCD group (369.9 mL vs. 83.1 mL; $p < .05$). Quality of life improvements were also significantly greater with NPCD (mean change of 1.01; $p < .05$) compared to APCD (0.17; $p > .05$). Additionally, patients reported higher adherence with the NPCD (81% vs. 56%; $p < .001$) and greater satisfaction (78% vs. 22%). No device-related adverse events were reported. While the study was industry-funded and subject to potential biases common in crossover designs, the authors concluded that the TEAYS findings, in conjunction with prior research, support the NPCD as a differentiated and potentially superior treatment option for managing lower extremity lymphedema.

PROFESSIONAL GUIDELINE(S)

Pneumatic Compression for Lymphedema

In 2022, the American Venous Forum (AVF), American Vein and Lymphatic Society (AVLS), and the Society for Vascular Medicine (SVM) published an expert opinion consensus statement on lymphedema diagnosis and treatment (Lurie 2022). The following statements were issued regarding use of pneumatic compression:

- "Sequential pneumatic compression should be recommended for lymphedema patients." (92% panel agreement; 32% strongly agree)
- "Sequential pneumatic compression should be used for treatment of early stages of lymphedema." (62% panel agreement - consensus not reached; 38% panel disagreement; 2% strongly disagreed)

Pneumatic Compression for Venous Insufficiency with Venous Ulcer(s)

According to the 2014 joint guidelines from the Society for Vascular Surgery and the American Venous Forum on the management of venous ulcers, when IPC is used, rapid compression cycling appears to improve ulcer healing rates compared to slow cycling (86% vs 61% at 6 months; p=.003) (O'Donnell 2014). The guidelines state:

- "We suggest use of intermittent pneumatic compression when other compression options are not available, cannot be used, or have failed to aid in venous leg ulcer healing after prolonged compression therapy." (Grade – 2, Level of Evidence – C).

The 2025 NCCN clinical practice guidelines on cancer survivorship, version 2.2025, recommend education to identify signs and symptoms of lymphedema, as well as self-care management, skin care, and self-bandaging. The guidelines also recommend consideration of compression garments, manual lymphatic drainage, and pneumatic compression for ongoing home management.

The Wound Healing Society updated guidelines for venous ulcers in 2015 (Marston 2016). The guidelines recommend that for patients with venous ulcers, intermittent pneumatic pressure can be used with or without compression dressings and can provide another option in patients who cannot or will not use an adequate compression dressing system. Venous ulcers of the lower extremity are a chronic, long-term problem. Recurrence rates are as high as 70%; therefore, long-term maintenance must be addressed even for healed ulcers.

In 2019, the American Academy of Family Physicians published recommendations for diagnosis and treatment of venous ulcers (Bonkemeyer 2019). The following statements were issued regarding use of intermittent pneumatic compression.

- "Intermittent pneumatic compression may be considered when there is generalized, refractory edema from venous insufficiency; lymphatic obstruction; and significant ulceration of the lower extremity. Although intermittent pneumatic compression is more effective than no compression, its effectiveness compared with other forms of compression is unclear. Intermittent pneumatic compression may improve ulcer healing when added to layered compression."

In 2022, the AFF/AFLS/SVM expert opinion consensus on lymphedema diagnosis and treatment reached consensus that all patients with chronic venous insufficiency (C3–C6) should be considered for treatment similar to lymphedema patients (Lurie 2022). Studies have demonstrated that sequential pneumatic compression (SPC) results in more rapid healing of chronic venous stasis ulcerations compared to traditional compression bandages.

The 2022 European Society for Vascular Surgery (ESVS) issued clinical practice guidelines on the management of chronic venous disease of the lower limbs (De Maeseneer 2022).

- IPC has a limited role in the conservative treatment of CVD. There are no consistent data available on the use of IPC in CEAP clinical class $C0_S$ - C4.
- For patients with active venous leg ulceration, intermittent pneumatic compression should be considered when other compression options are not available, cannot be used, or have failed to promote ulcer healing. (Class IIb recommendation; Level of evidence B)

<u>Pneumatic Compression for Arterial Insufficiency</u>

The Wound Healing Society updated its guidelines in 2023 for the treatment of arterial insufficiency ulcers, reaffirming its 2014 recommendation. The guidelines state that intermittent pneumatic compression (IPC) can increase blood flow and may be beneficial for limbs with impaired distal perfusion, either as a pre- or post-revascularization intervention (Level II evidence) (Federman 2014, 2024).

In 2024, the American College of Cardiology (ACC) and the American Heart Association (AHA), in collaboration with other organizations, issued a joint clinical practice guideline for the management of lower extremity peripheral artery disease (PAD) (Gornik 2024). For patients with chronic limb-threatening ischemia (CLTI) who are not candidates for revascularization, the use of arterial IPC devices may be considered to support wound healing and alleviate ischemic rest pain. This

recommendation carries a Class 2b strength (weak recommendation) and is based on moderate-quality evidence from non-randomized studies.

REGULATORY STATUS

The Federal Women's Health and Cancer Right Act (WHRCA) of 1998, as well as the New York Insurance Law, mandates coverage of all stages of reconstructive surgery (including surgery and reconstruction of other breast to produce symmetrical appearance, chest wall reconstruction, prosthesis and treatment of physical complication following mastectomy such as lymphedema) for all group health plans, whether insured or self-funded, that provide medical and surgical benefits including mastectomies. Federal laws do not require a diagnosis of breast cancer (preventive mastectomies are also covered).

According to the New York State Insurance Laws for prostheses and physical complications of all stages of the mastectomy, including lymphedemas, while an issuer may perform a medical necessity review of these items or services, the issuer should use appropriate written clinical criteria and the most recent medical literature to determine medical necessity.

The United States Food and Drug Administration (FDA) regulates compression pumps as medical devices. All devices require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Oct 21]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. on our website by the date that the FDA posts the information on our website. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls [accessed 2025 Oct 21]

Pneumatic Compression

Several pneumatic compression pumps, indicated for the primary or adjunctive treatment of primary or secondary (e.g., postmastectomy) lymphedema, have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Examples of devices with these indications intended for home or clinic/hospital use include the Sequential Circulator (Bio Compression Systems); the Lympha-Press and Lympha-Press Optimal (Mego Afek); the Flexitouch and Flexitouch Plus systems (Tactile Medical, formerly Tactile Systems Technology); the Powerpress Unit Sequential Circulator (Neomedic); and the EzLymph and EzLymph M (EEZCare Medical).

Several pneumatic compression devices have been cleared by the FDA for treatment of venous stasis ulcers. Examples include the Lympha-Press, Flexitouch, Flexitouch Plus, and Recovery+ (Pulsar Scientific).

Non-Pneumatic Compression

In 2021, the FDA granted Class II 510(k) clearance for marketing two non-pneumatic, battery-operated, wearable compressible limb devices: the Koya Dayspring System and Dayspring Lite.

- Koya Dayspring system is a prescription-only wearable compression device designed to enhance lymphatic flow. It is indicated for a wide range of conditions, including lymphedema (primary and secondary), post-mastectomy edema, edema following trauma or sports injuries, post-immobilization edema, venous insufficiency, delayed wound healing, stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, lipedema, and phlebolymphedema.
- Dayspring Lite is also a prescription-only wearable compression system, indicated for the treatment of chronic edema, lymphedema, venous insufficiency, and to support wound healing.

In 2008, the Venowave VW5 initially received FDA clearance in 2008 and was granted an updated 510(k) approval in 2024. This nonpneumatic, battery-operated device is intended for use in adults (18 years and older) to manage symptoms associated with post-thrombotic syndrome (PTS), reduce postoperative pain and swelling, and improve blood circulation. It is also indicated for the prevention of deep vein thrombosis (DVT), primary thrombosis, lymphedema, leg swelling due to vascular insufficiency, varicose veins, chronic venous insufficiency, and intermittent claudication.

The 2024 updated contraindications for the Venowave VW5 specify that the device "should not be used to treat patients who have open or freshly healed ulcers, other wounds, or otherwise fragile skin between the knee and ankle of the leg to be treated."

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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HCPCS Codes

Code	Description
E0650	Pneumatic compressor, nonsegmental home model
E0651	Pneumatic compressor, segmental home model without calibrated gradient pressure
E0652	Pneumatic compressor, segmental home model with calibrated gradient pressure

Code	Description
E0655	Nonsegmental pneumatic appliance for use with pneumatic compressor, half arm
E0656	Segmental pneumatic appliance for use with pneumatic compressor, trunk
E0657	Segmental pneumatic appliance for use with pneumatic compressor, chest
E0658	Segmental pneumatic appliance for use with pneumatic compressor, integrated, 2 full arms and chest (effective 10/01/25)
E0659	Segmental pneumatic appliance for use with pneumatic compressor, integrated, head, neck, and chest (effective 10/01/25)
E0660	Nonsegmental pneumatic appliance for use with pneumatic compressor, full leg
E0665	Nonsegmental pneumatic appliance for use with pneumatic compressor, full arm
E0666	Nonsegmental pneumatic appliance for use with pneumatic compressor, half leg
E0667	Segmental pneumatic appliance for use with pneumatic compressor, full leg
E0668	Segmental pneumatic appliance for use with pneumatic compressor, full arm
E0669	Segmental pneumatic appliance for use with pneumatic compressor, half leg
E0670	Segmental pneumatic appliance for use with pneumatic compressor, integrated, two full legs and trunk
E0671	Segmental gradient pressure pneumatic appliance, full leg
E0672	Segmental gradient pressure pneumatic appliance, full arm
E0673	Segmental gradient pressure pneumatic appliance, half leg
E0675 (E/I)	Pneumatic compression device, high pressure, rapid inflation/deflation cycle, for arterial insufficiency (unilateral or bilateral system)
E0676	Intermittent limb compression device (includes all accessories), not otherwise specified
E0677 (E/I)	Nonpneumatic sequential compression garment, trunk
E0678 (E/I)	Nonpneumatic sequential compression garment, full leg
E0679 (E/I)	Nonpneumatic sequential compression garment, half leg

Code	Description
E0680 (E/I)	Nonpneumatic compression controller with sequential calibrated gradient pressure
E0681 (E/I)	Nonpneumatic compression controller without calibrated gradient pressure
E0682 (E/I)	Nonpneumatic sequential compression garment, full arm
E0683 (E/I)	Nonpneumatic, nonsequential, peristaltic wave compression pump

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

Adams KE, Rasumussen JC, Darne C, et al. Direct evidence of lymphatic function improvement after advanced pneumatic compression device treatment of lymphedema. Biomed Opt Express. 2010 Aug;1(1):114-125.

Alvarez OM, et al. Faster healing, and a lower rate of recurrence of venous ulcers treated with intermittent pneumatic compression: results of a randomized controlled trial. Eplasty. 2020;20:e6.

Barfield M, et al. Results from a comparative study to evaluate the treatment effectiveness of a nonpneumatic compression device vs an advanced pneumatic compression device for lower extremity lymphedema swelling (TEAYS study). J Vasc Surg Venous Lymphat Disord. 2025 Jan;13(1):101965. Epub 2024 Sep 1. Erratum in: J Vasc Surg Venous Lymphat Disord. 2025 Sep;13(5):102272.

Bonkemeyer Millan S. Venous ulcers: diagnosis and treatment. Am Fam Physician. 2019 Sep 1;100(5):298-305. PMID: 31478635.

Cheng JT, et al. Rehabilitation interventions for head and neck cancer-associated lymphedema: a systematic review. JAMA Otolaryngol Head Neck Surg. 2023 Aug 01;149(8):743-753. PMID 37382963

Davies C, Levenhagen K, Ryans K, et al. Interventions for breast cancer–related lymphedema: clinical practice guideline from the Academy of Oncologic Physical Therapy of the American Physical Therapy Association (APTA). Phys Ther. 2020;100:1163-1179.

De Maeseneer MG, et al. Editor's choice - European Society for Vascular Surgery (ESVS) 2022 Clinical practice guidelines on the management of chronic venous disease of the lower limbs. Eur J Vasc Endovasc Surg. 2022 Feb;63(2):184-267. Erratum in: Eur J Vasc Endovasc Surg. 2022 Aug-Sep;64(2-3):284-285.

Desai SS and Shao M. Superior clinical, quality of life, functional, and health economic outcomes with pneumatic compression therapy for lymphedema. Ann Vasc Surg. 2020 Feb;63:298-306.

Dolibog P, et al. A comparative clinical study on five types of compression therapy in patients with venous leg ulcers. Int J Med Sci. 2013 Dec 14;11(1):34-43.

Dunn N, et al. Intermittent pneumatic compression for the treatment of lower limb lymphedema: a pilot trial of sequencing to mimic manual lymphatic drainage versus traditional graduated sequential compression. Lymphat Res Biol. 2022 Oct;20(5):514-521.

Faulkner J, et al. Effect of using home-based dynamic intermittent pneumatic compression therapy during periods of physical activity on functional and vascular health outcomes in chronic stroke: A randomized controlled clinical trial. PLoS One. 2025 Feb 18;20(2):e0318942.

Federman DG, et al. Wound Healing Society 2014 update on guidelines for arterial ulcers. Wound Repair Regen. 2016 Jan-Feb;24(1):127-35.

Federman DG, et al. Wound Healing Society 2023 update on guidelines for arterial ulcers. Wound Repair Regen. 2024 Sep-Oct;32(5):619-629.

Fife CE, et al. A randomized controlled trial comparing two types of pneumatic compression for breast cancer-related lymphedema treatment in the home. Support Care Cancer. 2012 Dec;20(12):3279-86.

Gornik HL, et al; Peer Review Committee Members. 2024 ACC/AHA/AACVPR/APMA/ABC/SCAI/SVM/ SVN/SVS/SIR/VESS guideline for the management of lower extremity peripheral artery disease: a report of the American College of Cardiology/American Heart Association Joint Committee on clinical practice guidelines. Circulation. 2024 Jun 11;149(24):e1313-e1410. Erratum in: Circulation. 2025 Apr 8;151(14):e918.

Gutierrez C, et al. Head and neck lymphedema: treatment response to single and multiple sessions of advanced pneumatic compression therapy. Otolaryngol Head Neck Surg. 2019 Apr;160(4):622-626.

Gutierrez C, et al. Longitudinal effects of a novel advanced pneumatic compression device on patient-reported outcomes in the management of cancer-related head and neck lymphedema: A preliminary report. Head Neck. 2020 Aug;42(8):1791-1799.

Haslett ML, et al. Evaluating the effectiveness of a compression sleeve in managing secondary lymphedema. J Wound Care. 2002 Nov;11(10):401-4.

Hassell a, et al. A retrospective study of the effects of the lymphapress pump on lymphedema in a pediatric population. Lymphol. 2001 Dec;34(4):156-65.

Hou S, et al. Efficacy of intermittent pneumatic compression on breast cancer-related upper limb lymphedema: a systematic review and meta-analysis in clinical studies. Gland Surg. Aug 31 2024; 13(8): 1358-1369. PMID 39282029

Lin Y, Yang Y, Xiaoyu Z, et al. Manual lmpatich drainage for breast cancer-related lymphedema: a systematic review and meta-analysis of randomized controlled trials. Clinical Breast Cancer. 2022 Jul;22(5):e664-e673

Lurie F, et al. The American Venous Forum, American Vein and Lymphatic Society and the Society for Vascular Medicine expert opinion consensus on lymphedema diagnosis and treatment. Phlebology. 2022 May;37(4):252-266.

Maldonado TS, et al. Assessment of quality of life changes in patients with lower extremity lymphedema using an advanced pneumatic compression device at home. J Vasc Surg Venous Lymphat Disord. 2021 May; 9(3);745-752.

Marston W, et al. Wound Healing Society 2015 update on guidelines for venous ulcers. Wound Repair Regen. 2016;24(1):136-144.

Mayrovitz HN, et al. Usability of advanced pneumatic compression to treat cancer-related head and neck lymphedema: A feasibility study. Head Neck. 2018 Jan;40(1):137-143. Epub 2017 Nov 13.

Moran PS, et al. A systematic review of intermittent pneumatic compression for critical limb ischaemia. Vasc Med. 2015;20:41-50

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology. Survivorship. Version 2.2025 – May 23, 2025 [accessed 2025 Oct 23]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/survivorship.pdf

Nelson EA, Hillman A, Thomas K. Intermittent pneumatic compression for treating venous leg ulcers. Cochrane Database Syst Rev. 2014 May;2014(5):CD001899. PMID 24820100.

Ridner SH, et al. A randomized clinical trial comparing advanced pneumatic truncal, chest, and arm treatment to arm treatment only in self-care of arm lymphedema. Breast Cancer Res Treat. 2012 Jan;131(1):147-58.

Ridner SH, et al. Advanced pneumatic compression for treatment of lymphedema of the head and neck: a randomized wait-list controlled trial. Support Care Cancer. 2021 Feb;29(2):795-803.

Rockson SG, et al. Clinical evaluation of a novel wearable compression technology in the treatment of lymphedema, an open-label controlled study. Lymphat Res Biol. 2022a Apr;20(2):125-132.

Rockson SG, et al. A non-randomized, open-label study of the safety and effectiveness of a novel non-pneumatic compression device (NPCD) for lower limb lymphedema. Sci Rep. 2022b Aug;12(1):14005.

Rockson SG, et al. Safety and effectiveness of a novel nonpneumatic active compression device for treating breast cancer-related lymphedema: A multicenter randomized, crossover trial (NILE). J Vasc Surg Venous Lymphat Disord. 2022c Nov;10(6):1359-1366.e1.

Rockson SG, et al. Effectiveness of a nonpneumatic active compression device in older adults with breast cancer-related lymphedema: a subanalysis of a randomized crossover trial. Lymphat Res Biol. 2023 Dec;21(6):581-584.

Shires CB, et al. Feasibility of machine-delivered sequential massage for the management of lymphedema in the head and neck cancer survivor. Laryngoscope Investig Otolaryngol. 2022 Jun;7(3):774-778. PMID 35734055

Tastaban E, et al. Role of intermittent pneumatic compression in the treatment of breast cancer-related lymphoedema: a randomized controlled trial. Clin Rehabil. 2020 Feb;34(2):220-228.

Tritter AG, et al. Pilot study: pneumatic compression garment therapy for postradiotherapy

laryngopharyngeal edema. Ear Nose Throat J. 2022 Jan;101(1):54-58. Epub 2020 Jul 20.

Xu Q, Li Z. Effects of pneumatic compression therapy on wound healing in patients with venous ulcers: A meta-analysis. Int Wound J. 2024 Mar;21(3):e14438. Retraction in: Int Wound J 2024 Aug;21(8):e70022. PMID: 37935456.

Yao M, et al. Comparison of intermittent pneumatic compression pump as adjunct to decongestive lymphatic therapy against decongestive therapy alone for upper limb lymphedema after breast cancer surgery: a systematic review and meta-analysis. Breast Care (Basel). 2024 Jun;19(3):155-164.

Zaki M, et al. The role of sequential pneumatic compression in limb salvage in non-reconstructable critical limb ischemia. Eur J Vasc Endovasc Surg. 2016;51:565–571.

Zaleska MT, Krzesniak NE. The intermittent pneumatic compression influences edema fluid movement and promotes the compensatory drainage pathways in patients with breast cancer related lymphedema. Lymphat Res Biol. 2025 Jun;23(3):160-168.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Pneumatic Compression Devices (NCD 280.6) [accessed 2025 Oct 25]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 7/26

Revised:

Reviewed:

Date	Summary of Changes

11/1/2026	• New

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

MEDICAL POLICY

Medical Policy Title	**Private Rooms**
Policy Number	**12.01.06**
Current Effective Date	**November 1, 2026**
Next Review Date	**November 2027**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Private rooms are generally excluded from coverage under the Health Plan's subscriber contracts and certificates.

II. A Health Plan Medical Director will review the physician's order and the patient's clinical record upon receipt of a request for a private room and may determine that a private room is **medically necessary** based on **ANY** of the following indications:

A. Patient has a contagious disease, and isolation is indicated to prevent its spread;

B. Patient is immunocompromised, and the risk of infection is serious;

C. Patient has radiation implants;

D. Patient has severe burns, there is no available bed in a burn unit;

E. Patient is a danger to self or others and requires one-on-one care by a staff member or seclusion due to extreme psychological conditions;

F. Patient has severe eclampsia.

RELATED POLICIES

Not Applicable

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

A private room is a hospital room that is occupied by a single patient. It is not designed for semi-private use and is billed by the hospital as a "private room."

SUPPORTIVE LITERATURE

Not Applicable

PROFESSIONAL GUIDELINE(S)

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

The Center for Disease Control's (CDC) guideline for isolation precautions to prevent transmission of infectious agents in the health care setting (CDC 2007, updated 2024) state single patient rooms are preferred when there is a concern about transmission of an infectious agent. Single-patient rooms are always indicated for patients placed on airborne precautions and in a protective environment and are preferred for patients who require contact or droplet precautions. They go on to say when there are only a limited number of single-patient rooms, it is prudent to prioritize them for those patients who have conditions that facilitate transmission of infectious material to other patients (e.g., draining wounds, stool incontinence, uncontained secretions) and for those who are at increased risk of acquisition and adverse outcomes resulting from hospital acquired infections (HAI) (e.g., immunosuppression).

REGULATORY STATUS

Not Applicable

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
Not Applicable	

REFERENCES

Siegel JD, et al., the Healthcare Infection Control Practices Advisory Committee. Center for Disease Control [Internet]. 2007 Guideline for isolation precautions: preventing transmission of infectious agents in healthcare settings. 2024 Sep [accessed 2025 Oct 1]. Available from: https://www.cdc.gov/infection-control/media/pdfs/Guideline-Isolation-H.pdf

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for private rooms. However, Bed and Board is addressed in the chapter on Inpatient Hospital Services Covered Under Part A, Section 10.1, in the Medicare Benefit Policy Manual. Please refer to the following website for Medicare members: http://www.cms.hhs.gov/manuals/Downloads/bp102c01.pdf [accessed 2025 Sep 30].

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POLICY HISTORY/REVISION

Committee Approval Dates

New: 7/26

Revised:

Reviewed:

Date	Summary of Changes
11/1/2026	• New

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: PROSTATE RECTAL SPACERS

POLICY EFFECTIVE DATE:	10/1/2023
Policy Control #:	1370/20.000505
Next Annual Review:	January, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

55874

DESCRIPTION

Prostate rectal spacers are various materials or devices placed between the prostate and anterior wall of the rectum for use in men receiving radiation therapy for prostate cancer. The anterior wall of the rectum is considered a major dose-limiting factor in radiation therapy of prostate cancer. Physical separation is proposed to allow reduced toxicity and treatment intensification.

The SpaceOAR(R) System is made up of materials that break down naturally by the action of biological agents and is placed inside the patient through a needle. The system retains its position throughout the duration of the patient's radiotherapy treatments and because the system is biodegradable, is absorbed by the patient's body over time.

Barrigel, an injectable gel, is an advanced prostate spacer made from Non-Animal Stabilized Hyaluronic Acid (known as NASHA®). It is used for separation of the prostate and rectum during radiotherapy. It is indicated to temporarily position the anterior wall of the rectum away from the prostate during radiotherapy for localized prostate cancer; and in creating this space, it is the intent of Barrigel to reduce the radiation dose delivered to the anterior rectum. Barrigel is composed of biodegradable hyaluronic acid and maintains space for the entire course of prostate radiotherapy treatment; and it is absorbed by the patient's body over time.

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POLICY NAME: PROSTATE RECTAL SPACERS

POSITION STATEMENT

CDPHP considers transperineal periprostatic placement of biodegradable material (i.e., SpaceOAR, Barrigel) medically necessary in patients with clinically localized prostate cancer when **both** of the following are met:

1. All of the following criteria are met:
   - Low* or favorable intermediate prostate cancer risk group (AUA or NCCN criteria)
   - Dose escalated (≥ 76 Gy) conventional fractionation (1.8-2 Gy fractions) or moderate hypofractionation (HFX) (2.4-3.4 Gy fractions) IG-IMRT planned
   - Eastern Cooperative Oncology Group (ECOG) performance status ≤ 1
   - Modern localization techniques insufficient to improve oncologic cure rates and/or reduce side effects due to at least one of the following:
     - Anatomic geometry precluding ideal rectal constraints
       - (V70 < 10%, V65 < 2 0%, V40 < 40%)
       - Moderate HPX (dose constraints not yet standardized; employ those used in the supporting phase III trials)
     - Medication usage (e.g., anticoagulants)
     - Comorbid conditions (e.g., increased age, history of MI or CHF)

and

2. None of the following criteria exist:
   - Less than five-year life expectancy and asymptomatic
   - Prior prostate cancer treatment (surgery or radiation therapy)
   - Active bleeding disorder or clinically significant coagulopathy
   - Active inflammatory or infectious disease in the perineum or injection area (e.g., prostatitis, anorectal IBD)
   - Prostate volume > 80 cc

*Life expectancy ≥ 20 y (very low risk); ≥ 10 y (low risk)

POLICY CONSIDERATIONS

Use of a prostate rectal spacer is allowed **once** for enrollees with clinically localized prostate cancer meeting the criteria stated above in policy.

The Eastern Cooperative Oncology group (ECOG) performance Status can be accessed at: ECOG Performance Status.

EXCLUSIONS

Patients with obvious rectal invasion or visible T3 and posterior extension should not undergo perirectal spacer implantation.

POLICY NAME: PROSTATE RECTAL SPACERS

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. Centers for Medicare and Medicaid Local Coverage determination: L37485 (Prostate Rectal Spacer) NGS
2. Space OAR™ Hydrogel manufacturer Information: https://www.spaceoar.com/what-is-spaceoar-hydrogel/
3. Clinically Localized Prostate Cancer: AUA/ASTRO/SUO Guideline. 2017; https://www.auanet.org/guidelines/prostate-cancer-clinically-localized-guideline
4. NCCN Guidelines- Prostate Cancer Version 4.2019. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
5. Mariados N, Sylvester J, Shah D, et al. Hydrogel spacer prospective multicenter randomized controlled pivotal trial: dosimetric and clinical effects of perirectal spacer application in men undergoing prostate image guided intensity modulated radiation therapy. Int J Radiat Oncol Biol Phys 2015; 92:971-977. Available at https://www.ncbi.nlm.nih.gov/pubmed/26054865
6. Hamstra DA, Mariados N, Sylvester J, et al. Continued benefit to rectal separation for prostate radiation therapy: final results of a phase III trial. Int J radiat Oncol Biol Phys 2017; 97:976-985. Available at https://www.ncbi.nlm.nih.gov/pubmed/28209443
7. Hayes Technology Brief, Absorbable Perirectal spacer (SpaceOAR System; Augmenix Inc.) During Radiation Therapy for Prostate Cancer, Apil 10, 2018. Annual Review May 1,2019. Available at https://evidence.hayesinc.com/report/htb.spaceoar3407
8. UroToday: Advanced Rectal Spacing in Prostate Cancer Radiation Therapy: The Benefits of Barrigel®: https://www.urotoday.com/video-lectures/aua-2023/video/3360-advancing-rectal-spacing-in-prostate-cancer-radiation-therapy-the-benefits-of-barrigel-neil-mariados.html#:~:text=The%20Barrigel%20trial%20showed%20a,for%20optimal%20radiation%20therapy%20outcomes
9. Barrigel website: https://barrigel.com/
10. Hayes Clinical Evidence Ad Hoc Research Brief: Barrigel

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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Capital District Physicians' Healthcare Network, Inc.

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POLICY NAME: PROSTATE RECTAL SPACERS

POLICY APPROVAL DATES

New: 01/20

Revised: 01/21, 1/23, 9/23

Reviewed: 01/22, 1/24, 1/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
10/1/2023	Added Barrigel® information to policy.
1/1/2023	Added Moderate HPX to criteria under the Position Statement, in accordance with Medicare LCD (L37485).
5/1/2021	Added moderate hypofractionation to criteria.
2/1/2020	New - criteria in policy aligns with Medicare local coverage determination.

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: PROTON BEAM THERAPY

POLICY EFFECTIVE DATE:	1/1/2020
Policy Control #:	1370/20.000495
Next Annual Review:	March, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

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PROCEDURE CODES

77520, 77522, 77523, 77525

DESCRIPTION

Proton beam therapy (PBT) is a form of external radiotherapy in which positively charged subatomic particles (protons) are precisely targeted to a specific tissue mass using a sophisticated stereotactic treatment planning-and-delivery system. The goal of proton beam therapy is to deliver a higher target dose with lower normal tissue exposure than is possible with conventional photon irradiation, thereby improving local control of tumors and reducing acute and late complications.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

Stereotactic Radiosurgery, 1370/20.000434

POSITION STATEMENT

CDPHP administers benefits for proton beam therapy in accordance with the Centers for Medicaid & Medicare Services local coverage determination as outlined below.

POLICY NAME: PROTON BEAM THERAPY

PBT is considered reasonable and necessary in instances where sparing the surrounding normal tissue cannot be adequately achieved with photon-based radiotherapy and is of added clinical benefit to the patient.

- The target volume is in close proximity to one or more critical structures, and a steep dose gradient outside the target must be achieved to avoid exceeding the tolerance dose to the critical structure(s).
- A decrease in the amount of dose inhomogeneity in a large treatment volume is required to avoid an excessive dose "hotspot" within the treated volume to lessen the risk of excessive early or late normal tissue toxicity.
- A photon-based technique would increase the probability of clinically meaningful normal tissue toxicity by exceeding an integral dose-based metric associated with toxicity.
- The same or an immediately adjacent area has been previously irradiated, and the dose distribution within the patient must be sculpted to avoid exceeding the cumulative tolerance dose of nearby normal tissue.

Proton beam therapy is considered medically necessary for any of the following conditions meeting at least one of the above stated criteria:

- Ocular tumors, including intraocular melanomas and melanoma of the uveal tract (includes the iris, ciliary body, and choroid)
- Tumors that approach or are located at the base of skull, including but not limited to:
    - Chordoma
    - Chondrosarcoma
    - Primary or metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment or where the spinal cord has previously been irradiated
- Unresectable benign or malignant central nervous system tumors to include but not be limited to primary and variant forms of astrocytoma, glioblastoma, medulloblastoma, acoustic neuroma, craniopharyngioma, benign and atypical meningiomas, pineal gland tumors, and arteriovenous malformations
- Primary hepatocellular cancer treated in a hypofractionated regimen
- Primary or benign solid tumors in children treated with curative intent and occasional palliative treatment when at least one of the four criteria noted above apply
- Patients with genetic syndromes making total volume of radiation minimization crucial, such as, but not limited to, NF-1 patients and retinoblastoma patients
- Pituitary neoplasm
- Advanced staged (e.g., T4) and/or unresectable lesions of the head and neck
- Malignant lesions of the paranasal sinuses and other accessory sinuses
- Unresectable retroperitoneal sarcomas

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POLICY NAME: PROTON BEAM THERAPY

While proton beam therapy is not a new technology, there is a need for continued clinical-evidence development and comparative-effectiveness analyses for the appropriate use of PBT for various disease sites. Coverage is provided for the following indications as long as the patient is enrolled in either an IRB-approved clinical trial or in a multi-institutional patient registry adhering to care requirements for clinical evidence development.

- Unresectable lung cancers and upper abdominal/peri-diaphragmatic cancers
- Advanced-stage, unresectable pelvic tumors including those with periaortic nodes or malignant lesions of the cervix
- Breast cancers
- Unresectable pancreatic and adrenal tumors
- Skin cancer with macroscopic perineural/cranial nerve invasion of skull base
- Unresectable malignant lesions of the liver, biliary tract, anal canal, and rectum
- Prostate cancer, without distant metastases
- Hodgkin or Non-Hodgkin Lymphoma involving the mediastinum or in non-mediastinal sites where PBT has the potential to reduce the risk of pneumonitis or late effects of radiation therapy (secondary malignancy, cardiovascular disease, or other chronic health conditions)
- Re-irradiation where prior radiation therapy to the site is the governing factor necessitating PBT in lieu of other radiotherapy

<u>Prostate Cancer</u>
Coverage and payments of proton beam therapy for prostate cancer will require:

a) Physician documentation of patient selection criteria (stage and other factors as represented in the NCCN guidelines);
b) Documentation and verification that the patient was informed of the range of therapy choices, including risks and benefits.

<u>Documentation Requirements:</u>

Documentation in the patient medical record must:

1. Support one or more medical necessity requirement(s) as stated above.
2. Include a treatment prescription that defines the goals of the treatment plan— including specific dose-volume parameters for the target and nearby critical structures--as well as pertinent details of beam delivery, such as method of beam modulation, field arrangement, and expected positional and range uncertainties.
3. Include a treatment plan, signed by a physician that meets the prescribed dose-volume parameters for the clinical target volume (CTV) and surrounding organs at risk (OARs) in the presence of expected uncertainties.
4. Describe the target setup verification methodology, including patient positioning, immobilization, and use of image guidance.
5. Include verification of planned dose distribution via independent dose calculation or physical measurement.

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POLICY NAME: PROTON BEAM THERAPY

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. American Society for Radiation Oncology (ASTRO) model policy: Proton Beam Therapy, June 2017, https://www.astro.org/uploadedFiles/_MAIN_SITE/Daily_Practice/Reimbursement/Model_Policies/Content_Pieces/ASTROPBTModelPolicy.pdf
2. CMS Local Coverage Determination for Proton Beam Therapy (L35075): Medicare Proton Beam Therapy Policy L35075 (NGS)
3. National Comprehensive Cancer Network (NCCN) Guidelines: Prostate Cancer. Version 2.2017: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
4. Other payer policies

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POLICY APPROVAL DATES

New: 03/18

Revised: 01/20

Reviewed: 03/19, 3/20, 3/21, 3/22, 3/23, 3/24, 3/25, 3/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
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POLICY NAME: PROTON BEAM THERAPY

Effective Date	Update
1/1/20	Replaced criteria in the Application section for proton beam therapy with Medicare criteria which now applies to all LOB.

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BEHAVIORAL HEALTH
RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: PSYCHOLOGICAL TESTING

POLICY EFFECTIVE DATE:	11/1/2021
Policy Control #:	1370/20.000461
Next Annual Review:	7/2025

DISCLAIMER

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PROCEDURE CODES

96130, 96131, 96136, 96137, 96138, 96139, 96146

DESCRIPTION

Psychological testing is a set of formal written, visual, or verbal evaluations that make use of reliable and valid tests. Testing is done to assess intellectual and cognitive ability, executive functioning, psychopathology, personality style and organization, emotional and/or interpersonal processes, behavioral functioning, and adaptive skills for the purposes of diagnostic clarification and treatment planning.

RELATED POLICIES/DOCUMENTS

Neuropsychological Testing 1370/20.000416

BEHAVIORAL HEALTH
RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: PSYCHOLOGICAL TESTING

POSITION STATEMENT

CDPHP administers benefits for psychological testing, under the mental health portion of the contract, when one or more of the indications listed below are met.

For psychological testing to be authorized, it is assumed that the testing is being requested because face-to-face clinical evaluation, behavioral rating scales, review of pertinent history and/or consultation with collateral sources are insufficient to determine diagnostic clarification and/or establish a treatment plan. Psychological testing is considered medically necessary for the following indications:

- Psychological testing contributes necessary clinical information for differential diagnostic clarification.
- Designing a treatment plan would be ineffective and/or inefficient without information that can only be obtained by psychological testing.
- Results of psychological testing are required to formulate an initial treatment plan or are required to make necessary revisions to an existing treatment plan.
- An individual has undergone a course of psychological or psychiatric treatment and the response is not as expected from the treatment plan.
- Evaluation of an individual's functional capability to participate in behavioral health treatment.
- To do ADHD assessment testing when there is a documented issue of differential diagnosis and to facilitate treatment planning.
- To do pervasive developmental disorders assessment testing when there is a documented issue of differential diagnosis and to facilitate treatment planning.
- Bariatric pre-surgical psychological testing is conducted when needing to rule out psychiatric conditions potentially contra-indicative of surgery, and/or to evaluate the individual's ability to understand the risks of surgery, and/or evaluate the individual's ability to participate responsibly in post-surgical recovery behaviors and lifestyle changes.

Psychological testing is performed by licensed psychologists (Ph.D., Psy.D), with training and expertise in the types of tests/assessment being requested and who can perform them at a level proficient to interpret testing data.

POLICY CONSIDERATIONS

Psychological testing will apply against an enrollee's outpatient mental health benefit.

The reimbursable time for test administration is based on published standards or time(s) reported by the test publisher and/or in published test usage surveys of psychologists engaged in testing activities.

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POLICY NAME: PSYCHOLOGICAL TESTING

EXCLUSIONS

Psychological testing is **not** considered reasonable and necessary for the following indications:

- The use of psychological testing for primarily educational purposes (e.g., to rule out learning disability, determine learning style and/or assess academic achievement), or to provide support for academic accommodations.
- The use of psychological testing for an individual with an alcohol or drug diagnosis and less than 90 days of abstinence.
- Other sources of the same information are available (e.g., clinical interview, behavioral observations, or review of pertinent history).
- When psychological assessments can be obtained through the clinical evaluation alone.
- When testing has been performed in the last 12 months, unless clinical indicated to assess for rapid change in cognitive functioning or changes associated with medication changes.
- The diagnosis appears clear without testing.
- The results of testing will have no significant effect on the design or implementation of the treatment plan for a psychological disorder.
- The rationale for testing is vague and without a specific outcome measure (e.g., "my child's pediatrician is asking for it").
- Testing is for legal purposes including custody evaluations, parenting assessments, or other court ordered requests.
- Testing related to licensure/certification or career or workplace behaviors.
- The results of testing are primarily used for admission into a crisis center or an acute care treatment facility.
- When administered or scored by technicians not meeting the requirements outlined in the NYS Office of the Professions Education Law.
- When administered using a computerized automated instrument (96146) as it does not require a physician, psychologist or licensed mental health provider to provide interpretation and preparation of the report.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP:	Subject to all terms and conditions noted above in application with the exception psychological testing is covered when ordered by the court or legal system.

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: PSYCHOLOGICAL TESTING

SOURCES

1. Contract Clarification.
2. Other Payers.
3. United Behavioral Health.
4. NYS Education Department, Office of the Professions License Requirements for Psychologist. http://www.op.nysed.gov/prof/psych/psychlic.htm
5. NYS Education Department, Office of the Professions, Use and Supervision of a Testing Technician by a Licensed Psychologist. http://www.op.nysed.gov/prof/psych/psychsupertesttech.htm

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Vanessa Bobb, MD, PhD, FAPA Date
VP, Behavioral Health and Medical Integration

POLICY APPROVAL DATES

New: 09/09

Revised: 07/10, 07/13, 09/13, 07/18, 09/18, 01/19, 09/19, 1/20

Reviewed: 07/11, 07/12, 07/14, 07/15, 07/16, 07/17, 07/19, 7/20, 7/21, 7/22, 7/23, 7/24

BEHAVIORAL HEALTH
RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: PSYCHOLOGICAL TESTING

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
1/1/2020	The limits for psychological testing were increased from 6 to 12 and clarification was made regarding the correct billing of units in the Application section. The statement regarding testing for the dx of intellectual disability being administered under the medical portion of the contract was remove from the Policy Considerations section. The Exclusions section was updated.
7/1/2021	Added reference to neuropsychological testing policy

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Policy/Procedure Name: QUTENZA (CAPSAICIN 8%) **Control Number: 1350/20.000251**

Disclaimer Notice

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Background

Peripheral neuropathy is characterized by weakness, numbness, and pain that results from damage to the peripheral nerves located outside the brain and spinal cord. These symptoms can range from mild to debilitating but are rarely life-threatening. Symptoms can develop over the course of several days to several years. Peripheral neuropathy often results from another condition that causes damage in the peripheral nerves, one such condition being herpes zoster.

Postherpetic Neuralgia (PHN) is classified as the persistence of pain three months after the resolution of an outbreak of latent herpes zoster. It can affect 10 to 15 percent of patients who recover from an acute zoster outbreak. Postherpetic neuralgia is a painful chronic condition that can severely limit a patient's quality of life. The pain can manifest as a burning, aching, itching, or electric-shock-like feeling. It can lead to dysesthesias, paresthesia, and allodynia.

The American Academy of Neurology Practice Parameter on the treatment of postherpetic neuralgia (2004) has been retired but the Neuropathic Pain Special Interest Group (NeuPSIG) of the International Association for the Study of Pain conducted a systemic review and published their meta-analysis in 2015. Based on their GRADE classification gabapentin or pregabalin, tricyclic antidepressants, and the SNRIs duloxetine or venlafaxine are recommended as first line therapy. Capsaicin and lidocaine are reserved as second line treatment.

Diabetic Peripheral Neuropathy (DPN) is the onset of peripheral neuropathy caused by nerve damage resulting from high blood glucose. Half of all people with diabetes have some form of nerve damage, and often this nerve damage manifests as peripheral neuropathy of the hands and feet. Current guidelines from the American Diabetes Association suggest the use of pregabalin, gabapentin, and duloxetine as first line agents, with tricyclic antidepressants, venlafaxine, and carbamazepine as possible alternative treatment.

Qutenza®, is a high concentration capsaicin patch. It was shown to provide sustained pain relief over three months after one application with an average 30 percent decrease in numeric pain-rating-scale scores compared to placebo. Consistent with recognized evidence-based and peer-reviewed clinical criteria, the following policy is described.

Summary

Effective date of policy:	12/3/2025
Indications	Management of neuropathic pain with postherpetic neuralgia (PHN) and diabetic peripheral neuropathy (DPN) of the feet
ICD10 diagnosis codes	B02.23, B02.29, E08.40, E08.42, E10.40, E10.41, E10.42, E11.40, E11.41, E11.42, E13.40, E13.41, E13.42
Availability	Qutenza (capsaicin) 8% contains 179 mg per patch, J7336
Duration	Initial approval: Three (3) months; Continued approval: Twelve (12) months

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve Qutenza:

Indication	Inclusion	Recommended Dosing Regimen
Postherpectic neuralgia (PHN) (FDA approval) ICD10:B02.23, B02.29	• The enrollee must have chronic PHN that has persisted for at least six months. • Documented date of onset of the zoster episode and location of the affected area are provided as part of the request for coverage. • Must be administered by a physician or by health care professionals under the direct supervision of a physician in an office-based setting. • Previous history that conventional PHN treatment courses of at least 30 days with each of the following medications was ineffective, unless contraindicated: o Gabapentin (Neurontin) or pregabalin (Lyrica); **and** o Either one SNRI or tricyclic antidepressant	Single 60-minute application of up to four patches every three months as needed

	○ SNRI: Duloxetine (Cymbalta) or venlafaxine (Effexor) ○ Tricyclic antidepressant: amitriptyline (Elavil), desipramine (Norpramin), or nortriptyline (Pamelor).	
Diabetic Neuropathy of the Feet (FDA approval) ICD: E08.40, E08.42, E10.40, E10.41, E10.42, E11.40, E11.41, E11.42, E13.40, E13.41, E13.42	• Must be administered by a physician or by health care professionals under the direct supervision of a physician in an office-based setting. • Previous history that conventional DPN treatment courses of at least 30 days with each of the following medications was ineffective, unless contraindicated: ○ Gabapentin (Neurontin) or pregabalin (Lyrica); **and** ○ Either one SNRI or tricyclic antidepressant ○ SNRI: Duloxetine (Cymbalta) or venlafaxine (Effexor) ○ Tricyclic antidepressant: amitriptyline (Elavil), desipramine (Norpramin), or nortriptyline (Pamelor). • Documented date of onset of the neuropathy and location of the affected area are provided as part of the request for coverage.	Single 30-minute application of up to four patches every three months as needed

Continuation Criteria

- Requests must include information on patient response to the initial treatment, and if approved, Qutenza will be approved for a period of up to 12 months (up to four patches per dose, no more often than every 12 weeks).
- Clinical response is maintained and there is an absence of unacceptable toxicity from the drug.

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.
- Prescription drug coverage with CDPHP is not required.
- Coverage for Qutenza® will be administered as a medical benefit when obtained and administered by a participating practitioner.
- Initial coverage approval will be for a single three-month treatment course of up to four patches.
- Requests for off-label uses of Qutenza® will be reviewed on a case-by-case basis. Please refer to pharmacy policy, Off-Label Uses of FDA Approved Drugs, control # 1350/20.000048.

References

		Accessed
1	Qutenza [package insert]. Morristown, NJ: Averitas Pharma, Inc.; 2024 Jul.	9/2024
2	Backonja M, Wallace MS, Blonsky ER, et al. NGX-4010, a high-concentration capsaicin patch, for the treatment of postherpetic neuralgia: a randomised, double-blind study. Lancet Neurol 2008; 7: 1106–12.	9/2023
3	Finnerup NB, Attal N, Haroutounian S, et al. Pharmacotherapy for neuropathic pain in adults: systematic review, meta-analysis and updated NeuPSIG recommendations.	9/2023
4	Saguil A, Kane S, Mercado M, et al Herpes zoster and postherpetic neuralgia: prevention and management. Am Fam Physician. 2017;96(10):656-663.	9/2023
5	Price R, Smith D, Franklin G, et al. Oral and topical treatment of painful diabetic polyneuropathy: Practice Guideline Update Summary: Report of the AAN Guideline Subcommittee. Neurology. 2022;98(1):31.	9/2023
8	Griebeler ML, Morey-Vargas OL, Brito JP, et al. Pharmacologic interventions for painful diabetic neuropathy: An umbrella systemic review and comparative effectiveness network meta-analysis. Ann Intern Med. 2014;161(9):639.	9/2023
9	Microvascular Complications and Foot Care: Standards of Medical Care in Diabetes-2021. American Diabetes Association. *Diabetes Care* 2021 Jan; 44(Supplement 1): S151-S167.	9/2023

Government Programs

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application

SELECT/HARP PLAN: Medical Benefit - Subject to all terms and conditions noted in above application.

Pharmacy Benefit - Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program

CDPHP Pharmacy Services
12/3/2025

Policy History

Date	Notes
04/2012	New Policy
04/2013, 04/2014, 04/2015, 04/2018, 04/2019, 04/2020, 04/2021, 12/2022, 12/2025	Reviewed with no changes
04/2016, 04/2017,	Revised
10/2021	Updated to include pregabalin as an acceptable prerequisite for post herpetic neuralgia and diabetic peripheral neuropathy. Added the new indication for diabetic peripheral neuropathy. Added SNRIs duloxetine and venlafaxine to possible prerequisite treatments to diabetic peripheral neuropathy along with the tricyclic antidepressants.
12/2023	Updated background and references to reflect the AAN guideline being retired. Added additional/new supportive evidence of first and second line treatments. Added SNRIs duloxetine and venlafaxine to possible prerequisite treatments for postherpetic neuralgia.
12/2024	Revised. Added additional ICD 10 codes.

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Background

A disease is considered rare if it affects less than 200,000 people in the United States. There are over 10,000 rare diseases and it is estimated that more than 30 million Americans live with a rare disease. The exact cause for many rare diseases remains unknown but it is believed that most are linked to a genetic mutation - approximately 80% of rare diseases have a genetic origin. Still, environmental factors may also play a role in some of these conditions. Considerable progress has been made in recent years to find ways to diagnose and treat rare diseases.

Summary

Effective Date of Policy:	10/1/2026

Actimmune (Interferon Gamma-1B) – Rx and Medical

1. For the treatment of Chronic Granulomatous Disease
    a. The prescribing physician is an infectious disease specialist or a hematologist/oncologist
    b. Diagnosis has been confirmed through neutrophil function tests
    c. Combination therapy with antibiotics (i.e., trimethoprim/sulfamethoxazole) and/or antifungals (i.e., itraconazole) have been shown to reduce the risk of severe infections.
2. In the treatment of severe, malignant osteopetrosis
    a. The prescribing physician is an orthopedic surgeon, hematologist, or an endocrinologist
    b. The diagnosis is confirmed through radiological evidence.
3. Approved dosing for those with a body surface area greater than 0.5 m^2 is 50 mcg/m^2 (1 million units/m^2) subcutaneously 3 times a week.
4. Doses above 50 mcg/m^2 will not be authorized.
5. Actimmune can be self-administered and therefore will be covered under the pharmacy benefit.
6. Actimmune will only be covered under the medical benefit if there is documentation that the patient has an inability to self-inject. For pediatric patients < 18 years of age, documentation must also include the inability of a caregiver to administer the medication. Self-injection criteria applies to:
    a. New Starts and recertification requests for all lines of business except Medicare Advantage.
7. Quantity limit: 1 vial per 28 days. Upon each review and dose escalation request, the allowed quantity will be reviewed in accordance with FDA-approved BSA-based dosing and, as such, will be limited to the minimum number of vials to obtain the appropriate weekly dose. For pediatric patients, a higher quantity may be allowed based on the patient's predicted growth, on a case-by-case basis.

Adzynma (apadamtase alfa) - Medical

1. Must be prescribed by, or in consultation with, a hematologist AND
2. Must have a diagnosis of congenital thrombotic thrombocytopenic purpura (cTTP) confirmed by all of the following (a, b, and c):
    a. ADAMTS13 activity < 10% AND
    b. Molecular genetic testing confirming a pathogenic variant or mutation of the ADAMTS13 gene [characterized by homozygous or compound heterozygous mutations] AND
3. Requests for prophylactic use of Adzynma for individuals new to therapy will require:
    a. The patient has a history of at least one documented TTP event OR
    b. The patient is currently receiving prophylactic therapy with commercially available plasma-based therapies (e.g., fresh frozen plasma, solvent/detergent-treated plasma, factor VIII/VWF concentrations)
4. See prescribing information for full dosing and administration information
5. Adzynma will not be authorized for any other non-FDA approved indication including immune mediated or acquired TTP

6. Initial approval will be for 6 months. Recertification will be for 12 months at a time and require documentation OR provider attestation that the following are met (a and b):
    a. The patient is responding to therapy (e.g., improvement in acute TTP events, TTP manifestations, thrombocytopenia events, microangiopathic hemolytic anemia events) AND
    b. Patient is not routinely using prophylactic plasma-based therapies OR routine use of prophylactic plasma-based therapies will be discontinued

HCPCS: J7171

Aldurazyme (laronidase) - Medical

1. Must have a diagnosis of Hurler, Hurler-Scheie, or Scheie form of MPS I confirmed by biochemical enzyme analysis for alpha-L-iduronidase enzyme deficiency in white blood cells or cultured skin fibroblasts
2. Patient must be followed by a physician experienced in metabolic disorders
3. Must have an affected 1st degree relative OR have clinical symptoms of the disease such as: Valvular heart disease, cardiomyopathy, obstructive sleep apnea, restrictive lung disease, reactive airway disease, joint stiffness, joint contractures, joint pain, spinal deformities, corneal clouding, glaucoma, developmental delay, mental retardation, communicating hydrocephalus, hearing loss, hepatomegaly, inguinal/umbilical hernia, and chronic infections
4. Must be ≥ 6 months of age
5. Current body weight and requested dose regimen must be submitted for initial review and each recertification request
6. Recommended Dosing: 0.58 mg/kg IV infusion once weekly

HCPCS: J1931

Aqvesme (mitapivat) - Rx

1. **Aqvesme is considered medically necessary for the treatment of anemia in <u>non-transfusion dependent alpha(α)-or beta(β)-thalassemia</u> when the following criteria are met:**
    i. Must have a diagnosis of α- or β-thalassemia (β-thalassemia with or without α-globin gene mutations, hemoglobin E (HbE)/β-thalassemia, or α-thalassemia (including hemoglobin H (HbH) disease)) based on Hb electrophoresis, Hb high-performance liquid chromatography (HPLC), and/or DNA analysis
        a. Aqvesme will not be covered for any other diagnoses including homozygous or heterozygous sickle hemoglobin (HbS) or hemoglobin C (HbC)
    ii. Must be at least 18 years of age
    iii. Must be prescribed by or in consultation with a hematologist or physician knowledgeable in the treatment of thalassemia
    iv. Must have documentation of hemoglobin (Hb) concentration ≤ 10.0 grams per deciliter (g/dL), based on an average of at least <u>two</u> Hb concentration measurements (separated by ≥ 7 days)
    v. Must be non-transfusion-dependent, defined as (a and b):
        a. ≤ 5 red blood cell (RBC) units transfused in the previous 24 weeks **AND**
        b. No RBC transfusion within the previous 8 weeks
    vi. Initial approval will be granted for 6 months. Recertification will require documented achieved hemoglobin response, defined as an increase in Hb by 1 g/dL or greater from baseline, based on an average of at least <u>two</u> Hb concentration measurements (separated by ≥ 4 weeks). Recertification will be for 12 months at a time.

2. **Aqvesme is considered medically necessary for the treatment of anemia in <u>transfusion-dependent alpha(α)-or beta(β)-thalassemia</u> when the following criteria are met:**
    i. Must have a diagnosis of α- or β-thalassemia (β-thalassemia with or without α-globin gene mutations, hemoglobin E (HbE)/β-thalassemia, or α-thalassemia (including hemoglobin H (HbH) disease)) based on Hb electrophoresis, Hb high-performance liquid chromatography (HPLC), and/or DNA analysis
        a. Aqvesme will not be covered for any other diagnoses including homozygous or heterozygous sickle hemoglobin (Hb S) or hemoglobin C (Hb C)
    ii. Must be at least 18 years of age
    iii. Must be prescribed by or in consultation with a hematologist or physician knowledgeable in the treatment of thalassemia
    iv. Must be transfusion-dependent, defined as (a and b):
        a. 6 to 20 red blood cells (RBC) units transfused in the previous 24 weeks **AND**
        b. Transfusion-free period no longer than 6 weeks in the previous 24 weeks
    v. **For individuals with <u>transfusion-dependent beta-thalassemia</u>**, must have serious side effects or drug failure with Reblozyl. This requirement does not apply to individuals with prior splenectomy.

a. This applies to new starts only

vi. Initial approval will be granted for 6 months. Recertification will require documented reduction in RBC transfusion burden after receiving Aqvesme. Recertification will be for 12 months at a time.

Quantity limit 56 tablets/28 days

Arcalyst (rilonacept) - Rx

1. Must have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) with one ofthe following conditions: Familial Cold Autoinflammatory Syndrome (FCAS) also known as Familial Cold Urticaria **OR** Muckle-Wells Syndrome (MWS) **AND**
    a. Patient must be at least 12 years of age
    b. Patient is not on concurrent therapy with any of the following – Ilaris, Kineret, Enbrel, Humira, infliximab or Simponi
    c. The recommended dose for CAPS, FCAS, MWS
        i. Adults: Loading dose: 320 mg, delivered as two 160 mg (2 mL) injections. Maintenance dose: 160 mg (2 mL) injection once weekly.
        ii. Pediatric patients 12 years to 17 years: Loading dose: 4.4 mg/kg, up to a maximum of 320 mg, delivered as 1 or 2 injections (not to exceed 2 mL/injection). Maintenance dose: 2.2 mg/kg, up to a maximum of 160 mg (2 mL) injection, once weekly.
    d. **Note** – it is not known whether Arcalyst is effective in patients with Neonatal-Onset Multisystem Inflammatory Disease (NOMID), also referred to as Chronic Infantile Neurologic CutaneousArticular Syndrome (CINCA). **OR**
2. Must have a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) confirmed by mutation in the *IL1RN* gene **AND**
    a. Must be prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory conditions **AND**
    b. Patient must weigh at least 10 kg **AND**
    c. According to the prescriber, the patient has demonstrated clinical benefit with Kineret (anakinra subcutaneous injection). Examples of clinical benefits include resolution of skin rash, bone pain, and fever, normal acute phase reactants (CRP < 0.5 mg/dL), objective absence of skin rash, no radiological evidence of active bone disease, reduction in the use of corticosteroids **AND**
    d. Patient is not on concurrent therapy with any of the following – Ilaris, Kineret, Enbrel, Humira, infliximab or Simponi
    e. The recommended dose of Arcalyst for DIRA is as follows:
        i. Adult and pediatric patients weighing at least 10 kg: 4.4 mg/kg up to a maximum of 320 mg delivered as 1 or 2 injections (2 mL/injection) once weekly **OR**
3. Must have diagnosis of recurrent pericarditis (RP) defined as a subsequent pericarditis episode after a symptom-free interval of at least 4-6 weeks
    a. Must be prescribed by or in consultation with a cardiologist **AND**
    b. Patient must be ≥ 12 years or older **AND**
    c. Patient must be presenting with at least a second pericarditis recurrence (third pericarditis episode at minimum) despite treatment with NSAIDs, colchicine or corticosteroids, in any combination
        i. The current episode is characterized by pericardial pain for ≥ 1 day with a numerical rating scale (NRS) pain score of ≥ 4 **AND** a C-reactive protein level of at least of at least 1 mg/dL **OR**
        ii. The current episode must have met two or more of the following:
            1. Pericarditis chest pain (typically sharp chest pain, improved with sitting up and leaning forward)
            2. Pericardial rubs (superficial scratchy or squeaking sound heard with the diaphragm of a stethoscope over the left sternal border)
            3. New widespread ST-elevation or PR depression on ECG
            4. Pericardial effusion (new or worsening) **AND**
    d. Prescriber must attest that the patient will attempt to taper and discontinue NSAIDs, colchicine and/or corticosteroids while on Arcalyst **AND**
    e. Arcalyst will not be approved for patients with pericarditis secondary to tuberculosis, post-thoracic blunt trauma, myocarditis, systemic autoimmune diseases (excluding Still's disease), or neoplastic, purulent, or radiation etiologies **AND**
    f. Arcalyst will not be approved for patients with incessant or chronic pericarditis **AND**
    g. Patient is not on concurrent therapy with any of the following – Ilaris, Kineret, Enbrel, Humira, infliximab or Simponi
    h. The recommended dose for RP is as follows:
        i. Adults: Loading dose: 320 mg, delivered as two 160 mg (2 mL) injections. Maintenance dose: 160 mg (2 mL) injection once weekly.
        ii. Pediatric patients 12 years to 17 years: Loading dose: 4.4 mg/kg, up to a maximum of 320 mg, delivered as 1 or 2 injections (not to exceed 2 mL/injection). Maintenance dose: 2.2 mg/kg, up to a maximum of 160 mg (2 mL) injection, once weekly.

i. Initial approval of Arcalyst for recurrent pericarditis will be for 3 months. Recertification will require documentation that the patient has had no pericarditis recurrence while using Arcalyst **AND** documentation that NSAIDs, colchicine and/or corticosteroid doses have been reduced or discontinued.

4. Quantity limit of 4 vials/28 days
   a. The allowed quantity will be reviewed in accordance with FDA-approved weight and age-based dosing and, as such, will be limited to the minimum number of vials to obtain the appropriate weekly dose.
   b. A one-time override of 5 vials per 28 days will be allowed for diagnosis of CAPs, FCAS, MWS and RP to accommodate for the loading dose. A quantity limit exception (8 vials/28 days) can be granted for diagnosis of DIRA requiring 2 injections administered once weekly.

Camzyos (mavacamten) - Rx

1. Must be ≥ 18 years of age **AND**
2. Camzyos must be prescribed by, or in consultation, with, a cardiologist **AND**
3. Must have a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) confirmed by echocardiogram **AND/OR** cardiac magnetic resonance showing <u>one</u> of the following (a or b):
   a. Maximal end-diastolic left ventricular wall thickness of ≥ 15 mm
   b. Maximal end-diastolic left ventricular wall thickness ≥ 13 mm **AND** <u>one</u> of the following (i or ii):
      i. Family history of HCM **OR**
      ii. A positive genetic test (e.g., *MYH7*, *TNNI3, TNNT2, TPM1, MYL2, MYL3, ACTC1)* **AND**
4. Diagnosis must not be due to a known infiltrative or storage disorder causing cardiac hypertrophy that mimicked obstructive HCM (i.e., Fabry disease, amyloidosis, or Noonan syndrome with left ventricular hypertrophy) **AND**
5. Must have New York Heart Association (NYHA) Class II or III functional status **AND**
6. Left ventricular ejection fraction (LVEF) must be ≥ 55% **AND**
7. Prescriber attestation must be received that REMS program requirements have been satisfied **AND**
8. Must have had serious side effects or drug failure to at least one non-vasodilating beta blocker (i.e., atenolol, bisoprolol, metoprolol) **AND** one non-dihydropyridine calcium channel blocker (must be separate trials), unless there is a documented medical reason why these agents cannot be used.
   a. Please note failure of non-vasodilating beta blocker or non-dihydropyridine calcium channel blocker therapy does not preclude concomitant use of these therapies with Camzyos**, AND**
9. Initial and subsequent approvals will be granted for 6 months at a time.
10. Subsequent approvals will require submission of progress notes documenting that the patient has achieved/maintained a positive clinical response to therapy.
    a. LVEF assessment by echocardiogram must be provided on each recertification request.
11. Camzyos will NOT be approved for continued therapy in patients with LVEF < 50%, symptomatic heart failure or worsening clinical status.
12. Camzyos will not be approved for any patients on strong or moderate CYP2C19 inhibitors or inducers, strong CYP3A4 inhibitors, or strong or moderate CYP3A4 inducers.
13. Quantity limit is 30 capsules/30 days.

Crenessity (crinecerfont) - Rx

1. Must be prescribed by or in consultation with an endocrinologist or pediatric endocrinologist AND
2. Must be 4 years of age and older AND
3. Must have a diagnosis of classic congenital adrenal hyperplasia (CAH) AND
   a. Note: Crenessity will not be authorized in patients with non-classic CAH which typically has a later-onset and presents with milder symptoms or may be asymptomatic
4. Must have 21-hydroxylase deficiency as confirmed by ONE of the following (a, b, c, OR d):
   a. Elevated 17-hydroxyprogesterone (17OHP) level
   b. Confirmed pathogenic variant in the CYP21A2 gene
   c. Positive newborn screening with confirmatory second-tier testing (e.g., liquid chromatography-tandem mass spectrometry)
   d. Cosyntropin stimulation that shows a markedly elevated 17OHP level from baseline AND
5. Must currently be receiving supraphysiological doses of glucocorticoid treatment at baseline AND
6. Crenessity must be used in combination with glucocorticoid treatment AND
7. Must have documentation of the following (a and b) prior to initiation of Crenessity in order to assess clinical response:
   a. Baseline glucocorticoid dose AND
   b. Baseline serum androstenedione level
8. Initial approval will be for 6 months. Continued approval will be for 12 months at a time and require documentation of ONE of the following (a or b):
   a. A reduction in glucocorticoid dose from baseline OR

b. A reduction in serum androstenedione from baseline

9. Quantity Limit:
    a. Capsules: 60 capsules/30 days
        i. For individuals concomitantly using a strong or moderate CYP3A4 inducers, a quantity limit exception will be authorized in accordance with FDA-approved labeling.
    b. Oral solution: 30 mL (1 bottle)/30 days
        i. Documentation that the patient is unable to swallow a capsule whole is required for the following scenarios
            1. For individuals weighing ≥ 55 kg OR
            2. For individuals weighing > 20 kg requiring a CYP3A4 dose adjustment
        ii. Upon each review and dose escalation request for the oral solution the allowed quantity will be reviewed in accordance with FDA-approved labeling (including dose adjustments required for strong or moderate CYP3A4 inducers) and as such will be limited to the minimum number of full bottles necessary to obtain the appropriate daily dose.

Cuprimine (penicillamine capsules) and penicillamine tablets - Rx

1. Must be used for an FDA approved indication: Wilson's Disease, Rheumatoid Arthritis or Cystinuria
2. For a diagnosis of Cystinuria:
    a. Must be prescribed by a nephrologist, urologist, or physician knowledgeable in the treatment of cystinuria **AND**
    b. Must have a diagnosis of cystinuria established by <u>one</u> of the following:
        i. Stone analysis showing 100% cystine calculi **OR**
        ii. Pathognomonic hexagonal cystine crystals on urine microscopy **OR**
        iii. Genetic test confirming two defects in SLC7A9 and/or ALC3A1 gene **AND**
    c. Prescriber must attest that the patient is unresponsive to high fluid intake, urine alkalization, and diet modification (i.e., sodium and protein restriction) **AND**
    d. Prescriber must attest that the patient will continue high fluid intake, urine alkalization, and diet modification in combination with requested therapy
    e. Initial authorization for cystinuria will be for 12 months. Recertification will be every 12 months and require evidence of clinical response defined as urinary cystine concentration < 250 mg/L **OR** decrease in cystine stone formation **AND**
3. **<u>For new starts and recertification requests (for all indications)</u>**:
    a. Brand Cuprimine will require documentation of serious side effects or drug failure with generic penicillamine capsules (generic Cuprimine) **AND** penicillamine tablets unless there is adequate justification as to why both penicillamine capsules **AND** tablets are not clinically appropriate.
    b. Penicillamine tablets will require documentation of serious side effects or drug failure with generic penicillamine capsules (generic Cuprimine) unless there is adequate justification as to why penicillamine capsules are not clinically appropriate.
4. Quantity limit: 180 capsules/30 days.
    a. A quantity limit exception of 480 capsules/30 days can be granted for a diagnosis of Cystinuria
    b. A quantity limit exception of 240 capsules/30 days can be granted for a diagnosis of Wilson's Disease

Fabhalta (iptacopan) - Rx

1. Fabhalta is considered medically necessary for the **treatment of paroxysmal nocturnal hemoglobinuria (PNH)** when the following criteria are met:
    a. Must be 18 years of age or older **AND**
    b. Must be prescribed by a hematologist or nephrologist **AND**
    c. Must have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by a flow cytometry test
    d. Initial approval for 6 months. Continued approval will be for 6 months and will require documentation that patient is tolerating therapy and is responding to treatment (i.e., decrease in number of transfusions, improvement in hemoglobin levels, normalization of LDH levels, symptom improvement) **OR**
2. Fabhalta is considered medically necessary for the treatment of **primary immunoglobulin A nephropathy (IgAN)** when the following criteria are met:
    a. Must be 18 years of age or older **AND**
    b. Must be prescribed, or in consultation with, a nephrologist **AND**
    c. Must have a diagnosis of primary immunoglobulin A nephropathy (IgAN), confirmed on biopsy **AND**
    d. Must have an eGFR <u>≥</u> 30 mL/min/1.73 m^2 **AND**
    e. Must provide baseline documentation that meets at least <u>one</u> of the following (note: documentation of the same laboratory parameter will be required upon recertification):
        i. A total urine protein <u>≥</u> 0.5 g/day **OR**
        ii. A urine protein-to-creatinine ratio (UPCR) <u>≥</u> 0.44 g/g **AND**
    f. Must have received the maximum or maximally tolerated dose of an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB) for a <u>minimum of 3 months</u> prior to starting Fabhalta, unless there is documentation

that the patient is unable to tolerate or has a contraindication to an ACEi or ARB **AND**

g. Must have documentation of drug failure of Filspari **OR** Tarpeyo
h. Initial and recertification approvals will be for 9 months at a time. Continuation of therapy will require the following (documentation must be provided):
    i. Evidence of **one** of the following:
        1. Reduction in total urine protein from baseline **OR**
        2. Reduction in UPCR from baseline **AND**
    ii. Must have an eGFR ≥ 30 mL/min/1.73 m^2 **OR**

3. Fabhalta is considered medically necessary for the treatment of **complement 3 glomerulopathy (C3G)** when the following criteria are met:
    a. Must be 18 years of age or older **AND**
    b. Must be prescribed by or in consultation with a nephrologist **AND**
    c. Must have a diagnosis of complement 3 glomerulopathy (C3G) confirmed on renal biopsy **AND**
    d. Must be on a maximally recommended or tolerated dose of an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) for at least 3 months prior to starting Fabhalta, unless there is documentation that the patient is unable to tolerate or has a contraindication to an ACEi or ARB **AND**
    e. Must meet one of the following (1 or 2):
        i. Must have documentation of drug failure (e.g., worsening kidney function and/or inadequate reduction in proteinuria) with systemic oral glucocorticoids (e.g., prednisone, methylprednisolone), unless there is documentation of serious side effects or contraindications to systemic oral glucocorticoids **OR**
        ii. Must have documentation of drug failure (e.g., worsening kidney function and/or inadequate reduction in proteinuria) with mycophenolate mofetil/mycophenolate sodium unless there is documentation of serious side effects or contraindications to mycophenolate mofetil/mycophenolate sodium **AND**
    f. Must have baseline documentation of a urine protein: creatinine ratio (UPCR) ≥ 1.0 g/g **AND**
    g. Must an estimated GFR ≥ 30 ml/min/1.73m^2
    h. Initial approval will be for 6 months, and recertification will be for 12 months at a time.
        i. Recertification will require documentation of the following:
            1. Reduction in UPCR from baseline **AND**
            2. Must have an eGFR of ≥ 30 ml/min/1.73m^2
4. Requests for non-FDA approved indications will not be covered.
5. Fabhalta will not be approved in combination with Trutakna, Voyxact or Vanrafia.
6. Concomitant use of another complement inhibitor (i.e., Soliris/Bkemv/Epysqli (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan)) will only be authorized for patients transitioning from Soliris/Bkemv/Epysqli (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan) to Fabhalta. After the initial approval period, requests for concomitant use of Fabhalta with Soliris/Bkemv/Epysqli (eculizumab), Ultomiris (ravulizumab), or Empaveli (pegcetacoplan) will be considered experimental/investigational and will not be approved.
7. Quantity limit: 60 capsules/30 days

Filspari (sparsentan) - Rx

1. Filspari is considered medically necessary for the treatment of **primary immunoglobulin A nephropathy (IgAN)** when the following criteria are met:
    a. Must be prescribed by, or in consultation with, a nephrologist **AND**
    b. Must be 18 years of age or older **AND**
    c. Must have a diagnosis of primary immunoglobulin A nephropathy (IgAN), confirmed on biopsy **AND**
    d. Must have an eGFR ≥ 30 mL/min/1.73 m^2 **AND**
    e. Must provide baseline documentation that meets at least one of the following (note: documentation of the same laboratory parameter will be required upon recertification):
        i. A total urine protein ≥ 0.5 g/day **OR**
        ii. A urine protein-to-creatinine ratio (UPCR) ≥ 0.44 g/g **AND**
    f. Must have received the maximum or maximally tolerated dose of an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB) for a minimum of 3 months prior to starting Filspari, unless there is documentation that the patient is unable to tolerate or has a contraindication to an ACEi or ARB **AND**
    g. Prescriber must attest, or documentation must demonstrate, that Filspari will not be used in combination with any of the following: Renin- angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs) or aliskiren. **AND**
    h. Must meet one of the following (i, ii, or iii):
        i. Must have documentation of drug failure after a minimum 3-month trial with an SGLT2 inhibitor, unless the patient has documentation of serious side effects or contraindication to an SGLT2 inhibitor **OR**

ii. Must have documentation of drug failure after a minimum 6-week trial of systemic oral glucocorticoids (i.e., prednisone, methylprednisolone), unless the patient has documentation of serious side effects or contraindication to systemic oral glucocorticoids **OR**
iii. Patient has one of the following (1 or 2):
1. Total urine protein > 1 g/day (UPCR > 0.8 g/g) **OR**
2. eGFR > 30 to < 60 mL/min/1.73 m^2

i. Initial and recertification approvals will be for 12 months at a time. Continuation of therapy will require the following (documentation must be provided):
i. Evidence of **one** of the following:
1. Reduction in total urine protein from baseline **OR**
2. Reduction in UPCR from baseline **AND**
ii. Must have an eGFR ≥ 30 mL/min/1.73 m^2 **OR**

2. Filspari is considered medically necessary for the treatment of **focal segmental glomerulosclerosis (FSGS)** when the following criteria are met:
a. Must be prescribed by, or in consultation with, a nephrologist **AND**
b. Must be 8 years of age and older **AND**
c. Must have a documented diagnosis of focal segmental glomerulosclerosis (FSGS) confirmed either by biopsy or genetic mutation in podocyte protein associated with FSGS (see Appendix) for genetic mutations **AND**
d. Must have eGFR ≥ 30 mL /min/1.73 m2 **AND**
e. Must have documented baseline urine protein to creatinine ratio (UPRC) of ≥ 1.5 g/g **AND**
f. Prescriber must attest, or documentation must demonstrate, that Filspari will not be used in combination with any of the following: Renin- angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs) or aliskiren.
g. Filspari will **not** be authorized if the patient has nephrotic syndrome, where nephrotic syndrome is defined as the presence of all the following (i, ii, and iii):
i. Proteinuria > 3.5 g/24 hour (adults) or UPCR > 2.0 g/g (pediatric patients < 18 years of age)
ii. Serum albumin of < 3.0 g/L
iii. Edema
h. Initial and recertification will be for 9 months at a time. Recertification will require improvement in UPCR from baseline.

3. Requests for non-FDA approved indications will not be covered.
4. Quantity Limit: 30 tablets/30 days
a. A quantity limit exception of 60 tablets/30 days for the 400 mg strength tablet may be granted for a diagnosis of FSGS in patients weighing 50 kg or greater.

Firdapse (amifampridine) - Rx

1. Must be prescribed by a neurologist or neuromuscular specialist
2. Must be 6 years of age or older
3. Must have a diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS) confirmed by electromyography OR calcium channel antibody testing
4. Quantity limit 300 tablets per 30 days

Forzinity (elamipretide) - Medical

For **Commercial Plans** (including Exchange, Essential Plan, Child Health Plus): Based on review of peer-reviewed evidence and the Health Plan's Not Medically Necessary criteria, Forzinity (elamipretide) has not been medically proven to be effective and is therefore considered Not Medically Necessary for treatment of Barth syndrome.

The justification for Forzinity to be considered Not Medically Necessary is as follows:

- Based upon our assessment of the peer-reviewed medical literature, there is inconclusive evidence of a definite positive effect on health outcomes.
  - The pivotal randomized trial failed both prespecified primary endpoints (6-minute walk test and fatigue score) during the placebo-controlled phase; the approval was based on an endpoint that did not demonstrate benefit in the randomized phase and was observed during an uncontrolled open-label extension.
- Based upon our assessment of the peer-reviewed medical literature, there is inconclusive evidence that the drug, over time, leads to improvement in health outcomes (e.g., the beneficial effects of the service outweigh any harmful effects).
  - Reported long-term improvements derive from uncontrolled extension data without a concurrent comparator, limiting ability to distinguish drug effect from natural history variability, maturation/practice effects, and regression to the mean; adverse event burden (including injection site reactions) must be weighed against benefits.

- Based upon our assessment of the peer-reviewed medical literature, there is inconclusive evidence that the drug provides improvement in health outcomes in standard conditions of medical practice, outside the clinical investigatory settings
    - Available evidence is derived from specialized investigational settings, with no published real-world effectiveness demonstrating benefit under routine conditions of care.

Galzin (zinc acetate capsule) - Rx

1. Must be 10 years of age or older **AND**
2. Must have a diagnosis of Wilson's Disease **AND**
3. Must have been previously treated with a chelating agent (e.g., penicillamine or trientine)
4. Quantity Limit: 90 capsules/30 days

Gamifant (emapalumab-lzsg) - Medical

1. Gamifant is considered medically necessary for the treatment of primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy when the following criteria are met:
    a. Prescribed by a physician who specializes in the treatment of HLH (such as a hematologist, oncologist, immunologist, or transplant specialist) **AND**
    b. The patient has a diagnosis of Primary HLH confirmed by at least ONE of the following (either i., ii., or iii)
        i. Genetic testing confirming biallelic pathogenic variants (e.g., PRF1, UNC13D/MUNC13-4, STX11 or STXBP2) **OR**
        ii. Positive family history (affected siblings or parental consanguinity) consistent with primary HLH in a symptomatic individual **OR**
        iii. Meet at least FIVE out of the following diagnostic criteria prior to treatment:
            1. Low or absent NK-cell activity (according to local laboratory reference)
            2. Fever ≥ 38.5°C (or 101.3°F)
            3. Splenomegaly
            4. Elevated ferritin ≥ 500 micrograms/L
            5. Elevated CD25 (i.e., soluble IL-2 receptor) ≥ 2,400 U/mL
            6. Hypertriglyceridemia (fasting triglycerides ≥ 265 mg/dL (3 mmol/L) and/or hypofibrinogenemia (fibrinogen ≤ 1.5g/L)
            7. Hemophagocytosis in bone marrow or spleen or lymph nodes
            8. Cytopenias affecting at least 2 of 3 lineages in the peripheral blood:
                a. Hemoglobin < 9 g/dL (or < 10 g/dL in infants < 4 weeks of age)
                b. Platelets < 100 x 10^9 /L
                c. Neutrophils < 1 x 10^9 /L, **AND**
    c. Evidence of active disease that is refractory, recurrent, or progressive despite at least ONE conventional HLH therapy OR severe intolerance to at least ONE conventional therapy. Examples of conventional HLH treatments include etoposide and dexamethasone, cyclosporine A, antithymocyte globulin and intrathecal methotrexate following a standard of care treatment protocol **AND**
    d. Administer dexamethasone concomitantly with Gamifant, **AND**
    e. Administer Gamifant until hematopoietic stem cell transplantation (HSCT) is performed or unacceptable toxicity. Discontinue Gamifant when patient no longer requires therapy for the treatment of HLH.
    f. Gamifant is dosed based on body weight. Therefore, current body weight and requested dose regimen must be submitted for initial review and each recertification request **AND**
    g. Initial approval for primary HLH will be for 2-month duration. Continuation of therapy at 2-month intervals will require the following documentation of therapeutic benefit:
        i. Complete response defined as normalization of all HLH abnormalities (i.e., no fever, no splenomegaly, neutrophils > 1x10^9 /L, platelets > 100x10^9 /L, ferritin < 2,000 ug/L, fibrinogen > 1.50 g/L, D-dimer < 500 ug/L, normal CNS symptoms, no worsening of sCD25 > 2-fold baseline); **OR**
        ii. Partial response defined as normalization of ≥ 3 HLH abnormalities, **OR**
        iii. HLH improvement defined as ≥ 3 HLH abnormalities improved by at least 50% from baseline **OR**
2. Gamifant is considered medically necessary for the treatment of HLH/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA), with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS when the following criteria are met:
    a. Prescribed by a physician who specializes in the treatment of HLH (such as a hematologist, oncologist, immunologist, or transplant specialist) or physician who specializes in sJIA/Still's disease (such as a rheumatologist) **AND**
    b. The patient has a diagnosis of HLH/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA) **AND**
    c. Must have a diagnosis of active MAS defined as having met both of the following (i and ii):
        i. Ferritin > 684 ng/mL **AND**

ii. Must have at least TWO of the following:
1. Platelet count ≤ 181×10^9 /L
2. AST > 48 U/L
3. Triglycerides > 156 mg/dL
4. Fibrinogen levels ≤ 360 mg/dL A**ND**

d. Must have ONE of the following (i or ii):
i. Inadequate response, intolerance, or contraindication to high-dose intravenous glucocorticoids **OR**
ii. Recurrent MAS (defined as two or more episodes of MAS) **AND**

e. Gamifant is dosed based on body weight. Therefore, current body weight and requested dose regimen must be submitted for initial review and each recertification request

f. For HLH/macrophage activation syndrome (MAS) in the setting of Still's disease (including sJIA), initial approval will be for a 2-month duration.

g. Continuation of therapy will be at 2-month intervals and will require documentation of (i and ii):
i. Improvement in MAS signs/symptoms (i.e., fever, skin rash, hemorrhagic manifestations, CNS symptoms, respiratory function,) **AND**
ii. At least ONE of the following objective responses:
1. White blood cell above lower limit of normal (LLN)
2. Platelet count above LLN
3. Lactate dehydrogenase (LDH) below 1.5×the upper limit of normal (ULN)
4. ALT below 1.5× ULN
5. AST below 1.5×ULN
6. Fibrinogen > 100 mg/dL
7. Ferritin levels decreased ≥ 80% from baseline or < 2000 ng/mL

3. Prior authorization for Gamifant will apply regardless of the site of administration (applies to both the inpatient and outpatient setting). Gamifant must be administered by a healthcare professional and is covered under the medical benefit Recommended Dosing:
a. Primary HLH recommended starting dosage: 1 mg/kg as an intravenous infusion over 1 hour twice per week.
b. HLH/MAS in Still's disease recommended starting dose: 6 mg/kg, followed by 3 mg/kg every 3 days for 5 doses, then 3 mg/kg twice per week. Given as an intravenous infusion over 1 hour.
c. For both indications, the dose may be titrated up to a maximum of 10 mg/kg.

HCPCS: J9210

Ilaris (canakinumab) - Medical

1. Must meet the following prescriber requirement based on indication:
a. For treatment of active systemic juvenile idiopathic arthritis (SJIA) or Adult-Onset Still's Disease (AOSD), must be prescribed by a rheumatologist or immunologist
b. For treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) or Periodic Fever Syndrome (PFS), must be prescribed by a geneticist, dermatologist, or prescriber who specializes in management of CAPS/PFS.
c. For treatment of acute gout flare, must be prescribed by a rheumatologist. **AND**
2. Must be at least 4 years of age and have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) with one of the following conditions
a. Familial Cold Autoinflammatory Syndrome (FCAS) also known as Familial Cold Urticaria OR
b. Muckle-Wells Syndrome (MWS)
c. Dose is not to exceed 150 mg every 8 weeks **OR**
3. Must be at least 2 years of age with a diagnosis of active systemic juvenile idiopathic arthritis (SJIA)
a. Must have failed to respond to and/or is intolerant to approved disease- modifying antirheumatic drugs (DMARDs) agents, such as methotrexate, NSAIDs, analgesics or corticosteroids either alone or in combination
b. Dose is not to exceed 300 mg every 4 weeks **OR**
4. Must be at least 18 years of age with a diagnosis of Adult-Onset Still's Disease (AOSD)
a. Must have failed to respond to and/or is intolerant to approved disease- modifying antirheumatic drugs (DMARDs) agents, such as methotrexate, NSAIDs, analgesics or corticosteroids either alone or in combination
b. Dose is not to exceed 300 mg every 4 weeks **OR**
5. Must be at least 2 years of age with a diagnosis of one of the following Periodic Fever Syndromes (Hereditary Periodic Fevers)
a. Tumor Necrosis Factor-Receptor Associated Periodic Syndrome (TRAPS)
b. Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD)
c. Familial Mediterranean Fever (FMF)
d. Dose is not to exceed 300 mg every 4 weeks.
6. Must be at least 18 years of age or older and used for treatment of an acute gout flare **AND**
e. Must be prescribed by a rheumatologist **AND**

f. Must have documentation that management of lifestyle factors have been implemented as appropriate (e.g., limiting alcohol intake, dietary modifications, weight loss) **AND**
g. Must have documentation of serious side effects or drug failure to the maximally tolerated dose, or contraindication, to all the following:
   i. NSAIDs **AND**
   ii. Colchicine **AND**
   iii. Corticosteroids (oral and injectable) **AND**
h. The patient must currently be taking, or prescriber must attest that the patient will initiate a urate lowering medication for the prevention of recurrent gout (e.g., allopurinol, probenecid, febuxostat).
i. Approval will be for 3 months to allow for treatment of one acute gout flare (150 mg subcutaneously).
j. Treatment for subsequent acute gout flares will not be authorized unless the following are met:
   i. Patient is optimized on urate lowering therapy for prevention (e.g., allopurinol, probenecid, febuxostat) **AND**
   ii. There has been an interval of at least 12 weeks before a new dose of Ilaris will be administered
   iii. For subsequent flare; approval will be for 3 months to allow for treatment of one acute gout flare (150 mg subcutaneously).

7. Patient does not have an infection and is not at high risk for infection
8. Patient is not on concurrent therapy with any of the following – Arcalyst, Kineret, Enbrel,Humira, infliximab or Simponi

Note – it is not known whether Ilaris is effective in patients with Neonatal-Onset Multisystem Inflammatory Disease (NOMID), also referred to as Chronic Infantile Neurologic Cutaneous Articular Syndrome (CINCA).

HCPCS: J0638

Imcivree (setmelanotide) - Rx

Based upon our review and assessment of peer-reviewed literature, Imcivree, has been medically proven to be effective and therefore **medically necessary** in the treatment of:

A. **Acquired hypothalamic obesity (HO**) if **ALL** the following criteria are met:
   1. Must be prescribed by, or in consultation with, an endocrinologist, expert in rare genetic disorders of obesity, or a medical geneticist **AND**
   2. Must be ≥ 4 years of age or older **AND**
   3. Must have evidence of acquired HO with documentation of hypothalamic injury or dysfunction (e.g., hypothalamic lesion, hypothalamic tumor, hypothalamic damage) **AND**
   4. Must have weight gain associated with the hypothalamic injury, with weight gain occurring within 12 months post-hypothalamic injury/dysfunction **AND**
   5. Must have a BMI of ≥ 30 kg/m2 for patients ≥ 18 years of age or BMI ≥ 95th percentile for age and sex for patients 4 to < 18 years of age **AND**
   6. Documentation of a recent (within the past month) height measurement, weight measurement, BMI, and growth chart (for pediatric patients) must be submitted for each review (initial and recertifications)
   7. Initial approval for acquired HO will be for 12 months.
   8. **Recertification for acquired HO** after the initial 12-month approval will require documentation of a ≥ 5% decrease from baseline body weight, or a ≥ 5% decrease from baseline body mass index (BMI) for patients with continued growth potential (pediatric patients). **OR**

B. **Obesity due to variants in the POMC, PCSK1, or LEPR genes** that are interpreted as 'pathogenic, likely pathogenic, or of uncertain significance (VUS),' or **Bardet-Biedl syndrome (BBS)** if **ALL** the following criteria are met:
   1. Must be prescribed by, or in consultation with, an endocrinologist, expert in rare genetic disorders of obesity, or a medical geneticist **AND**
   2. Must be ≥ 2 years of age or older **AND**
   3. Must have one of the following diagnoses **(a or b):**
   a. Must have a diagnosis of obesity due to POMC, PCSK1, and LEPR deficiencies that includes **ALL** the following (i-iv)
      i. A diagnosis of Obesity is defined as:
         1. Adult patients with a BMI of ≥ 30 kg/m2 **OR**
         2. Pediatric patients (6-17 years): For diagnosis of POMC, PCSK1, and LEPR deficiencies with body weight ≥ 95th percentile for age using growth chart assessments **OR**
         3. Pediatric patients (2 to less than 6 years): For diagnosis of POMC, PCSK1, and LEPR deficiencies with baseline BMI ≥ 97th percentile for age and sex and body weight ≥ 20 kg **AND**
      ii. Documentation of a recent (within the past month) height measurement, weight measurement, BMI, and growth chart (for pediatric patients) must be submitted for each review (initial and recertifications) **AND**
      iii. Obesity must be due to a homozygous or presumed compound heterozygous variant in at least one of the following genes, confirmed by genetic testing, **AND**:
         1. Proopiomelanocortin (POMC)

2. Proprotein convertase subtilisin/kexin type 1 (PCSK1)
3. Leptin receptor (LEPR)

iv. Documentation of genetic testing demonstrating that the variants in POMC, PCSK1, or LEPR genes are interpreted **as 'pathogenic,' 'likely pathogenic,' OR 'of uncertain significance (VUS)'** must be submitted. **Coverage will not be provided for variants identified as 'benign' or 'likely benign.'** Note, direct to consumer (DTC) testing will not be accepted as these tests do not determine if the gene variant is disease-causing.

v. Initial approval will be for 4 months **OR**

b. Must have a diagnosis of monogenic or syndromic obesity due to Bardet-Biedl syndrome (BBS) which includes the following (i-iii):

i. A diagnosis of Obesity is defined as:
1. Adult patients with a BMI of ≥ 30 kg/m2 **OR**
2. Pediatric patients (6-17 years): For diagnosis of BBS ≥ 97th percentile using growth chart assessments **OR**
3. Pediatric patients (2 to less than 6 years): For diagnosis of BBS with baseline BMI ≥ 97th percentile for age and sex and body weight ≥ 20 kg **AND**

ii. Documentation of a recent (within the past month) height measurement, weight measurement, BMI, and growth chart (for pediatric patients) must be submitted for each review (initial and recertifications) **AND**

iii. Patient has either 4 primary features **OR** 3 primary and 2 secondary features of BBS:
1. **Primary features:** Rod-cone dystrophy, Polydactyly, Obesity, Learning disabilities, Hypogonadism in males, Renal anomalies
2. **Secondary features:** Speech disorder/delay, Strabismus/cataracts/astigmatism, Brachydactyly/syndactyly, Developmental delay, Polyuria/polydipsia (nephrogenic diabetes insipidus), Ataxia/poor coordination/imbalance, Mild spasticity (especially lower limbs), Diabetes mellitus, Dental crowding/ hypodontia/small roots/high arched palate, left ventricular hypertrophy/congenital heart disease, Hepatic fibrosis **AND**
3. Initial approval will be for 12 months.

Recertification for obesity due to variants in the POMC, PCSK1, or LEPR genes:
After the initial approval of 4 months will require documentation of a ≥ 5% decrease of baseline body weight, or a ≥ 5% decrease of baseline body mass index (BMI) for patients with continued growth potential (pediatric patients). If the patient meets for recertification, approval will be for 8 months.

Recertification at the 1-year mark will require documentation that the patient achieved a ≥ 10% decrease of baseline body weight or a ≥ 10% decrease of BMI for patients with continued growth potential (pediatric patients). If the patient meets for recertification, approval will be for 1 year.

Recertifications thereafter will require documentation that the patient maintains a weight loss of ≥ 10% decrease of baseline body weight or a ≥ 10% decrease of BMI for patients with continued growth potential (pediatric patients). If the patient meets for recertification, approval will be for 1 year.

Recertification for obesity due to Bardet-Biedl syndrome (BBS) after the initial approval of 12 months will require documentation of a ≥ 5% decrease of baseline body weight, or a ≥ 5% decrease of baseline body mass index (BMI) for patients with continued growth potential (pediatric patients). If the patient meets for recertification, approval will be for 1 year.

Recertifications thereafter will require documentation that the patient maintains a weight loss of ≥ 5% decrease of baseline body weight or a ≥ 5% decrease of BMI for patients with continued growth potential (pediatric patients). If the patient meets for recertification, approval will be for 1 year.

C. Quantity Limit of 9 milliliters (9 vials) per 30 days.
   a. See prescribing information for dosage and administration details.
D. Imcivree will not be covered in the following circumstances:
   a. Non-FDA approved genetic conditions that can cause obesity (such as: Alström syndrome, Prader-Willi syndrome [PWS], etc.)
   b. A lifetime history of suicide attempt or any suicidal behavior within the last month
   c. Imcivree will not be authorized if the member has prior gastric bypass surgery resulting in > 10% weight loss durably maintained from the baseline pre-operative weight, with no evidence of weight regain

Increlex (mecasermin, recombinant rh-IGF-1) - Rx

1. Must be prescribed by an endocrinologist or pediatric endocrinologist
2. Patient must be 2 years old or greater
3. Patient must have severe primary IGF-1 deficiency (Primary IGFD) defined as:
    a. height standard deviation score < -3.0
    b. basal IGF-1standard deviation score < -3.0
    c. normal or elevated GH OR
4. Patient must have growth hormone (GH) gene deletion with the development of neutralizing antibodies to GH
5. Normal dose of 40-120 mcg/kg SQ twice daily given 20 minutes before or after a meal or snack to avoid hypoglycemia. Doses greater than 120 mcg/kg will not be covered
6. Increlex will not be covered for growth promotion in patients with closed epiphyses or as a substitute for growth hormone replacement therapy.

Isturisa (osilodrostat) - Rx

1. Must be 18 years of age or older
2. Must be prescribed by, or in consultation with, an endocrinologist
3. Must have a diagnosis of endogenous Cushing's Syndrome
4. Must have a mean urinary free cortisol (UFC) level that is at least 1.5x the upper limit of normal measured over three 24-hour measurements (ULN = 50 micrograms/24 hours or 145 nmol/24 hours)
5. Must have documentation of symptoms of Cushing's Syndrome (such as diabetes, central obesity, moon face, buffalo hump, osteoporosis, muscle wasting, hypertension, depression, and anxiety)
6. Must have documentation of a failed pituitary surgery or contraindication to Cushing's syndrome specific surgery
7. Must have had serious side effects or drug failure with oral ketoconazole **AND**
8. For Individuals with a diagnosis of Cushing's disease (Cushing's Syndrome that is caused by a pituitary adenoma), must have documentation of serious side effects or drug failure with at least 2 of the following (Note: if patient has had previous trial and failure of metopirone (metyrapone) then only 1 of the following is required):
    a. Signifor (either LAR or SC formulation)
    b. Lysodren (mitotane)
    c. Cabergoline
9. Initial approval will be for 3 months. Recertification at 3 months and thereafter will require laboratory results to document a recent UFC level within normal limits **AND** improvement in the symptoms of Cushing's Syndrome.
10. For recertification, the prescriber must also make clear the maintenance dose they are planning to use. Approval will be allowed for this amount for 1 year.
11. Dose increases beyond the initial 3 months will require documentation to show UFC levels above the upper limit of normal and documentation that the patient is still experiencing Cushing's Syndrome symptoms. If approved, dosage increase authorizations will be for 1 year and will allow the amount requested only.
12. Dosing must be in accordance with FDA labeling, starting at 2 mg twice daily, and increased by 1 mg or 2 mg twice daily, no more frequently than every 2 weeks based on the rate of cortisol changes, individual tolerability, and improvement in signs and symptoms.
13. Please see the Isturisa Efficient Dosing chart at the bottom of this document (Figure 1A) for information on the number of tablets allowed per 30 days of each strength for a given dosing.

Joenja (leniolisib) - Rx

1. Must be prescribed by an immunologist, allergist, hematologist, or prescriber who specializes in the treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS)
    a. Note: APDS is also known as PI3Kδ-activating mutation causing senescent T cells, lymphadenopathy, and immunodeficiency (PASLI) AND
2. Must be ≥ 4 years of age to 75 years old AND
3. Must be > 27 kg AND
4. Must have confirmed APDS-associated genetic PI3Kδ mutation with a documented variant in either PIK3CD or PIK3R1 AND
5. Must meet at least one of the following(a-c):
    a. Have nodal and/or extranodal lymphoproliferation OR
    b. Have presence of > 1 measurable nodal lesion on CT or MRI OR
    c. Have clinical findings and manifestations compatible with APDS (such as history of repeated otosino-pulmonary infections, organ dysfunction (i.e., lung, liver), bronchiectasis, cytopenias, gastrointestinal disease, immune dysregulation (i.e., decreased naive B cells, reversed CD4/CD8 ratio))
6. Initial approval will be for 3 months. Recertification will require documentation that the patient has responded to therapy (i.e., improvement in clinical findings and/or manifestations of APDS such lymphoproliferation, recurrent infections, cytopenia, immunophenotyping). Recertification will be for 6 months at a time.

7. Recommended dosage: 70 mg administered orally twice daily approximately 12 hours apart, with or without food, in adult and pediatric patients 12 years of age and older and weighing ≥ 45kg. Note: Prior to treatment with Joenja, verify pregnancy status in individuals of reproductive potential prior to initiating treatment.
8. Quantity limit: 60 tablets/30 days

Juxtapid (lomitapide capsules) - Rx

1. Must be prescribed by or in consultation with a cardiologist, lipid specialist or endocrinologist AND
2. 2. Must be ≥ 2 years of age with a diagnosis of homozygous familial hypercholesteremia AND
    a. Genetic testing must demonstrate evidence of two mutant alleles at the low-density lipoprotein receptor (LDLR), apolipoprotein B (APOB), proprotein convertase subtilisin kexin type 9 (PCSK9) or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1) gene OR
    b. Patient has a history of untreated LDL-C > 400 mg/dL or treated LDL-C > 300 mg/dL with either (i or ii):
        i. Xanthoma before the age of 10 years OR
        ii. ii. Evidence of heterozygous FH in one parent AND
3. 3. One of the following must be met (a or b):
    a. For individuals 10 years of age and older, member must have failed to reach target LDL-C while receiving treatment with maximally tolerated high potency statin (goal is atorvastatin 40-80 mg daily or rosuvastatin 20-40 mg daily), in combination with ezetimibe, and a PCSK9 inhibitor (Repatha, Praluent) for at least 8 weeks. A trial with a PCSK9 inhibitor is not required if the member is known to have two LDL-receptor negative alleles (null homozygous). OR
    b. For individuals 2 to 9 years of age, member must have failed to reach target LDL-C while receiving treatment with at least one lipid lowering therapy (e.g., statins, ezetimibe, lipoprotein apheresis) for at least 8 weeks. AND
4. LDL-C must be > 70 mg/dL for patients with clinical atherosclerotic cardiovascular disease (ASCVD) OR LDL-C must be > 100 mg/dL for patients without documented clinical ASCVD a. Clinical ASCVD defined as having a history of acute coronary syndrome, myocardial infarction (MI), stable or unstable angina, coronary/other arterial revascularization, stroke, TIA, peripheral arterial disease, or other documented atherosclerotic disease (such as coronary atherosclerosis, renal atherosclerosis, aortic aneurysm secondary to atherosclerosis, or Carotid plaque with ≥ 50% stenosis)
5. If patient is unable to tolerate statin therapy, documentation in progress notes must include:
    a. A contraindication to statin therapy according to FDA labeling OR
    b. History of statin-related rhabdomyolysis i. Must have symptoms consistent with rhabdomyolysis (i.e., muscle pain, swelling, and weakness, dark urine) AND ii. Must have creatine kinase (CK) level > 10 times upper limit of normal, myoglobinuria, or acute renal failure (increase in serum creatinine > 0.5 mg/dL) AND
    c. Patient was receiving a statin at the time of the event and symptoms resolved upon discontinuation of the statin OR
    d. History of statin intolerance. Documentation must include the following:
    e. Inability to tolerate at least 2 different statins
        i. At least 1 statin must be hydrophilic (such as pravastatin, fluvastatin, or rosuvastatin) starting at the lowest starting average daily dose AND
        ii. Intolerance associated with confirmed, intolerable statin-related adverse effects (i.e., muscle related symptoms) or significant biomarker abnormalities (i.e., ALT/AST > 3 times the upper limit of normal accompanied by increase in total bilirubin > 2 times the upper limit of normal) AND
        iii. Non-statin causes of muscle symptoms or biomarker abnormalities have been ruled out (for example, hypothyroidism, reduced renal function, reduced hepatic function, rheumatologic disorders such as polymyalgia rheumatic, steroid myopathy, vitamin-D deficiency, or primary muscle disease)
6. Must have had trial and failure/intolerance to a PCSK9 inhibitor (i.e., Praluent, Repatha) when used in combination with a maximally tolerated statin plus ezetimibe
    a. If patient is known to have two LDL-receptor negative alleles (null homozygous) then trial of PCSK9 inhibitor is not required
7. Documentation of baseline LDL-C level must be provided-measurement must occur within 60 days prior to treatment AND
8. Prescriber must attest that a discussion with the patient has taken place regarding a heart healthy diet, the importance of exercise, and smoking cessation (if applicable)
9. Initial approval will be for 8 weeks. Further approval will require evidence of an adequate reduction in LDL-C level defined as reduction in LDL-C level as compared to baseline LDL-C. Recertification will be required yearly thereafter.
10. Juxtapid will not be approved in combination with Evkeeza unless the patient has demonstrated failure to achieve target LDL-C while on Evkeeza in combination with:
    a. High-intensity or maximally tolerated statin therapy AND
    b. Ezetimibe AND
    c. A PCSK9 inhibitor (i.e., Praluent, Repatha) AND
    d. The patient has been on this drug combination for at least 6 months.
11. Quantity limit of 28 capsules per 28 days for 2.5 mg, 5 mg, and 10 mg and 56 capsules per 28 days for 20 mg and 30 mg strengths

Keveyis, generic dichlorphenamide and Ormalvi (dichlorphenamide) - Rx

1. Diagnosis must be made by a neurologist or muscle disease specialist.
2. Member must have a diagnosis of primary hypokalemic periodic paralysis AND
    a. The diagnosis must be confirmed by BOTH of the following:
        i. A genetic test confirming a skeletal muscle calcium or sodium channel mutation AND
        ii. Serum potassium concentration of less than 3.5 mEq/L during a paralytic attack
    b. Must have had trial and failure with prescription potassium supplementation AND
    c. The patient must have had a trial with oral acetazolamide therapy that did not result in improvement in severity or frequency of attacks OR
3. Member must have a diagnosis of primary hyperkalemic periodic paralysis AND
    a. The diagnosis must be confirmed by BOTH of the following:
        i. A genetic test confirming a skeletal muscle sodium channel mutation AND
        ii. Serum potassium concentration of greater than 5.0 mEq/L during a paralytic attack AND
    b. The patient must have had a trial with oral acetazolamide therapy that did not result in improvement in severity or frequency of attacks AND
4. Requests for Keveyis and Ormalvi require documentation of serious side effects or drug failure with generic dichlorphenamide.
5. For hypokalemic or hyperkalemic periodic paralysis, initial approval will be for 2 months. Recertification will require a documented improvement in the frequency or severity of attacks while taking Keveyis or generic dichlorphenamide. Recertification will be approved for 1 year
6. Initial dosing is one 50 mg tablet twice daily and can be titrated up to a maximum of 200 mg daily.
7. Quantity limit of 120 tablets per 30 days

Korlym and generic mifepristone 300 mg tablets - Rx

1. Must be 18 years of age or older
2. Member must have a diagnosis of endogenous Cushing's syndrome
3. Must also have a diagnosis of type 2 diabetes mellitus or glucose intolerance
4. Must have failed surgery or is not a candidate for surgery
5. Must be prescribed by, or in consultation with, an endocrinologist
6. Patients who meet the criteria for approval for treatment with Korlym will be approved for 12 months. Recertification will require patients to have stabilization/decrease in A1C or objective clinical response.
7. Requests for brand Korlym require documentation of serious side effects or drug failure with generic mifepristone 300 mg tablets (generic Korlym) will be required.
8. Recommended initial dosing is 300 mg once daily with a meal.
9. Increase in 300 mg increments to a maximum of 1200 mg once daily based on clinical response and tolerability. Do not exceed 20 mg/kg per day.
10. Quantity limit of 120 tablets per 30 days.

Mycapssa (octreotide acetate) - Rx

1. Must be prescribed by, or in consultation with, an endocrinologist AND
2. Must be 18 years of age or older AND
3. Must have a diagnosis of acromegaly AND
4. Must have failed pituitary surgery and/or radiation, or patient is not a candidate for surgery and/or radiation AND
5. Must be receiving treatment with either an injectable octreotide product (i.e., octreotide, Sandostatin, Sandostatin LAR) or injectable lanreotide products (i.e., lanreotide acetate injection, Somatuline Depot) for at least 6 months, with a stable dose for at least the last 3 months of therapy AND
6. Must have documented clinical response (defined as improvement or normalization of growth hormone (GH) and/or insulin-like growth factor-1 (IGF-1)) with either an injectable octreotide product or lanreotide acetate AND patient is tolerating therapy.
7. Recommended dosing: Initiate Mycapssa at dosage of 40 mg daily, administered as 20 mg orally twice daily. Monitor insulin-like growth factor (IGF-1) levels and patient's signs and symptoms every two weeks during titration. Titrate dosage based on IGF-1 levels and patient's signs/symptoms. Increase dose in increments of 20 mg daily. The maximum recommended dosage of Mycapssa daily dosage is 80 mg daily. See prescribing information for full details on recommended dosage, titration, and monitoring.
8. Initial approval for acromegaly will be for 12 months. Recertification for any further approval will require documentation of stable or improved GH and/or IGF-1 while on Mycapssa therapy.
9. Quantity limit: 120 capsules/30 days

Myqorzo –(aficamten) - Rx

1. Must be 18 years of age or older **AND**
2. Must be prescribed by, or in consultation with, a cardiologist **AND**

3. Must have a diagnosis of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) confirmed by echocardiogram and/or cardiac magnetic resonance showing one of the following (a or b):
    a. Maximal end-diastolic left ventricular wall thickness of ≥ 15 mm **OR**
    b. Maximal end-diastolic left ventricular wall thickness ≥ 13 mm **AND** one of the following (1 or 2):
        i. Family history of HCM **OR**
        ii. A positive genetic test (e.g., MYH7, TNNI3, TNNT2, TPM1, MYL2, MYL3, ACTC1) **AND**
4. Diagnosis must not be due to a known infiltrative or storage disorder causing cardiac hypertrophy that mimicked obstructive HCM (i.e., Fabry disease, amyloidosis, or Noonan syndrome with left ventricular hypertrophy) **AND**
5. Must have resting left ventricular outflow tract gradient (LVOT-G) ≥ 30 mmHg or LVOT-G ≥ 50 mmHg after provocation (Valsalva maneuver or post-exercise) **AND**
6. Must have left ventricular ejection fraction (LVEF) ≥ 55% **AND**
7. Must have New York Heart Association (NYHA) Class II or III functional status **AND**
8. Must have had serious side effects or drug failure to at least one non-vasodilating beta blocker (i.e., atenolol, bisoprolol, metoprolol) AND one non-dihydropyridine calcium channel blocker (must be separate trials), unless there is a documented medical reason why these agents cannot be used.
    a. Please note failure of non-vasodilating beta blocker or non-dihydropyridine calcium channel blocker therapy does not preclude concomitant use of these therapies with Myqorzo **AND**
9. Prescriber attestation must be received that REMS program requirements have been satisfied
10. Initial and subsequent approvals will be granted for 6 months at a time. Subsequent approvals will require submission of progress notes documenting that the patient has achieved/maintained a positive clinical response to therapy.
    a. LVEF assessment by echocardiogram must be provided on each recertification request.
11. Myqorzo will NOT be approved for continued therapy in patients with LVEF < 40%, or if the patient has symptomatic heart failure or worsening clinical status due to systolic dysfunction.
    a. According to FDA labeling, after treatment interruption due to low LVEF, resume treatment no earlier than 7 days, when LVEF ≥ 55% and re-initiate dose titration at the starting dose of 5 mg. Reauthorization for individuals with interrupted treatment must provide documentation of LVEF > 55%.
12. Quantity limit is 30 tablets/30 days.

Palsonify (paltusotine) - Rx

1. Must be prescribed by, or in consultation with, an endocrinologist AND
2. Must be 18 years of age or older AND
3. Must have a diagnosis of acromegaly AND
4. Must have inadequate response despite pituitary surgery and/or radiation, or patient is not a candidate for surgery and/or radiation AND
5. Must have serious side effects or drug failure with maximally tolerated dose of lanreotide acetate (J1930 or J1932) or Somatuline Depot (J1930) AND
6. Documentation of baseline growth hormone (GH) and insulin-like growth factor-1 (IGF-1) will be required
7. Initial approval will be for 6 months. Recertification for further approval will require documentation of a decrease or normalization of GH and/or IGF-1 from baseline and will be for 12 months at a time.
8. Quantity limit: 60 tablets/30 days
    a. A quantity limit exception of up to 120 tablets/30 days of the 30 mg strength may be authorized for individuals on moderate to strong CYP3A4 Inducers

Recorlev (levoketoconazole) - Rx

1. Must be prescribed by, or in consultation with, an endocrinologist AND
2. Must be 18 years of age or older AND
3. Must have a diagnosis of endogenous Cushing's syndrome AND
4. Must have a mean urinary free cortisol (UFC) level that is at least 1.5x the upper limit of normal (ULN) measured over three 24-hour measurements (In clinical trials for Recorlev, ULN = 50 micrograms/24 hours or 138 nmol/24 hours) AND
5. Must have documentation of symptoms of Cushing's Syndrome (such as diabetes, central obesity, moon face, buffalo hump, osteoporosis, muscle wasting, hypertension, depression, and anxiety) AND
6. Must have documentation of failure of or contraindication to Cushing's syndrome specific surgery AND
7. Must have documentation of serious side effects or drug failure with oral ketoconazole AND
8. Individuals with a diagnosis of Cushing's Disease (Cushing's Syndrome that is caused by a pituitary adenoma) must have documentation of serious side effects or drug failure with at least 2 of the following. (Note: if patient has had previous trial and failure of metopirone (metyrapone) then only 1 of the following is required):
    a. Signifor (either LAR or SC formulation)
    b. Lysodren (mitotane)
    c. Cabergoline

9. Recorlev will not be approved for individuals with pituitary or adrenal carcinoma
10. Recorlev will not be approved for the treatment of fungal infections
11. Initial approval will be for 6 months. Recertification at 6 months and thereafter will require laboratory results to document a recent UFC level within normal limits AND improvement in symptoms of Cushing's Syndrome. Recertification will be annually thereafter.
    a. At the time of recertification, the prescriber must also make clear the maintenance dose they are planning to use. Approval will be allowed for this amount for 1 year.
12. Recommended dosing initially is 150 mg twice daily with or without food. Titrate the dosage by 150 mg daily not more frequently than every 2-3 weeks based on 24-hour urine free cortisol levels and patient tolerability. Monitor cortisol levels from at least two 24-hour urine free cortisol collections every 2-3 weeks until an adequate clinical response is achieved. The maximum recommended dosage is 1200 mg per day, administered as 600 mg twice daily. See full prescribing information for complete dosage and administration instructions.
13. Quantity limit: 60 tablets/30 days. The maximum quantity allowed for any dose request is 240 tablets/30 days.
    a. Initial approval will be limited to 60 tablets/30 days
    b. For dose escalation request during the initial titration period, the allowed quantity will be reviewed as follows:
        i. Documentation of a recent, within the past 2-3 weeks, UFC level above the upper limit of normal must be submitted
        ii. Each dose escalation request will be limited to 1 additional 150 mg tablet per day
        iii. Approval will be granted until the end of the drug approval period or for 1 year
    c. For dose escalation requests after the initial approval period, the allowed quantity will be reviewed as follows:
        i. Documentation showing a recent UFC level above the upper limit of normal
        ii. Documentation that the patient is still experiencing Cushing's Syndrome symptoms
        iii. Approval will be granted until the end of the drug approval period or for 1 year

Redemplo (plozasiran) - Rx

1. Must be prescribed by or in consultation with a cardiologist, lipid specialist, or endocrinologist **AND**
2. Must be 18 years of age and older **AND**
3. Must have a diagnosis of Familial Chylomicronemia Syndrome (FCS) **AND**
4. Must have fasting triglycerides (TGs) of ≥ 880 mg/dL (or 10 mmol/L) within the past 6 months **AND**
5. Must have genetic testing performed and meet one of the following (a or b):
    a. Genetic testing confirms biallelic pathogenic variants (i.e., homozygosity, compound heterozygosity, or double heterozygosity) in FCS-causing genes.
        i. Examples of FCS-causing genes include lipoprotein lipase (LPL), apolipoprotein C-II (APOC2), apolipoprotein C-VI (APOA5), glycosylphosphatidylinositol-anchored high-density lipoprotein1binding protein 1 (GPIHBP1), lipase maturation factor 1 (LMF1) **OR**
    b. Genetic testing is inconclusive (i.e., one or more variants of uncertain significance were identified) and one of the following are met (i, ii, or iii.):
        i. Must have a familial chylomicronemia syndrome (FCS) score ≥ 10 [see Appendix in Rare Diseases CRPA (Pharmacy-99)] **OR**
        ii. Must have a North American familial chylomicronemia syndrome (NAFCS) score ≥ 45 [see Appendix in Rare Diseases CRPA (Pharmacy-99)]
            A. NOTE: In patients ≥ 10 years of age, the NAFCS tool should only be used for patients who are not responsive to fibrates and high-dose omega-3 fatty acids even when the patient is compliant with therapy (i.e., TGs do not decrease by 20% or more and do not remain reduced). **OR**
        iii. Must meet the following:
            A. Must be refractory to refractory to standard triglyceride therapies (e.g., statins, fibrates, high-dose omega-3 fatty acids) **AND**
            B. Other causes of hypertriglyceridemia have been ruled out (e.g., alcohol excess, uncontrolled type 2 diabetes, medications, and medical conditions known to raise triglycerides) **AND**
            C. One of the following is met:
                1. History of acute pancreatitis **OR**
                2. History of recurrent abdominal pain without other known cause **AND**
6. Must have documentation or prescriber attestation that the patient has implemented appropriate dietary fat restrictions (e.g., consuming ≤ 20 g of fat per day) to manage FCS.
7. Redemplo will not be covered for any other non-FDA approved indications
8. Initial approval is for 6 months. Recertification will be every 12 months. Recertifications will require documentation of reduction in fasting TGs from baseline.
9. Quantity Limit: 25 mg/0.5 mL (1 pre-filled syringe) per 90 days

Sandostatin LAR and octreotide intramuscular injection - Rx and Medical

1. Must be 18 years of age or older **AND**
2. Must have a diagnosis of **acromegaly AND**
    a. Must be prescribed by, or in consultation with, an endocrinologist
    b. Must have persistent disease despite pituitary surgery and/or radiation, or patient is not a candidate for surgery and/or radiation
    c. **For New Starts Only for acromegaly diagnosis –must have serious side effects or drug failure with maximally tolerated dose of lanreotide acetate (J1930 or J1932) or Somatuline Depot (J1930).**
    d. Documentation of baseline growth hormone (GH) and insulin-like growth factor-1 (IGF-1) will be required
    e. Initial approval for acromegaly will be for 12 months. Recertification for any further approval will require documentation of a decrease or normalization of GH and/or IGF-1 from baseline **OR**
3. Must have a **cancer** diagnosis that meets the following:
    a. Must prescribed by, or in consultation with an Oncologist, Hematologist, or appropriate specialist [i.e., endocrinologist or gastroenterologist for neuroendocrine/adrenal tumor diagnosis] **AND**
    b. The requested use (indication AND regimen) must meet **one** of the following:
        i. Approved by the U.S. Food and Drug Administration (FDA) **OR**
        ii. A National Comprehensive Cancer Network (NCCN) category level 1 or 2A recommendation **OR**
        iii. Satisfied by the criteria required for the applicable line of business (LOB) for the treatment of cancer in the Off-Label Use of FDA Approved Drugs policy (Pharmacy-32) **AND**
    c. Step therapy requirements must be met for select indications as outlined below:
        i. **For all shared FDA label indications or compendia supported indications/regimens (defined as NCCN level of evidence 1 or 2A) related to neuroendocrine and/or adrenal tumor diagnosis**
        ii. **For New Starts Only—must have serious side effects or drug failure with lanreotide acetate (J1930 or J1932) or Somatuline Depot (J1930).**
    d. Initial certification for cancer diagnosis will be for 12 months. Recertification will require demonstration of stable or improved disease.
4. Recommended dosing (see package labeling for complete dosing recommendations):
    a. Patients Not Currently Receiving Sandostatin Injection Subcutaneously:
        i. Acromegaly: 50 mcg three times daily Sandostatin Injection subcutaneously for 2 weeks followed by Sandostatin LAR/ octreotide intramuscular injection 20 mg intragluteally every 4 weeks for 3 months
        ii. Carcinoid Tumors and VIPomas: Sandostatin Injection subcutaneously 100 to 600 mcg/day in 2-4 divided doses for 2 weeks followed by Sandostatin LAR/ octreotide intramuscular injection 20 mg every 4 weeks for 2 months
    b. Patients Currently Receiving Sandostatin Injection Subcutaneously:
        i. Acromegaly: 20 mg every 4 weeks for 3 months
        ii. Carcinoid Tumors and VIPomas: 20 mg every 4 weeks for 2 months
5. Quantity Limit: 1 kit/28 days. For the treatment of acromegaly, a quantity limit exception of 2 kits/28 days may be granted for the 20 mg strength to allow for a maximum daily dose of 40 mg.

HCPCS: J2353

Signifor LAR (pasireotide) - Medical

1. Must be prescribed by, or in consultation with, an endocrinologist **AND**
2. Must have a diagnosis of Cushing's disease
    a. Must not be a candidate for surgery or have had treatment failure with previous surgery. A non-surgical candidate is defined as either having a medical contraindication to surgery or having a tumor which is surgically unapproachable.
    b. A mean free cortisol (mUFC) level will be required at baseline and upon recertification.
    c. Initial approval for Cushing's disease will be for 3 months. Continuation of therapy will require evidence of a reduction in mUFC from baseline. For individuals who achieve a reduction in mUFC after 3 months, recertification will be required every 12 months. **OR**
3. Must have a diagnosis of acromegaly
    a. Must fail to achieve full biochemical control (Growth hormone < 2.5 mcg/L and normal IGF1) on maximally tolerated treatment with lanreotide acetate (J1930 or J1932) or Somatuline Depot (J1930).

i. The required use of lanreotide acetate (J1930 or J1932) or Somatuline Depot (J1930) applies to all lines of business for new starts only.

b. Recommended dosing for acromegaly: The initial dose is 40 mg by intramuscular injection once every 4 weeks. The dose may be increased to a maximum of 60 mg for patients who have not normalized growth hormone (GH) and/or age and sex adjusted insulin-like growth factor-1 (IGF-1) levels after 3 months of treatment with Signifor LAR at 40 mg and who tolerate this dose.

c. Initial approval and recertification for acromegaly will be for 12 months at a time.

d. Recertification will require the following:

i. Recertification after the initial 12 months will require documentation of response to therapy, including:

1. Reduction or stabilization in tumor volume from baseline assessed by MRI after initial 6 months of therapy **OR**

2. Mean growth hormone (GH) less than 2.5 mcg/L and/or a normal insulin-like growth factor- 1 (IGF-1) level after at least 12 months of initial therapy

ii. Yearly recertification thereafter will require documentation that the patient has maintained a clinical response to treatment.

4. Quantity limit of 1 injection (maximum 60 mg) every 28 days.

HCPCS: J2502

Signifor SC (pasireotide solution) - Rx

1. Must be prescribed by, or in consultation with, an endocrinologist AND
2. Must have a diagnosis of Cushing's disease AND
3. Must not be a candidate for surgery or have had treatment failure with previous surgery. A nonsurgical candidate is defined as either having a medical contraindication to surgery or having a tumor which is surgically unapproachable.
4. A mean free cortisol (mUFC) level will be required at baseline and upon recertification.
5. Initial approval will be for 3 months. Continuation of therapy will require evidence of a reduction in mUFC from baseline. For individuals who achieve a reduction in mUFC after 3 months, recertification will be required every 12 months.
6. Usual dosage is 0.3 to 0.9 mg SC twice a day
7. Quantity limit of 60 doses per 30 days

Skyclarys (omaveloxolone) - Rx

1. Must be prescribed by a neurologist or prescriber knowledgeable in the management of Friedreich's ataxia (FA) AND
2. Must be 16 age or older AND
3. Must have a diagnosis of FA confirmed by genetic testing [Note: 96% of affected individuals have homozygous GAA trinucleotide repeat expansions in the first intron of the FXN gene with the remaining individuals being compound heterozygous for a GAA expansion and a FXN point/insertion/deletion mutation]
4. Initial and recertification will be for 12 months at a time.
5. Recertification requests will require documentation that the patient continues to benefit from therapy (i.e., medical assessment demonstrating disease progression has slowed). NOTE: Due to the heterogeneous nature of the disease, physician attestation of clinical benefit may be considered upon recertification.
6. Quantity limit: 90 capsules/30 days

Sohonos (palovarotene) - Rx

1. Must be prescribed by or in consultation with an endocrinologist, geneticist, orthopedists, or prescriber specializing in fibrodysplasia ossificans progressiva (FOP) AND
2. Must have a diagnosis of FOP AND
3. Must have confirmed ACVR1 R206H mutation AND
4. Must have radiographic evidence of heterotopic ossification (HO) (computed tomography (CT) scan, magnetic resonance imaging (MRI), x-ray, positron emission tomography (PET) scan, etc.) AND
5. Must meet at least one of the following (a or b):
   a. Must be 8 years and older and designated female at birth OR
   b. Must be 10 years and older and designated male at birth
6. Sohonos will not be authorized in combination with another therapy for FOP (e.g. Pasatru)

7. Initial and recertification approvals will be for 6 months at a time. Recertification requests will require provider attestation that the patient is experiencing clinical benefit from treatment (reduction in annualized HO volume, reduction frequency/intensity of flare-ups, improvement in range of motion, etc.).
8. Quantity limit:
    a. 1 mg: 112 tablets/28 days
    b. 1.5 mg: 112 tablets/28 days
    c. 2.5 mg: 140 tablets/28 days
    d. 5 mg: 140 tablets/28 days
    e. 10 mg: 56 tablets/28 days

Syprine, generic trientene capsules, and Cuvrior (trientene tablets) - Rx

1. Must have a diagnosis of Wilson's Disease AND
2. The following age requirements must be met based on the product being requested:
    a. Requests for Syprine or generic trientine capsules: 6 years and older
    b. Requests for Cuvrior: 18 years and older AND
3. Must have had serious side effects or drug failure with penicillamine capsules (generic for Cuprimine) AND
4. Based on comparable indications, efficacy, safety profiles and dosing, ALL requests for trientine 500 mg capsules, Cuvrior, and Syprine will require use of generic trientine 250 mg capsules unless there is adequate justification by the prescriber as to why generic trientine 250 mg capsules are not clinically appropriate.
5. Quantity limit
    a. Syprine and generic trientine 250 mg capsules: 240 capsules per 30 days
    b. Cuvrior: 280 tablets per 28 days
    c. Trientine 500 mg capsules: 120 capsules per 30 days

Tarpeyo (budesonide delayed release capsules) - Rx

1. Must be prescribed by, or in consultation with, a nephrologist **AND**
2. Must be 18 years of age or older **AND**
3. Must have a diagnosis of primary immunoglobulin A nephropathy (IgAN), confirmed on biopsy **AND**
4. Must have an eGFR $\geq$ 30 mL/min/1.73 m^2 **AND**
5. Must have proteinuria defined as $\geq$ 0.5 g/day **OR** urine protein creatinine ratio (UPCR) $\geq$ 0.44 g/g **AND**
6. Must be on an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB) at the maximum or maximally tolerated dose for a minimum of 3 months, unless there is documentation that the patient is unable to tolerate or treatment with an ACEi or ARB is contraindicated **AND**
7. Must meet one of the following:
    a. Must have documentation of drug failure after a minimum 3-month trial with an SGLT2 inhibitor, unless the patient has documentation of serious side effects or contraindication to an SGLT2 inhibitor **OR**
    b. Must have documentation of drug failure after a minimum 6-week trial of systemic oral glucocorticoids (i.e., prednisone, methylprednisolone), unless the patient has documentation of serious side effects or contraindication to systemic oral glucocorticoids **OR**
    c. Patient has one of the following:
        i. Total urine protein > 1 g/day (UPCR > 0.8 g/g) **OR**
        ii. eGFR > 30 to < 60 mL/min/1.73 m^2
8. Requests for non-FDA approved indications will not be covered.
9. Approval will be granted for 10 months. Retreatment will not be covered as the safety and efficacy of treatment with subsequent courses of Tarpeyo have not been established.
10. Recommended dosage is 16 mg administered orally once daily in the morning at least 1 hour before a meal. When discontinuing, reduce dosage to 8 mg once daily for the last two weeks.
11. Quantity Limit: 120 capsules/30 days (maximum of 1,108 capsules/365 days). Quantity limit exceptions will not be authorized.

Thiola, generic tiopronin, Thiola EC, Venxxiva, and generic tiopronin delayed release - Rx

1. Must be prescribed by a nephrologist, urologist, or physician knowledgeable in the treatment of cystinuria AND
2. Must have a diagnosis of severe homozygous cystinuria established by ONE of the following:
    a. Stone analysis showing 100% cystine calculi OR
    b. Pathognomonic hexagonal cystine crystals on urine microscopy OR

c. Genetic test confirming two defects in SLC7A9 and/or ALC3A1 gene AND
3. Must weigh 20 kg or greater AND
4. Prescriber must attest that the patient is unresponsive to high fluid intake, urine alkalization, and diet modification (i.e., sodium and protein restriction) AND
5. Prescriber must attest that the patient will continue high fluid intake, urine alkalization, and diet modification in combination with requested therapy
6. Initial authorization will be for 12 months. Recertification will be every 12 months and require evidence of clinical response defined as urinary cystine concentration < 250 mg/L OR decrease in cystine stone formation.
7. Quantity Limit:
   a. Thiola/tiopronin 100 mg: 300 tablets/30 days
   b. Thiola EC/Venxxiva/tiopronin delayed-release
      i. 100 mg: 300 tablets/30 days
      ii. 300 mg: 90 tablets/30 days

Note: Initial dosing is 800 mg per day. A multi-clinic trial demonstrated an average dose of approximately 1,000 mg/day. Dosage can be adjusted depending on urinary cystine levels.

Exceptions to the quantity limit can be made when there is documentation of conservative therapy in combination with standard dosing of Thiola/tiopronin. Conservative treatment includes Intake of at least 3 L of fluid (ten 10 oz. glassfuls), including 2 glasses with each meal and at bedtime. The patients should be expected to awake at night to urinate; they should drink 2 more glasses of fluids before returning to bed. Additional fluids should be consumed if there is excessive sweating or intestinal fluid loss. A minimum urine output of 2 L/day on a consistent basis should be sought. A modest amount of alkali should be provided in order to maintain urinary pH at a high normal range (6.5 to 7).

Trutakna (atacicept) - Rx

1. Must be prescribed by, or in consultation with, a nephrologist **AND**
2. Must be 18 years of age or older **AND**
3. Must have a diagnosis of primary immunoglobulin A nephropathy (IgAN), confirmed on biopsy **AND**
4. Must have an eGFR $\geq$ 30 mL/min/1.73 m^2 **AND**
5. Must provide baseline documentation that meets at least one of the following (note: documentation of the same laboratory parameter will be required upon recertification):
   a. A total urine protein $\geq$ 0.5 g/day **OR**
   b. A urine protein-to-creatinine ratio (UPCR) $\geq$ 0.44 g/g **AND**
6. Must have received the maximum or maximally tolerated dose of an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB) for a minimum of 3 months prior to starting Trutakna, unless there is documentation that the patient is unable to tolerate or has a contraindication to an ACEi or ARB **AND**
7. Must meet one of the following:
   a. Must have documentation of drug failure after a minimum 3-month trial with an SGLT2 inhibitor, unless the patient has documentation of serious side effects or contraindication to an SGLT2 inhibitor **OR**
   b. Must have documentation of drug failure after a minimum 6-week trial of systemic oral glucocorticoids (i.e., prednisone, methylprednisolone), unless the patient has documentation of serious side effects or contraindication to systemic oral glucocorticoids
8. Initial and recertification approvals will be for 9 months at a time. Continuation of therapy will require the following (documentation must be provided):
   a. Evidence of **one** of the following:
      i. Reduction in total urine protein from baseline **OR**
      ii. Reduction in UPCR from baseline **AND**
   b. Must have an eGFR $\geq$ 30 mL/min/1.73 m^2
9. Requests for non-FDA approved indications will not be covered.
10. Trutakna will not be approved in combination with Fabhalta, Vanrafia, or Voyxact.
11. Quantity Limit: 4 prefilled autoinjectors per 28 days
12. This indication is approved under accelerated approval based on a reduction of proteinuria. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

Tryngolza (olezarsen) - Rx

Tryngolza is considered medically for the treatment of **Familial Chylomicronemia Syndrome (FCS)** when the following criteria are met:
1. Must be prescribed by or in consultation with a cardiologist, lipid specialist, endocrinologist, or gastroenterologist **AND**

2. Must be 18 years of age and older **AND**
3. Must have a diagnosis of Familial Chylomicronemia Syndrome (FCS) **AND**
4. Must have fasting triglycerides (TGs) of ≥ 880 mg/dL (or 10 mmol/L) within the past 6 months **AND**
5. Must have genetic testing performed and meet one of the following (a or b):
    a. Genetic testing confirms biallelic pathogenic variants (i.e., homozygosity, compound heterozygosity or double heterozygosity) in FCS-causing genes.
        i. Examples of FCS-causing genes include lipoprotein lipase (LPL), apolipoprotein C-II (APOC2), apolipoprotein C-VI (APOA5), glycosylphosphatidylinositol-anchored high-density lipoprotein1binding protein 1 (GPIHBP1), lipase maturation factor 1 (LMF1) **OR**
    b. Genetic testing is inconclusive (i.e., one or more variants of uncertain significance were identified) and one of the following are met (i, ii, or iii):
        i. Must have a familial chylomicronemia syndrome (FCS) score ≥ 10 [see Appendix] **OR**
        ii. Must have a North American familial chylomicronemia syndrome (NAFCS) score ≥ 45 [see Appendix]
            A. NOTE: In patients ≥ 10 years of age, the NAFCS tool should only be used for patients who are not responsive to fibrates and high-dose omega-3 fatty acids even when the patient is adherent to therapy **OR**
        iii. Must meet the following (A, B, and C)**:**
    A. Must be refractory to refractory to standard triglyceride therapies (e.g., statins, fibrates, high-dose omega-3 fatty acids) **AND**
    B. Other causes of hypertriglyceridemia have been ruled out (e.g., alcohol excess, uncontrolled type 2 diabetes, medications and medical conditions known to raise triglycerides) **AND**
    C. One of the following is met (1 or 2):
        1. History of acute pancreatitis **OR**
        2. History of recurrent abdominal pain without other known cause **AND**
6. Must have documentation or prescriber attestation that the patient has implemented appropriate dietary fat restrictions (e.g., consuming < 20 g of fat per day) to manage FCS.

Tryngolza is considered medically for the treatment of **severe hypertriglyceridemia** when the following criteria are met:
1. Must be prescribed by or in consultation with a cardiologist, lipid specialist, endocrinologist, or gastroenterologist **AND**
2. Must be 18 years of age and older **AND**
3. Must have a diagnosis of severe hypertriglyceridemia, confirmed by fasting triglycerides (TGs) > 500 mg/dL, despite the ALL of following interventions (provider attestation is acceptable for criterion 3a-3c):
    a. Management of lifestyle factors have been implemented as appropriate (e.g., limiting alcohol intake, dietary modifications, weight loss) for at least 12 weeks
    b. Implementation of appropriate dietary restrictions (e.g., limiting added sugar intake to < 5% of total calories and total dietary fat intake to ≤ 20-25% of total calories; < 5% dietary fat per day if TG > 1000 mg/dL)
    c. Other causes of hypertriglyceridemia have been ruled out and/or addressed (e.g. alcohol excess, uncontrolled type 2 diabetes, medications and medical conditions known to raise triglycerides)
    d. Must have had trial and failure of a maximally tolerated high potency statin (goal is atorvastatin 40-80 mg daily or rosuvastatin 20-40 mg daily), in combination with either an omega-3 fatty acids (e.g. icosapent ethyl) or fibric acid derivative (e.g. fenofibrate) for at least 4 weeks (documentation is required)
4. Documentation of baseline TG level must be submitted within 60 days prior to treatment with Tryngolza. A baseline TG level is defined as a TG level collected while maintained on or following completion of an adequate trial with combination therapy as listed in criterion 3d

- Tryngolza will not be covered for any other non-FDA approved indications
- Initial approval is for 6 months. Recertification will be every 12 months. Recertifications will require documentation of reduction in fasting TGs from baseline.
- Quantity Limit: 1 autoinjector per 28 days

Uplizna (inebilizumab-cdon) - medical

For treatment of Neuromyelitis Optica Spectrum Disorder (NMOSD), please refer to Pharmaceutical Treatment of Neuromyelitis Optica Spectrum Disorder, 1350/20.000393

Uplizna is considered medically necessary for the treatment of **Immunoglobulin (Ig) G4-related disease (IgG4-RD)** when the following criteria are met:
1. Must be 18 years of age or older **AND**
2. Must be prescribed by or in consultation with a rheumatologist, immunologist, endocrinologist, nephrologist, or prescriber experienced treating IgG4-RD **AND**

3. Must have a diagnosis of IgG4-RD **AND**
4. Must meet all the following to confirm diagnosis:
    a. Must have documentation of ≥ 2 organ system/sites involvement at any time during the disease course and at least ONE of the following organs are affected: pancreas, bile ducts/biliary tree, orbits, lungs, kidneys, lacrimal glands, major salivary glands, retroperitoneum, aorta, pachymeninges, and/or thyroid gland **AND**
    b. Must have documentation that other condition that mimic IgG4-RD have been ruled out (e.g., infection, malignancy, other autoimmune conditions) **AND**
5. Must be currently experiencing IgG4- related disease flare (or had a recent flare within the past 12 months) requiring glucocorticoid treatment **AND**
6. Must have evidence of steroid-refractory disease (e.g., symptoms do not sufficiently improve, inadequate decrease in serum IgG4 concentrations) or patient is glucocorticoid-dependent and cannot reduce dose sufficiently without experiencing a flare or worsening of symptoms (e.g., patient developing a flare upon the tapering of prednisone below 10 mg/day).
7. Initial and recertification authorizations will be for 12 months at a time.
    a. Recertification will require documentation that patient is experiencing clinical benefit from therapy (e.g., reduction in flares, reducing glucocorticoid use, symptom improvement).

Uplizna is considered medically necessary for the treatment of **generalized myasthenia gravis (gMG)** when the following criteria are met:
1. Must be 18 years of age or older **AND**
2. Must be prescribed by or in consultation with a neurologist. If geographically available, it is also recommended for patients to have been evaluated by a neuromuscular specialist. **AND**
3. Must have a diagnosis of generalized myasthenia gravis (gMG) **AND**
4. Must have Myasthenia Gravis Foundation of America (MGFA) clinical classification class II to IV **AND**
5. Must be anti-acetylcholine receptor (AchR) antibody positive or Muscle-specific kinase (MuSK) positive **AND**
6. Must have documentation of a baseline Myasthenia Gravis Activities of Daily Living (MG-ADL) score of at least 6 **AND**
7. Must meet one of the following (i or ii)
    a. Must have had serious side effects or drug failure to ONE of the following treatments for gMG (1 or 2).
        i. Corticosteroids for at least 3 months of treatment **OR**
        ii. Non-steroidal immunosuppressive therapy (i.e., azathioprine, mycophenolate mofetil, cyclosporine) for at least 6 months of treatment **OR**
    b. Despite treatment with at least ONE immunosuppressant agent (i.e., corticosteroid, non-steroidal immunosuppressive therapy), the member required at least ONE treatment with plasma exchange, plasmapheresis, or intravenous immunoglobulin within the previous 12 months. **AND**
8. **For individuals with AChR positive gMG**: Must have had serious side effects or drug failure with Vyvgart Hytrulo prefilled syringe (PFS). This applies to New Starts only for all lines of business **except Medicare Part B.**
9. Uplizna will not be approved in combination with Soliris/Bkemv/ Epysqli, Ultomiris, Vyvgart/Vyvgart Hytrulo, Imaavy, Rystiggo or Zilbrysq, as Uplizna has not been studied in combination with these therapies.
10. Initial approvals will be for 6 months.
11. Continued approval will require documentation of ≥ 2-point improvement in the MG-ADL scale from baseline **OR** prescriber attests that patient is experiencing clinical benefit from treatment (i.e., reduction of myasthenia gravis exacerbations, improvement in symptoms such as swallowing, mobility, breathing). Recertification will be required every 12 months.

HCPCS: J1823

Vanrafia (atrasentran) - Rx

1. Must be prescribed by, or in consultation with, a nephrologist **AND**
2. Must be 18 years of age or older **AND**
3. Must have a diagnosis of primary immunoglobulin A nephropathy (IgAN), confirmed on biopsy **AND**
4. Must have an eGFR ≥ 30 mL/min/1.73 m^2 **AND**
5. Must provide baseline documentation that meets at least one of the following (note: documentation of the same laboratory parameter will be required upon recertification):
    a. A total urine protein ≥ 0.5 g/day **OR**
    b. A urine protein-to-creatinine ratio (UPCR) ≥ 0.44 g/g **AND**
6. Must have received the maximum or maximally tolerated dose of an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB) for a minimum of 3 months prior to starting Vanrafia, unless there is documentation that the patient is unable to tolerate or has a contraindication to an ACEi or ARB **AND**

7. Must have documentation of drug failure of Filspari **OR** Tarpeyo
8. Initial and recertification approvals will be for 9 months at a time. Continuation of therapy will require the following (documentation must be provided):
    a. Evidence of **one** of the following:
        i. Reduction in total urine protein from baseline **OR**
        ii. Reduction in UPCR from baseline **AND**
    b. Must have an eGFR ≥ 30 mL/min/1.73 m^2
9. Requests for non-FDA approved indications will not be covered.
10. Vanrafia will not be approved in combination with Trutakna, Voyxact or Fabhalta
11. Quantity Limit: 30 tablets/30 days
12. This indication is approved under accelerated approval based on a reduction of proteinuria. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

Vijoice (alpelisib) - Rx

1. Must be 2 years of age or older AND
2. Must be prescribed by a prescriber who specializes in PIK3CA-Related Overgrowth Spectrum (PROS) AND
3. Must have a diagnosis of PROS, confirmed by a prescriber specializing in PROS AND
4. Must have documentation of a mutation in the PIK3CA gene AND
5. Prescriber must attest that the patient's condition is severe or life threatening AND
6. Must have at least one target lesion identified on imaging at baseline AND
7. Must provide a baseline sum of measurable target lesion volume
8. Vijoice will not be covered for any other diagnosis
9. Recommended dosing in adult patients is 250 mg orally, once daily, administered as recommended until disease progression or unacceptable toxicity. Recommended dosing in pediatric patients (2 to less than 18 years of age) is 50 mg orally, once daily, administered as recommended until disease progression or unacceptable toxicity. See full prescribing information for complete dosing and administration recommendations.
10. Initial approval will be for 6 months. Recertification will be for 12 months at a time and will require documentation of:
    a. A decrease from baseline in sum of measurable target lesion volume, without debulking surgery, confirmed by at least one imaging assessment, in the absence of > 20% increase from baseline in any target lesion, progression of a non-target lesions, or appearance of any new lesions
11. Quantity limit:
    a. 50 mg oral granules: 28 packets/28 days
    b. 50 mg/day pack and 125 mg/day pack: 28 tablets/28 days
    c. 250 mg/day pack: 56 tablets/28 days
12. This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Voxzogo (vosoritide) - Rx

1. Must be prescribed by, or in consultation with, a geneticist, skeletal dysplasia specialist or pediatric endocrinologist AND
2. Must be less than 18 years of age AND
3. Must have a diagnosis of achondroplasia, confirmed by genetic testing (gain of function FGFR3 gene mutation) AND
4. Documentation of a recent (within previous 6 months) annualized growth velocity (AGV) to establish baseline AGV AND
5. One of the following must be met (a or b):
    a. Annualized growth velocity (AGV) > 1.5 cm/year (based on documentation provided to satisfy criterion #4) OR
    b. Radiographic evidence (within previous 6 months) demonstrating open epiphyses
6. Must not have previous treatment with growth hormone, insulin-like growth factor 1, or anabolic steroids within the previous 6 months
7. Prescriber must attest that patient does not have planned or expected limb-lengthening surgery
    a. If the patient had limb-lengthening surgery, it must have occurred at least 18 months prior to the Voxzogo request
8. For individuals 2 years and older, must have serious side effects or drug failure with Yuviwel
9. Initial approval will be for 6 months. Recertification requests will be granted for 6 months and require recent (within 6 months) documentation of the following (a and b):
    a. One of the following are met (i or ii)
        i. A recent AGV ≥ 1.5 cm/year **OR**
        ii. Radiographic evidence demonstrating open epiphyses

AND

b. Evidence of an increase in AGV from baseline

10. Voxzogo will not be authorized if there is documented evidence of closed epiphyses
11. Voxzogo will not be authorized for use in combination with Yuviwel
12. The recommended dose of Voxzogo is based on the patient's body weight (see prescribing information)
13. Quantity limit: 30 vials (3 co-packs)/30 days
14. This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

Voydeya (danicopan) - Rx

1. Must be 18 years of age or older AND
2. Must be prescribed by a hematologist or nephrologist AND
3. Must have a diagnosis of paroxysmal nocturnal hemoglobinuria (PNH) confirmed by a flow cytometry test AND
4. Must be receiving ravulizumab (e.g., Ultomiris) or eculizumab (e.g., Soliris, Bkemv, Epysqli) therapy for at least 6 months AND
5. Must have documented evidence of extravascular hemolysis (EVH) while receiving ravulizumab (e.g., Ultomiris) or eculizumab (e.g., Soliris, Bkemv, Epysqli). [examples of EVH: anemia, elevated absolute reticulocyte count, elevated LDH, elevated bilirubin, increase in transfusion requirements, etc.] AND
6. Prescriber must attest that Voydeya will be used in combination with ravulizumab (e.g., Ultomiris) or eculizumab (e.g., Soliris, Bkemv, Epysqli) AND
7. Voydeya will not be authorized in combination with any other complement inhibitor beyond those included in the FDA-labeled indication (e.g., Empaveli (pegcetacoplan), Fabhalta (iptacopan), Piasky (crovalimab)) as these combinations have not been studied and will be considered experimental/investigational.
8. Voydeya will not be authorized for any other non-FDA approved indication
9. Initial approval for 6 months. Continued approval will be for 6 months and will require documentation that the patient is tolerating therapy and is responding to treatment (i.e., decrease in number of transfusions, improvement in hemoglobin levels, normalization of LDH levels, symptom improvement).
10. Quantity Limit: 180 tablets/30 days

Voyxact (sibeprenlimab) - Rx

1. Must be prescribed by, or in consultation with, a nephrologist **AND**
2. Must be 18 years of age or older **AND**
3. Must have a diagnosis of primary immunoglobulin A nephropathy (IgAN), confirmed on biopsy **AND**
4. Must have an eGFR > 30 mL/min/1.73 m^2 **AND**
5. Must provide baseline documentation that meets at least one of the following (note: documentation of the same laboratory parameter will be required upon recertification):
    a. A total urine protein > 0.5 g/day **OR**
    b. A urine protein-to-creatinine ratio (UPCR) > 0.44 g/g **AND**
6. Must have received the maximum or maximally tolerated dose of an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin II receptor blocker (ARB) for a minimum of 3 months prior to starting Voyxact, unless there is documentation that the patient is unable to tolerate or has a contraindication to an ACEi or ARB **AND**
7. Must meet one of the following:
    a. Must have documentation of drug failure after a minimum 3-month trial with an SGLT2 inhibitor, unless the patient has documentation of serious side effects or contraindication to an SGLT2 inhibitor **OR**
    b. Must have documentation of drug failure after a minimum 6-week trial of systemic oral glucocorticoids (i.e., prednisone, methylprednisolone), unless the patient has documentation of serious side effects or contraindication to systemic oral glucocorticoids **OR**
    c. Patient has one of the following:
        i. Total urine protein > 1 g/day (UPCR > 0.8 g/g) **OR**
        ii. eGFR > 30 to < 60 mL/min/1.73 m^2
8. Initial and recertification approvals will be for 9 months at a time. Continuation of therapy will require the following (documentation must be provided):
    a. Evidence of one of the following:
        i. Reduction in total urine protein from baseline **OR**

ii. Reduction in UPCR from baseline **AND**

b. Must have an eGFR > 30 mL/min/1.73 m^2

9. Requests for non-FDA approved indications will not be covered.
10. Voyxact will not be approved in combination with Fabhalta, Trutakna, or Vanrafia
11. Quantity Limit: 400 mg/2mL (1 prefilled syringe) per 28 days
12. This indication is approved under accelerated approval based on a reduction of proteinuria. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

Vykat XR (diazoxide choline) - Rx

1. Must be prescribed by or in consultation with an endocrinologist, medical geneticist, or prescriber who specializes in the treatment of Prader-Willi syndrome (PWS)
2. Must be 4 years of age or older
3. Must have a diagnosis of PWS confirmed with generic testing establishing abnormal DNA methylation of chromosome 15q11.2-q13
4. Must have documentation of hyperphagia (e.g., intense/persistent hunger, extreme food-seeking behaviors)
5. Must have documentation of recent weight (within 30 days) to ensure appropriate dose
6. Provider must attest that caregiver or patient have implemented and will continue strategies to establish a food-secure environment
7. Vykat XR will not be authorized for treatment of hyperphagia in patients without Prader-Willi syndrome
8. Initial approval and continues may be issued for 6 months at a time. Continuation of therapy will require:
    a. Recent (within 30 days) documentation of weight to ensure appropriate dose
    b. Documentation or provider attestation that Vykat XR is providing clinical benefit (e.g., decrease in food-related symptoms that interfere with activities of daily living)
9. Quantity limit: 30 tablets/30 days
    a. Upon each drug review and dose escalation request, the allowed quantity will be reviewed in accordance with FDA-approved weight-based dosing and, as such, will be limited to the minimum number of tablets to obtain the appropriate daily dose.

Xolremdi (mavorixafor) - Rx

1. Must be prescribed by an immunologist, hematologist, or prescriber who specializes in the management of WHIM (warts, hypogammaglobulinemia, infections and myelokathexis) syndrome **AND**
2. Must be 12 years of age or older **AND**
3. Must have a diagnosis of WHIM syndrome confirmed by genotype variant of CXCR4 **AND**
4. Must have documentation of the following laboratory values at baseline, to assess clinical response to treatment:
    a. Absolute lymphocyte count (ALC) **AND**
    b. Absolute neutrophil count (ANC) **AND**
5. Must have ANC of ≤ 400 cells/μL prior to starting Xolremdi
6. Initial approval will be for 6 months. Recertification will be for 12 months at a time and requires documentation of improvement of ALC and/or ANC from baseline.
    a. NOTE: If ALC and ANC values do not improve from baseline while on Xolremdi, then documentation must be submitted demonstrating objective clinical response to therapy that warrants continuation of Xolremdi (e.g., reduction or improvement in frequency, duration, or severity of infections; reduction in the need for antibiotics; fewer warts; improvement in white blood cell count (WBC) or absolute monocyte count (AMC)).
7. Quantity Limit: 120 capsules/30 days

Yartemlea (narsoplimab-wuug) – Medical

1. Must be prescribed by, or in consultation with, a hematologist, oncologist, transplant specialist, or specialist in the treatment of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA) AND
2. Must be 2 years of age or older AND
3. Must be post-hematopoietic stem cell transplant (HSCT) AND
4. Must have documentation of laboratory results indicating a diagnosis of hematopoietic stem cell transplant-associated thrombotic microangiopathy (TA-TMA), defined as both of the following (a and b).
    a. Platelet count < 150 x 10^9/L AND
    b. Evidence of microangiopathic hemolysis, defined as one of the following (i, ii, or iii):
        i. Presence of schistocytes

ii. Serum lactate dehydrogenase (LDH) above the upper limit of normal (ULN)
iii. Haptoglobin below the lower limit of normal (LLN) AND

5. Yartemlea will not be authorized in combination with a complement inhibitor (including but not limited to eculizumab, ravulizumab, pegcetacoplan)
6. Initial approval will be for 6 months. Recertification will be for 12 months at a time and require one of the following is met (a or b)
    a. Member is responding to therapy, defined as both of the following (i and ii):
        i. Improvement in clinical status of at least one organ system (e.g., blood, kidney, pulmonary, gastrointestinal, neurological) [See Considerations for examples of clinical status improvement by organ] or independence from red blood cell (RBC) and/or platelet transfusions AND
        ii. Both of the following are met (1 and 2):
            1. LDH level is less than 1.5x ULN AND
            2. Platelet count is improved, defined as:
                a. For baseline platelet count ≤ 20,000/µL (i, ii, and iii):
                    i. ≥ 3-fold increase in platelet count AND
                    ii. Post-baseline platelet count ≥ 30,000/µL AND
                    iii. Receipt of no platelet transfusions within 2 days prior to the platelet count assessment OR
                b. For baseline platelet count > 20,000/µL (i, ii, and iii):
                    i. ≥ 50% increase in platelet count AND
                    ii. Platelet count ≥ 75,000/µL AND
                    iii. Receipt of no platelet transfusions within 2 days prior to the platelet count assessment. OR
    b. Member has had inadequate improvement in TA-TMA signs and symptoms and requires escalation in dosing frequency to twice weekly, based on FDA approved labeling.

Yorvipath (palopegteriparatide) - Rx

1. Must be 18 years of age and older AND
2. Must be prescribed by or in consultation with an endocrinologist AND
3. Must have a diagnosis of chronic hypoparathyroidism of postsurgical, autoimmune, genetic, or idiopathic etiologies for at least 6 months AND
4. Must have documented history of hypocalcemia in the setting of inappropriately low serum parathyroid (PTH) levels AND
5. Patient must currently be receiving conventional therapy for hypoparathyroidism consisting of active vitamin D (calcitriol) and calcium supplementation AND
6. Prescriber must attest to the following (a and b):
    a. The patient's hypoparathyroidism cannot be adequately controlled with conventional therapy alone AND
    b. Prior to initiating Yorvipath, the following will be verified in accordance with the FDA-approved prescribing information (i and ii):
        i. Serum 25(OH) vitamin D levels are within normal range AND
        ii. Albumin-corrected serum calcium is > 7.8 mg/dL (or ionized serum calcium is > 4.40 mg/dL) AND
7. Yorvipath will not be authorized for acute postsurgical hypoparathyroidism (defined as postsurgical hypoparathyroidism for a duration of less than 6 months) AND
8. Yorvipath will not be authorized in combination with any other PTH analogs (e.g., teriparatide) AND
9. Yorvipath will not be authorized for non-FDA approved indications.
10. Initial and recertification approval will be for 12 months at a time. Recertification requests will require prescriber attestation the patient is demonstrating clinical benefit from therapy (e.g., reduction in dose or discontinuation of active vitamin D and/or therapeutic doses of elemental calcium; maintenance of albumin-adjusted serum calcium within normal range).
11. Quantity limit: 2 pens per 28 days

Yuviwel (navepegritide) – Rx

1. Must be prescribed by, or in consultation with, a geneticist, skeletal dysplasia specialist or pediatric endocrinologist AND
2. Must be 2 years of age to less than 18 years of age AND
3. Must have a diagnosis of achondroplasia, confirmed by genetic testing (gain of function FGFR3 gene mutation) AND
4. Must have documentation of a recent (within previous 6 months) annualized growth velocity (AGV) to establish baseline AGV AND
5. One of the following must be met (a or b):

a. Annualized growth velocity (AGV) ≥ 1.5 cm/year (based on documentation provided to satisfy criterion #4) OR
b. Radiographic evidence (within previous 6 months) demonstrating open epiphyses AND

6. Must not have previous treatment with growth hormone, insulin-like growth factor 1, or anabolic steroids within the previous 6 months
7. Prescriber must attest that patient does not have planned or expected limb-lengthening surgery
    a. If the patient had limb-lengthening surgery, it must have occurred at least 18 months prior to the Yuviwel request
8. Initial approval will be for 6 months. Recertification requests will be granted for 6 months and require recent (within 6 months) documentation of the following (a and b):
    a. One of the following are met (i or ii)
        i. A recent AGV ≥ 1.5 cm/year OR
        ii. Radiographic evidence demonstrating open epiphyses AND
    b. Evidence of an increase in AGV from baseline
9. Yuviwel will not be authorized if there is documented evidence of closed epiphyses.
10. Yuviwel will not be authorized for use in combination with Voxzogo
11. The recommended dosage of Yuviwel is based on the patient's body weight (see prescribing information)
12. Quantity limit: 4 kits (4 vials) per 28 days
    a. A quantity limit exception will be authorized for patients weighing 56 kg or more to allow for 8 kits (8 vials) per 28 days
13. This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s)

Ztalmy (ganaxolone) - Rx

1. Must be prescribed by or in consultation with a neurologist
2. Patient must be 2 years of age or older
3. Must have a diagnosis of seizures associated with cyclin-dependent kinase-like 5 deficiency disorder (CDD) confirmed by CDKL5 genetic testing
4. Documented trial and failure of at least two antiepileptic therapies
5. Initial approval will be for 6 months and require documentation of baseline monthly seizure frequency.
6. Recertification will require documentation of a sustained reduction in monthly seizure frequency compared to baseline.
7. Quantity limit: 1 bottle per 28 days. Upon each review and dose escalation request, the allowed quantity will be reviewed in accordance with FDA-approved weight-based dosing and, as such, will be limited to the minimum number of bottles to obtain the appropriate daily dose.

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.

The 2019 American College of Rheumatology/European League Against Rheumatism classification criteria for IgG4-related disease
Step 3 Inclusion criteria: domains and items**

Domain and Items	Score¶
Histopathology	
Uninformative biopsy	0
Dense lymphocytic infiltrate	+4
Dense lymphocytic infiltrate and obliterative phlebitis	+6
Dense lymphocytic infiltrate and storiform fibrosis with or without obliterative phlebitis	+13
***Immunostaining**#*	
IgG4+:IgG+ ratio is 0 to 40% or indeterminate and the number of IgG4+ cells/HPF is 0 to 9.‡	0
IgG4+:IgG+ ratio is ≥ 41% and the number of IgG4+ cells/HPF is 0 to 9 or indeterminate; or the IgG4+:IgG+ ratio is 0 to 40% or indeterminate and the number of IgG4+ cells/HPF is ≥ 10 or indeterminate.	+7
IgG4+:IgG+ ratio is 41 to 70% and the number of IgG4+ cells/HPF is ≥ 10; or the IgG4+:IgG+ ratio is ≥ 71% and the number of IgG4+ cells/HPF is 10 to 50.	+14
IgG4+:IgG+ ratio is ≥ 71% and the number of IgG4+ cells/HPF is ≥ 51.	+16
Serum IgG4 concentration	
Normal or not checked	0

> Normal but < 2 times upper limit of normal	+4
2 to 5 times upper limit of normal	+6
> 5 times upper limit of normal	+11
Bilateral lacrimal, parotid, sublingual, and submandibular glands	
No set of glands involved	0
1 set of glands involved	+6
2 or more sets of glands involved	+14
Chest	
Not checked or neither of the items listed is present	0
Peribronchovascular and septal thickening	+4
Paravertebral band-like soft tissue in the thorax	+10
Pancreas and biliary tree	
Not checked or none of the items listed is present	0
Diffuse pancreas enlargement (loss of lobulations)	+8
Diffuse pancreas enlargement and capsule-like rim with decreased enhancement	+11
Pancreas (either of above) and biliary tree involvement	+19
Kidney	
Not checked or none of the items listed is present	0
Hypocomplementemia	+6
Renal pelvis thickening/soft tissue	+8
Bilateral kidney cortex low-density areas	+10
Retroperitoneum	
Not checked or neither of the items listed is present	0
Diffuse thickening of the abdominal aortic wall	+4
Circumferential or anterolateral soft tissue around the infrarenal aorta or iliac arteries	+8

¶ Only the highest-weighted item in each domain is scored.
# Biopsies from lymph nodes, mucosal surfaces of the gastrointestinal tract, and skin are not acceptable for use in weighting the immunostaining domain.
** "Indeterminate" refers to a situation in which the pathologist is unable to clearly quantify the number of positively staining cells within an infiltrate yet can still ascertain that the number of cells is at least 10/high-power field (hpf). For a number of reasons, most often pertaining to the quality of the immunostain, pathologists are sometimes unable to count the number of IgG4+ plasma cells with precision yet even so, can be confident in grouping cases into the appropriate immunostaining result category.

**Full classification criteria may be found at: https://acrjournals.onlinelibrary.wiley.com/doi/epdf/10.1002/art.41120

Source: Wallace ZS, Naden RP, Chari S, et al. The 2019 ACR/EULAR Classification Criteria for IgG4-Related Disease. Arthritis Rheumatol. 2020;72(1):7-19. doi:10.1002/art.41120

Yartemlea organ system clinical status improvement

Organ	Improvement in Clinical Status
Blood	Freedom from red blood cell (RBC) and/or platelet transfusion
Kidney	Reduction in creatinine >40% OR Creatinine below the upper limit of normal and reduction of creatinine >20% OR Discontinuation of renal replacement therapy
Pulmonary	Extubation and discontinuation of ventilator support OR Discontinuation of noninvasive mechanical ventilation
Gastrointestinal (GI)	Improvement assessed using GI measures in Mount Sinai Acute GVHD International Consortium (MAGIC) criteria
Neurologic	Improvement in reversible neurological conditions (e.g., cessation of seizures) OR Stabilization of irreversible neurological conditions (e.g., stability of neurological deficits following stroke without further deterioration or subsequent strokes).

Khaled SK, Claes K, Goh YT, et al. Narsoplimab, a Mannan-Binding Lectin-Associated Serine Protease-2 Inhibitor, for the Treatment of Adult Hematopoietic Stem-Cell Transplantation-Associated Thrombotic Microangiopathy. *J Clin Oncol*. 2022;40(22):2447-2457. doi:10.1200/JCO.21.02389

Figure 1A: Isturisa Efficient Dosing Chart
This chart reflects the number of tablets of each strength that will be covered to make any given dose of Isturisa within the FDA approved

limit.

Dose	**1 mg**	**5 mg**
2 mg BID	120 tablets/30 days	
3 mg BID	180/30	
4 mg BID	240/30	
5 mg BID		60/30
6 mg BID	60/30	60/30
7 mg BID	120/30	60/30
8 mg BID	180/30	60/30
9 mg BID	240/30	60/30
10 mg BID		120/30
11 mg BID	60/30	120/30
12 mg BID	120/30	120/30
13 mg BID	180/30	120/30
14 mg BID	240/30	120/30
15 mg BID		180/30
16 mg BID	60/30	180/30
17 mg BID	120/30	180/30
18 mg BID	180/30	180/30
19 mg BID	240/30	180/30
20 mg BID		240/30
21 mg BID	60/30	240/30
22 mg BID	120/30	240/30
23 mg BID	180/30	240/30
24 mg BID	240/30	240/30
25 mg BID		300/30
26 mg BID	60/30	300/30
27 mg BID	120/30	300/30
28 mg BID	180/30	300/30
29 mg BID	240/30	300/30
30 mg BID		360/30

References

		Updated	Accessed
1	National Organization for Rare Disorders (NORD®). Available at https://rarediseases.org/		2/2026
2	Filspari (sparsentan) prescribing information. Travere Therapeutics, Inc., San Diego, CA 92130	8/2025	2/2026
3	Uplizna (inebilizumab-cdon) prescribing information, Viela Bio, In., Gaithersburg, MD 20878	12/2025	2/2026
4	Vanrafia (atrasentan) prescribing information. Novartis Pharmaceuticals Corporation East Hanover, New Jersey 07936	4/2025	2/2026
5	Wheeler DC, Toto RD, Stefánsson BV, et al. DAPA-CKD Trial Committees and Investigators. A pre-specified analysis of the DAPA-CKD trial demonstrates the effects of dapagliflozin on major adverse kidney events in patients with IgA nephropathy. Kidney Int. 2021 Jul;100(1):215-224.doi: 10.1016/j.kint.2021.03.033. Epub 2021 Apr 18. PMID: 33878338.	7/2021	2/2026

6	Aqvesme (mitapivat) prescribing information. Agios Pharmaceuticals, Inc. Cambridge, MA 02139	12/2025	2/2026
7	Prescribing information for: Cuprimine, penicillamine tablets, Galzin		2/2026

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted in above application if administered under the medical benefit. Forzinity: Not applicable
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application if administered under the medical benefit. Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program.

CDPHP Pharmacy Services 10/1/2026

New: 2/2026

Revised	Reviewed
3/2026, 5/2026, 6/2026, 7/2026, 8/2026, 9/2026	

Revision Date	Changes Made
2/2026	Added Forzinity, Redemplo, and Tryngolza.
3/2026	Added Aldurazyme. Updated Tryngolza to remove step through Redemplo.
5/2026	Added Myqorzo, Voyxact. Moved Juxtapid, Gamifant, Voxzogo, Xolremdi, Skyclarys from standalone policy to this policy.
5/2026	Added Yartemlea and Yuviwel Added Recorlev
5/2026	Moved Palsonify and Ilaris from standalone policies Added Mycapssa, Sandostatin LAR and Signifor LAR
6/2026	Added Juxtapid 2.5 mg QL Updated Voxzogo criteria
7/2026	Added Adzynma
8/2026	Added Arcalyst, Crenessity, Imcivree, Increlex, Isturisa, and Trutakna Moved Camzyos, Fabhalta, Joenja, Sohonos, Tarpeyo, trientene/Syprine/Cuvrior, Vijoice, Voydeya, Vykat XR, Yorvipath, and Ztalmy from standalone policies Updated proteinuria levels and combination therapy language for Fabhalta, Vanrafia, Voyxact, Filspari, and Tarpeyo Removed Adzynma requirement the patient does not have anti-ADAMTS13 autoantibodies Added new Tryngolza indication for new indication for severe hypertriglyceridemia Removed accelerated approval statement from Fabhalta for IgAN Added Trutakna as a drug Fabhalta. Vanrafia, and Voyxact cannot be used in combination with Uplizna - For a diagnosis of IgG4-RD, removed requirement of > 20 score on the 2019 ACR/EULAR HgG4-RD classification criteria
8/2026	Added Actimmune, Keveyis, generic dichlorphenamide and Ormalvi (dichlorphenamide), Firdapse, Korlym

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	and generic mifepristone, Signifor SC, Thiola, generic tiopronin, Thiola EC, Venxxiva, and generic tiopronin delayed release
9/2026	Added statement urine protein and eGFR to Filspari, Tarpeyo, and Voyxact Added step requirement for Voxzogo
10/2026	Updated age and weight requirements based on expanded indication for Joenja Added statement Sohonos will not be authorized in combination with another therapy for FOP (e.g. Pasatru)

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Policy/Procedure Name: RDEB Pharmaceutical Treatment **Control Number: 1350/20.000484**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Vyjuvek is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy (gel formulation) indicated for the treatment of wounds in patients six months of age and older with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene. Those with autosomal dominant DEB (DDEB) have lower than normal functional anchoring fibrils and those with autosomal recessive DEB (RDEB) have no functional anchoring fibrils.

Dystrophic epidermolysis bullosa is one of the major forms of epidermolysis bullosa. The signs and symptoms can vary widely among affected children and adults. In mild cases, blistering may primarily affect the hands, feet, knees, and elbows whereas severe cases involve widespread blistering. Some children even develop blisters in the moist tissue that line the mouth, throat, stomach, intestines, and rectum, even food friction or bowel movements can cause painful blisters. This disease process can lead to vision loss, disfigurement, and other serious medical problems. DEB is even associated with fatal skin cancers, known to be aggressive and difficult to treat. DEB is caused by changes (mutations) in the *COL7A1* gene and may be inherited in an autosomal dominant or autosomal recessive manner depending on the subtype.

Treatment is aimed at managing a few aspects of the disease including wound care, and pain management. The blistering and raw skin, infections and even normal GI processes, all cause pain in this population.

Dystrophic epidermolysis bullosa (DEB) is caused by mutation(s) in the COL7A1 gene, which results in reduced or absent levels of biologically active COL7. Upon topically applying Vyjuvek to wounds, it can transduce both keratinocytes and fibroblasts, and upon entry into the cells the vector genome is deposited into the nucleus. At this point, the transcription of the encoded human COL7A1 is initiated, which allows for the production and secretion of COL7 by the cell in its mature form. COL7 arrange themselves into long, thin bundles that form anchoring fibrils which hold the epidermis and dermis together and are essential for maintaining skin integrity.

The efficacy of Vyjuvek in subjects one year of age and older with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the COL7A1 gene was evaluated in one randomized, double-blind, intra-subject placebo-controlled trial. All study subjects had clinical manifestations consistent with DEB and genetically confirmed mutation(s) in the COL7A1 gene. Two comparable wounds in each subject were selected and randomized to receive either topical application of Vyjuvek gel or the placebo (excipient gel) weekly for 26 weeks. There were 31 subjects enrolled, including 30 with autosomal recessive DEB and one with autosomal dominant DEB, ages between 1 and 44 years. Efficacy was established on the basis of improved wound healing defined as the difference in the proportion of complete (100%) wound closure at 24 weeks confirmed at two consecutive study visits two weeks apart, weeks 22 and 24 or at weeks 24 and 26. Efficacy was supported by the difference in the proportion of complete wound closure assessed at weeks 8 and 10 or at weeks 10 and 12 between the Vyjuvek and placebo arms. Complete (100%) wound closure was defined as durable wound closure evaluated at two consecutive visits two weeks apart (as noted above). At weeks 22 & 24 or 24 & 26, in those receiving Vyjuvek, 20 subjects or 65% had complete wound closure, compared to 8 or 26%, 39% treatment difference, p = 0.012. Adverse reactions include itching, chills, redness, rash, cough, and runny nose. There were no discontinuations due to adverse reactions.

Summary

Effective Date of Policy:	2/12/2026
Indications	Dystrophic epidermolysis bullosa with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene
ICD10 Diagnosis Codes	Q81.2
Availability	Vyjuvek is a biological suspension, mixed into excipient gel, for topical application. Vyjuvek biological suspension is supplied as a 1.0 mL extractable volume in a single dose vial at a nominal concentration of 5×10^9 PFU/mL. The excipient gel is supplied as a 1.5 mL fill volume in a separate single use vial. Vyjuvek biological suspension (1 mL) is mixed into the excipient gel vial prior to administration as Vyjuvek gel. Filsuvez is supplied in 25 mL white aluminum tubes containing 23.4 grams of gel per tube

	Zevaskyn is supplied in sheets of 41.25 m^2 (5.5 cm x 7.5 cm) and up to 12 sheets may be manufactured from the patient's biopsies and supplied for potential use. Due to Zevaskyn's autologous nature, a repeated biopsy may be required if manufacturing failure occurs.
Duration	Six months

Required Criteria for Initial Approval	
All of the following conditions for the requested indication must be met in order to approve therapy:	
Filsuvez (birch triterpenes)	1. Must be prescribed by, or in consultation, with a dermatologist or pediatric dermatologist, or clinical expert in epidermolysis bullosa (EB) AND 2. Must be 6 months of age or older AND 3. Must have a diagnosis of dystrophic epidermolysis bullosa (DEB) or junctional epidermolysis bullosa (JEB), confirmed on genetic testing (e.g., mutations in COL7A1 or PLOD3 for DEB and LAMA3, LAMB3, LAMC2, COL17A1, ITGA6, ITGB4, or ITGA3 for JEB) AND 4. Must have documentation within the previous month indicating which cutaneous wound(s) will be treated with Filsuvez AND 5. Prescriber must attest the following (a and b): a. The wound(s) being treated is (are) 10 cm^2 to 50 cm^2 AND b. The wound(s) being treated is (are) aged > 21 days to < 9 months AND 6. Filsuvez will not be authorized in combination with Vyjuvek or Zevaskyn for the treatment of the same wound(s). 7. Filzuvez will not be authorized for concomitant use with Vyjuvek or Zevaksyn for the treatment of different wounds located on different areas of the body, unless there is adequate documentation justifying the need for separate products on different wounds located on different areas of the body. 8. Use of Filsuvez on a wound(s) previously treated with Vyjuvek or Zevaskyn requires adequate documentation demonstrating inadequate response or treatment failure to previous treatment(s). 9. Initial and recertification approval will be for 3 months at a time. Recertification will require documentation of clinical improvement of the treated wound (s) AND a. The treated wound(s) has not completely closed or has re-opened OR b. New, previously untreated wound(s) require treatment. 10. Quantity Limit: 15 tubes/30 days a. Requests for higher quantities will require the prescriber provide an estimate of how frequently the patient will require wound dressing changes (e.g., daily, every other day) AND number of wounds being treated
Vyjuvek (beremagene geperpavec-svdt)	1. Must be prescribed by, or in consultation with, a dermatologist or pediatric dermatologist, or clinical expert in epidermolysis bullosa (EB) **AND** 2. Must have a diagnosis of dystrophic epidermolysis bullosa (DEB) [either recessive DEB (RDEB) or dominant DEB (DDEB)] **AND** 3. Must have confirmed mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene **AND** 4. Must have documentation within the previous month indicating which cutaneous wound(s) will be treated with Vyjuvek. 5. If Vyjuvek is being administered by the patient or caregiver, Vyjuvek will be considered for coverage on the pharmacy benefit. If Vyjuvek is being administered by a healthcare professional, Vyjuvek will be considered for coverage on the medical benefit. 6. Vyjuvek will not be authorized in combination with Filsuvez (birch triterpenes gel) or Zevaskyn for the treatment of the same wound(s) 7. Vyjuvek will not be authorized for concomitant use with Filsuvez or Zevaskyn for the treatment of different wounds located on different areas of the body, unless there is adequate documentation justifying the need for separate products on different wounds located on different areas of the body. 8. Use of Vyjuvek on a wound(s) previously treated with Filsuvez or Zevaskyn requires adequate documentation demonstrating inadequate response or treatment failure to previous treatment(s). 9. The recommended dosage of Vyjuvek gel is based on age (see prescribing information for dosing) and is applied topically to wound(s) once a week. Based on the prescribing information, no more than one vial per week of mixed Vyjuvek gel should be used (NOTE: mixed Vyjuvek gel includes Vyjuvek biological suspension combined with excipient gel).

	10. Initial approval will be for 6 months. Recertification will be for 6 months at a time and require documentation of clinical improvement in the treated wound(s) **AND** a. The treated wound(s) has not completely closed or has re-opened **OR** b. New, previously untreated wound(s) require treatment 11. Quantity Limit: 10 mL allowed in a 28-day period
Zevaskyn (prademagene zamikeracel)	1. Must be prescribed by, or in consultation, with a dermatologist or pediatric dermatologist, or clinical expert in epidermolysis bullosa (EB) **AND** 2. Must be 6 years of age or older **AND** 3. Must have a diagnosis of **recessive** dystrophic epidermolysis bullosa (RDEB) confirmed by mutations in both *COL7A1 genes* **AND** 4. Must have documentation within the previous month indicating which cutaneous wound(s) will be treated with Zevaskyn **AND** 5. The wound(s) being treated must be a stage 2 wound, defined as an open skin wound with partial thickness loss of dermis that has not extended through the dermis into subcutaneous tissue **AND** 6. Zevaskyn will not be authorized in combination with Vyjuvek or Filsuvez for treatment of the same wound(s). 7. Zevaskyn will not be authorized for concomitant use with Vyjuvek or Filsuvez for the treatment of different wounds located on different areas of the body, unless there is adequate documentation justifying the need for separate products on different wounds located on different areas of the body. 8. Use of Zevaskyn on a wound(s) previously treated with Vyjuvek or Filsuvez requires adequate documentation demonstrating inadequate response or treatment failure of previous treatment(s). 9. A one-time approval will be authorized for the designated wound(s) to be treated that meet the above criteria. Approval will be authorized for 6 months to allow adequate time to schedule and perform surgical application. a. Reauthorization will not be allowed for wound(s) previously treated with Zevaskyn. b. A new request is required for subsequent wound(s) that have not previously been treated with Zevaskyn. Documentation of wound(s) previously treated with Zevaskyn will be required.

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.

References

		Updated	Accessed
1	Pfendner EG, et al. Dystrophic Epidermolysis Bullosa. GeneReviews, 2006. Available at: https://www.ncbi.nlm.nih.gov/books/NBK1304/	9/2018	2/2024
2	ClinicalTrials.gov. Ph 3 Efficacy and Safety of B-VEC for the Treatment of DEB (GEM-3). Last updated: 2/17/2023. NCT04491604. Available at: https://clinicaltrials.gov/ct2/show/NCT04491604	2/2023	2/2024
3	Marinkovic MP, Gonzalez ME, Guide S, et al. PowerPoint presented: GEM-3: A Phase 3 study of Beremagene Geperpavec (B-VEC), an investigational, topical gene therapy, for the treatment of dystrophic epidermolysis bullosa (DEB). Krystal Biotech, Inc. September 2022; Pittsburgh, PA.	9/2022	2/2024
4	National Organization for Rare Disorders – Dystrophic epidermolysis bullosa. Available at: https://rarediseases.org/gard-rare-disease/dystrophic-epidermolysis-bullosa/		2/2024
5	American Academy of Dermatology Association – Epidermolysis Bullosa. Available at: https://www.aad.org/public/diseases/a-z/epidermolysis-bullosa-treatment#:~:text=Medication%20is%20often%20needed%20to,medication%20to%20someone%20with%20EB.		2/2024
6	Vyjuvek prescribing information, Krystal Biotech, Inc., Pittsburgh, PA 15203	5/2023	3/2025
7	Zevaskyn prescribing information, Abeona Therapeutics Inc., Cleveland, OH 44103.	8/2025	8/2025
	Filsuvez prescribing information. Pharmazeutische Fabrik. Germany	5/2024	1/2026

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE CHOICES:	Subject to all terms and conditions noted in above application.
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application. Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program

CDPHP Pharmacy Services 2/12/2026

New: 6/2023

Revised	Reviewed
6/2024, 6/2025, 2/2026	

Revision Date	Changes Made
6/2024	Removed criteria "Enrollee is not positive for anti-COL7 antibodies at baseline" Added statement "Non-FDA approved uses for Vyjuvek will not be covered"
6/2025	Added "Documentation of cutaneous wound(s) that require treatment" to inclusion criteria Added "Vyjuvek will not be authorized in combination with Filsuvez (birch triterpenes gel)" Removed exclusion criteria section
9/2025	Changed name to "RDEB Pharmaceutical Treatment" Added Zevaskyn to policy
2/2026	Removed age requirement for Vyjuvek Added timeframe for documentation of wounds for Vyjuvek Added Vyjuvek will not be authorized in combination with Zevaskyn Added Filsuvez

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Policy/Procedure Name: Reblozyl (luspatercept-aamt) **Control Number: 1350/20.000585**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Beta-thalassemia is an inherited hemoglobinopathy characterized by hemoglobin subunit beta (HBB) gene mutations, impairing beta-globin production. Transfusion-dependent beta-thalassemia (TDT, also known as beta-thalassemia major and Cooley's anemia) is one of the more severe forms of thalassemia because patients are unable to make enough beta-globin to form normal adult hemoglobin. For patients with TDT, transfusions are required every 2–5 weeks. Patients with TDT experience severe symptoms related to anemia (e.g., fatigue, weakness, shortness of breath) and iron overload that can also damage the heart, liver, and other endocrine organs. TDT can also cause ineffective erythropoiesis, which contributes to bone deformities and growth retardation in children. One recent study found that the median age of death for patients with TDT was 45 years (interquartile range [IQR]: 29–52 years) and the mean age was 43.9 years.

The current standard of care for treatment of TDT is a combination of blood transfusions and iron chelation therapy to manage secondary iron overload from the transfusions. In November 2019, Reblozyl (luspatercept)/BMS, an erythroid maturation agent, was approved for treatment of TDT. Use of this agent is intended to reduce the number of required blood transfusions.

Myelodysplastic syndromes (MDS) are a heterogeneous group of clonal hematopoietic cell disorders characterized by abnormal differentiation, morphology, and maturation of myeloid cells. Systemic consequences include anemia, bleeding, an increased risk of infection, and an increased risk of transformation to acute leukemias (acute myeloid leukemia [AML] in 20%–50% of MDS patients). Distinction and classification of MDS and AML are somewhat arbitrary, as patients with 20%–30% blasts are considered to have MDS by French-American-British (FAB) criteria, but AML by the World Health Organization (WHO) classification. Precise estimates of MDS incidence are unknown, as results from epidemiologic studies vary from 10,000 to 40,000 new cases in the United States each year. The nonspecific symptoms or lack of symptoms entirely in the early stages of the disease may not be recognized, and testing via bone marrow biopsy may be delayed due to comorbidities.

Reblozyl was FDA approved for the treatment of anemia failing an erythropoiesis-stimulating agent (ESA) and requiring 2 or more red blood cell (RBC) units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) in April 2020. Approval was based on the Phase 3 MEDALIST trial where 229 patients randomized 2:1 to receive either subcutaneous luspatercept at a starting dose level of 1 mg/kg every 3 weeks, with titration up to 1.75 mg/kg, if needed (n = 153), or placebo subcutaneously every 3 weeks (n = 76) for ≥ 24 weeks The primary endpoint was RBC-TI for ≥ 8 weeks between Week 1 and Week 24; secondary endpoints included RBC-TI for ≥ 12 weeks between Week 1 and Week 24, and between Week 1 and Week 48. Moreover, achievement of modified hematologic improvement-erythroid (mHI-E) response for any consecutive 56-day period was assessed using International Working Group 2006 criteria. Findings demonstrated that 37.9% of patients treated with luspatercept experienced RBC transfusion independence (RBC-TI) for ≥ 8 weeks versus 13.2% in those who received placebo (odds ratio [OR], 5.1; P <.0001) Moreover, 52.9% of patients treated with luspatercept achieved an mHI-E response versus 11.8% of those who received placebo (P <.0001), and 28.1% of patients in the luspatercept arm achieved RBC-TI for ≥ 12 weeks versus 7.9% of the placebo group (OR, 5.1; P = .0002).

On August 28th, 2023 the FDA approved Reblozyl for the treatment of anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions. This expanded indication to the first-line setting is based on interim results from the pivotal Phase 3 COMMANDS trial, in which Reblozyl demonstrated superior efficacy of concurrent RBC transfusion independence (RBC-TI) and hemoglobin (Hb) increase compared to epoetin alfa, an ESA, regardless of ring sideroblast status. The COMMANDS (NCT03682536) is a Phase 3, open-label, randomized study that compares the effectiveness and safety of Reblozyl to epoetin alfa for treating anemia due to myelodysplastic syndrome (MDS) with a risk level of very low-, low-, or intermediate-risk (IPSS-R). The patients involved in the study were dependent on red blood cell (RBC) transfusions and had not previously received erythropoiesis stimulating agents (ESA). The primary endpoint of the study was to evaluate RBC transfusion independence (RBC-TI) for a duration of 12 weeks, with a mean hemoglobin increase of at least 1.5 g/dL. Additionally, key secondary endpoints included RBC-TI for 24 weeks, RBC-TI for a minimum of 12 weeks, and assessing erythroid response (HI-E) for at least 8 weeks during weeks 1-24 of the study. The trial, results showed 58.5% (n=86) of patients treated with Reblozyl vs. 31.2% (n=48) of patients treated with epoetin alfa achieved the primary endpoint of RBC-TI of at least 12 weeks with a mean Hb increase of at least 1.5 g/dL within the first 24 weeks (p<0.0001). The most common (> 10%) adverse reactions were diarrhea, fatigue, hypertension, peripheral edema, nausea, and dyspnea. 58.5% (n=86) of patients receiving Reblozyl vs. 31.2% (n=48) of patients receiving epoetin alfa

achieved the primary endpoint of RBC-TI of at least 12 weeks with concurrent mean Hb increase of at least 1.5 g/dL within the first 24 weeks (p<0.0001). HI-E increase of at least 8 weeks was achieved by 74.1% (n=109) of Reblozyl patients vs. 51.3% (n=79) of epoetin alfa patients (p<0.0001). Within the first 24 weeks of treatment, RBC-TI of at least 24 weeks was achieved by 47.6% (n=70) of Reblozyl patients vs. 29.2% (n=45) of epoetin alfa patients (p=0.0012). RBC-TI of at least 12 weeks was achieved by 66.7% (n=98) of Reblozyl patients vs. 46.1% (n=71) of epoetin alfa patients (p=0.0003).

Summary	
Effective Date of Policy:	2/12/2026
Indications	• Anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions • Anemia without previous erythropoiesis stimulating agent use (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes (MDS) who may require regular red blood cell (RBC) transfusions • Anemia failing an erythropoiesis stimulating agent and requiring 2 or more RBC units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)
HCPCS Code	J0896
Availability	25 mg or 75 mg lyophilized powder in a single-dose vial for reconstitution
Duration	Initial: 6 months Continuation: 6 months

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy

Indication	Inclusion Criteria	Dosing Regimen

Indication
Anemia in adults with beta thalassemia
 	
ICD10: D56.1, D56.5
	• Must have a diagnosis of beta thalassemia (including HbE/beta thalassemia and beta thalassemia combined with alpha-thalassemia) based on Hb electrophoresis, Hb high-performance liquid chromatography (HPLC), and/or DNA analysis
	  o Reblozyl will not be covered for any other diagnoses including alpha thalassemia and sickle cell beta thalassemia (also known as hemoglobin S/β-thalassemia)
	• Must be at least 18 years of age
	• Must be followed by a hematologist or physician knowledgeable in the treatment of beta thalassemia
	• Must require regular RBC transfusions defined as:
	  o A need for at least 6 RBC units in the previous 24 weeks
	  o No transfusion-free period greater than 35 days in the previous 24 weeks
	• Reblozyl must be given by a healthcare professional and therefore, will only be covered under the medical benefit
	• Current body weight and requested dosing regimen must be submitted for initial review and each recertification request
	• Initial approval will be granted for 6 months
		• Dosing for beta thalassemia should be initiated at 1 mg/kg every 3 weeks
		• If there is no reduction in RBC transfusion burden after 6 weeks of treatment (2 doses) at 1 mg/kg dosing, the dose should be increased to 1.25 mg/kg every 3 weeks
		• If there is no reduction in RBC transfusion burden after 9 weeks of treatment (3 doses) at the maximum dose (1.25 mg/kg every 3 weeks), treatment should be discontinued and will not be approved for additional administration
		• The maximum recommended dose for this indication is 1.25 mg/kg every 3 weeks. **Requests for higher doses will not be approved.**

Indication
Anemia in adults with myelodysplastic syndromes (MDS)
 	
ICD10: select subcodes of D46
	Diagnosis of **very low-to intermediate-risk myelodysplastic syndrome** AND:
	• Must be at least 18 years of age AND
	• Must be followed by a hematologist, oncologist, or physician knowledgeable in the treatment of myelodysplastic syndromes AND
	• Patient must have required two or more RBC units over an eight-week period in the preceding 16 weeks; AND
	  o Patient has no prior treatment with erythropoiesis stimulating agents (ESA); OR
	  o Patient must be refractory to an erythropoiesis stimulating agent, where refractory is defined as lack of 1.5 gm/dL rise in hemoglobin or lack of decrease in RBC transfusion requirement by 6 to 8 weeks of treatment OR
	  o Patient must have documented ineligibility to an ESA which is defined as a serum erythropoietin (EPO) level ≥ 500 mU/mL OR
	  o Patient must have documented intolerance, adverse event, or contraindication to an ESA
	
	Diagnosis of **very low-to intermediate-risk myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T)** AND
	• Must be at least 18 years of age AND
	• Must be followed by a hematologist, oncologist, or physician knowledgeable in the treatment of myelodysplastic syndromes AND
	• Must have presence of ring sideroblasts is defined as ≥ 15% ring sideroblasts or ≥ 5% ring sideroblasts with an SF3B1 mutation AND
	• Must have required two or more RBC units over an eight-week period in the preceding 16 weeks AND
	  o Patient must be refractory to an erythropoiesis stimulating agent, where refractory is defined as lack of 1.5 gm/dL rise in hemoglobin or lack of decrease in RBC transfusion requirement by 6 to 8 weeks of treatment OR
	  o Patient must have documented ineligibility to an ESA which is defined as a serum EPO level ≥ 500 mU/mL OR
	  o Patient must have documented intolerance, adverse event, or contraindication to an ESA
	• Reblozyl must be given by a healthcare professional and therefore, will only be covered under the medical benefit
	• Current body weight and requested dosing regimen must be submitted for initial review and each recertification request
		• Dosing for MDS associated anemia should be initiated at 1 mg/kg every 3 weeks
		• If patient is not RBC transfusion-free after 6 weeks of treatment (2 doses) at 1 mg/kg dosing, the dose should be increased to 1.33 mg/kg every 3 weeks
		• If patient is not RBC transfusion-free after 6 weeks of treatment (2 doses) at 1.33 mg/kg dosing, the dose should be increased to 1.75 mg/kg every 3 weeks
		• If patient has not had any reduction in RBC transfusion burden after 9 weeks of treatment (3 doses) at 1.75 mg/kg dosing, treatment should be discontinued and will not be approved for additional administration
		• The maximum recommended dose for this indication is 1.75 mg/kg every 3 weeks. **Requests for higher doses will not be approved**

Continuation Criteria		
• Recertification will require documented reduction in RBC transfusion burden after receiving Reblozyl • Approval timeframes after the initial 6 months will be granted for 6 months		

Considerations

- Patient must have medical drug coverage administered by CDPHP.
- Prior authorization is obtained through the CDPHP pharmacy department.

References

		Updated	Accessed
1	Reblozyl [prescribing information]. Celgene Corporation, a Bristol-Myers Squibb Company. Summit, NJ.	5/2024	1/2026
2	Beta Thalassemia. National Organization for Rare Disorders (NORD). Available at: https://rarediseases.org/rare-diseases/thalassemia-major/	5/2023	1/2026
3	Hematology: Thalassemia. IPD Analytics. Subscription required.		1/2026
4	Endocrinology and Metabolic Agents: Pompe Disease. IPD Analytics. Subscription required.		1/2026

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted in above application.
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 2/12/2026

New: 2/2026

Revised	Reviewed

Revision Date	Changes Made

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MEDICAL POLICY

Medical Policy Title	**Reduction Mammaplasty (Mammoplasty)**
Policy Number	**7.01.39**
Current Effective Date	**October 1, 2026**
Next Review Date	**July 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

This policy does not address reduction mammaplasty for males, refer to InterQual.

POLICY STATEMENT(S)

Post-Mastectomy

I. Reduction mammaplasty (also known as reduction mammoplasty or breast reduction) performed to achieve symmetry of the contralateral (opposite) breast following a mastectomy or partial mastectomy (e.g., lumpectomy, segmentectomy, quadrantectomy) is considered **medically appropriate** consistent with Federal and New York State law (see Regulatory Section).

Symptomatic Macromastia

II. Reduction mammaplasty is considered **medically appropriate** for the treatment of symptomatic macromastia when **ALL** of the following criteria are met:

   A. The individual is at least 18 years of age or has completed breast growth with documented stable breast size for at least one (1) year;

   B. At least two (2) of the following persistent physical symptoms have affected activities of daily living for at least one (1) year:

      1. Back, neck, or shoulder pain;
      2. Breast pain;
      3. Headache;
      4. Upper extremity paresthesia;
      5. Persistent shoulder grooving from bra straps; **or**
      6. Intertrigo at the inframammary fold;

   C. The planned amount of breast tissue to be removed per breast meets **either** of the following:

      1. At least the 22nd percentile on the Schnur Sliding Scale based on the individual's body surface area (BSA) (see Policy Guideline III); **or**
      2. At least 500 grams per breast or 1,000 grams bilaterally, regardless of BSA.

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III. Reduction mammaplasty is considered **not medically necessary** when the above criteria are not met, including but not limited to asymptomatic macromastia or pendulous breasts, difficulty with clothing fit, or nipple-areolar distortion.

RELATED POLICIES

Corporate Medical Policy

7.01.11 Cosmetic and Reconstructive Procedures

10.01.01 Breast Reconstruction Surgery

POLICY GUIDELINE(S)

I. Medical record documentation must include a detailed description of symptoms (including functional impairments and duration of symptoms), the patient's height and weight, and the amount of breast tissue to be removed (in grams). Photographs may be beneficial and may be requested as part of the medical necessity review.

II. The Schnur Sliding Scale is a guideline that establishes a minimum per-breast tissue resection weight based on BSA. Resection weights at or above the 22nd percentile are considered to meet the required threshold, while resection weights below the 22nd percentile are considered cosmetic. BSA may be calculated using either the Mosteller or Du Bois formula.

III. When choice of formula results in differing eligibility determinations for requests near the 22nd percentile threshold, individual consideration will be based on a review by a Health Plan Medical Director, using the individual's medical record in conjunction with policy criteria.

Schnur Sliding Scale (Lower 22nd Percentile)	
BSA (in meters squared [m^2])	Minimum grams of breast tissue to be removed (per breast)
1.35	199
1.40	218
1.45	238
1.50	260
1.55	284
1.60	310
1.65	338
1.70	370
1.75	404
1.80	441
1.85	482
1.90	527
1.95	575

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2.00	628
2.05	687
2.10	750
2.15	819
2.20	895
2.25	978
2.30	1068
2.35	1167
2.40	1275
2.45	1393
2.50	1522
2.55	1662

DESCRIPTION

Breast hypertrophy, or macromastia, is a condition characterized by excessive breast tissue that causes persistent physical symptoms due to increased breast volume and weight. The resulting mechanical strain on the musculoskeletal system commonly leads to neck, back, and shoulder pain; painful shoulder grooving from bra straps; inframammary intertrigo; headaches; breast pain; and upper extremity paresthesias. Gigantomastia is a rare form of macromastia characterized by excessive breast growth that may occur during puberty or pregnancy, or with the use of certain medications.

Reduction mammaplasty is the surgical excision of excess skin and underlying breast tissue to reduce breast volume. When performed for symptomatic macromastia, the goal is to relieve pain and improve functional impairment.

Breast development in adolescents progresses through recognized stages of maturation (Tanner stages I–V), typically reaching full maturity by Tanner stage V. However, the timing of breast maturity varies considerably among individuals and may be influenced by body habitus. For the purposes of surgical timing, breast maturity should be assessed using Tanner staging, with postmenarcheal status and documented stability of breast size as supportive indicator of maturity.

The Schnur Sliding Scale (Schnur 1991) is an objective tool used to help differentiate between cosmetic and medically necessary reduction mammaplasty. It was developed in response to a need from health insurance carriers for an evidence-based method to evaluate medical necessity. Using data collected from plastic surgeons, Schnur and colleagues created a scale correlating body surface area (BSA) with the weight of breast tissue removed. The scale stratifies individuals into three groups based on resection weight relative to BSA, with a weight at or above the 22nd percentile considered medically necessary. Despite its known limitations as a predictor of resection weight, the Schnur Sliding Scale remains widely used as criterion for reduction mammaplasty.

SUPPORTIVE LITERATURE

Studies have consistently demonstrated that reduction mammaplasty results in significant improvement in symptoms related to macromastia, including chronic neck, back, and shoulder pain. Additional documented benefits include improvements in respiratory function, sleep, headaches, and psychological outcomes (e.g., self-esteem, sexual function, and quality of life), as well as increased participation in exercise programs and other physical and social activities (Singh and Losken 2012; Hernanz 2016; Elfanagely 2021; Torresetti 2022; Crittenden 2023; Wang 2023).

Kerrigan et al (2002) conducted the BRAVO (Breast Reduction: Assessment of Value and Outcomes) trial, a prospective multicenter study, to assess existing prediction rules for reduction mammaplasty eligibility. The authors reported that neither the Schnur Sliding Scale nor the 500-gram minimum rule was able to successfully predict which group of women would gain greater improvement from surgery. The BRAVO study proposed a symptom-based definition of medical necessity using a Physical Symptoms Count instrument assessing seven symptoms: upper back pain, neck pain, shoulder pain, numbness, arm pain, bra strap grooves, and rashes. The presence of two or more of these symptoms, occurring most or all of the time, successfully differentiated surgical candidates from controls (89.9% vs. 2%).

Lin et al (2021) conducted a systematic review and meta-analysis of randomized controlled trials (RCTs) (N=285) comparing reduction mammaplasty with a control intervention (nonoperation or physiotherapy exercises) for the treatment of breast hypertrophy. Four RCTs were included in meta-analyses reporting on change in pain, physical function, and psychological function after interventions. The analysis confirmed statistically significant ($p<.00001$) post-operative improvements in pain, physical function, and psychological function compared to the control intervention. The authors concluded that mammaplasty had a positive and significant effect on health-related quality of life, including pain, physical, and psychological functioning, in individuals with breast hypertrophy.

Adolescents (under 18 years of age)

The evidence supports reduction mammaplasty in adolescents with symptomatic macromastia. Prospective studies have demonstrated significant and sustained improvements in pain, physical function, self-esteem, and quality of life; with complication rates comparable to those observed in adults (Nuzzi 2017; Nuzzi 2019; Hudson 2021; Morrison 2023; Payne 2023). Current evidence does not support strict age-based exclusions; rather, individualized assessment based on breast maturity, symptom severity, and physiologic and emotional readiness is recommended.

Nuzzi et al (2020) conducted a cross-sectional study reviewing the medical records of 481 women aged 12 to 21 years who underwent reduction mammaplasty to predict the optimal timing, or biological "sweet spot," for reduction mammaplasty to minimize the risk of breast regrowth in adolescents. Surgery performed less than 3 years after menarche increased the likelihood of glandular regrowth by over 700 percent in healthy-weight and overweight subjects (OR, 7.43; 95% CI, 1.37 to 40.41). Breast size appears to stabilize considerably later in obese adolescents, and breast growth in obese macromastia patients may not end until 9 years after menarche; operating on obese women before this time point increased the likelihood of glandular breast regrowth by almost 120 percent (OR, 1.18; 95% CI, 1.11 to 1.26). The authors concluded that these findings suggest that age restrictions imposed by care providers and third-party payors may be arbitrary. Surgical

readiness should be determined on an individual basis incorporating the patient's biological and psychological maturity, obesity status, potential for postoperative benefit, and risk tolerance for postoperative breast growth.

PROFESSIONAL GUIDELINE(S)

The American College of Obstetricians and Gynecologists Committee Opinion No. 686 (2017; reaffirmed in 2020 and 2024) acknowledged that breast reduction surgery in adolescents with large breasts can relieve back, shoulder, and neck pain.

- Adolescent recommendations for timing of surgery include postponing surgery until breast maturity is reached, waiting until there is stability in cup size over 6 months, and waiting until the age of 18 years. Although there is no one consensus on timing, it may reasonably be determined by the severity of symptoms.

In 2022, the American Society of Plastic Surgeons (ASPS) (Perdikis 2022) issued a revised guideline through a multidisciplinary workgroup consisting of the American Society of Plastic Surgeons, the American Society of Breast Surgeons, and the American Physical Therapy Association.

- Strong recommendation that post-menarche female patients presenting with breast hypertrophy should be offered reduction mammaplasty surgery as first-line therapy over nonoperative therapy based solely on the presence of multiple symptoms rather than resection weight. This indicates that reduction mammaplasty is considered standard of care for symptomatic patients, even without documentation of symptoms for a significant length of time.

The ASPS 2022 guideline acknowledged that numerous studies, including the BRAVO study conducted by Kerrigan and colleagues in 2002, have demonstrated the lack of correlation between the amount of resected weight and symptomatic relief. The society reported evidence demonstrating that resection weight does not accurately predict patient-oriented outcomes such as alleviation of pain and related symptoms; therefore, resected weight should not be the primary determinant of medical necessity.

REGULATORY STATUS

The Women's Health and Cancer Rights Act of 1998 (WHCRA) is a federal law that mandates coverage of all stages of reconstructive surgery (including surgery and reconstruction of the other breast to produce symmetrical appearance, prostheses, and treatment of complications following mastectomy) for all group health plans, whether insured or self-funded, that provide medical and surgical benefits, including for mastectomies.

New York State Insurance (ISC) Laws mandate coverage for surgery and reconstruction of the contralateral breast or chest wall to produce a symmetrical appearance after a mastectomy or partial mastectomy; in the manner determined by the attending physician and the patient to be appropriate.

CODE(S)

- Codes may not be covered under all circumstances.

- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
19318	Breast reduction

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

American College of Obstetricians and Gynecologists [Internet]. Breast and labial surgery in adolescents. Committee opinion no. 686. Obstet Gynecol. 2017 Jan [reaffirmed 2024; accessed 2026 Jun 18]. Available from: https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/01/breast-and-labial-surgery-in-adolescents

American Society of Plastic Surgeons [Internet]. ASPS recommended insurance coverage criteria. Reduction mammaplasty. 2011 May [updated and reaffirmed 2021 Mar; accessed 2026 Jun 18]. Available from: https://www.plasticsurgery.org/for-medical-professionals/health-policy/recommended-insurance-coverage-criteria

Bohmer EM, et al. The impact of reduction mammaplasty on back pain and posture in patients with macromastia: a systematic review and meta-analysis. Plast Reconstr Surg. 2025.

Crittenden TA, et al. Long-term outcomes of breast reduction surgery: a prospective cohort study. J Plast Reconstr Aesthet Surg. 2023 Apr;79:58-67.

Elfanagely O, et al. A matched comparison of the benefits of breast reduction on health-related quality of life. Plast Reconstr Surg. 2021 Oct;148(4):729-735.

Hernanz F, et al. Impact of reduction mammoplasty on the quality of life of obese patients suffering from symptomatic macromastia: A descriptive cohort study. J Plast Reconstr Aesthet Surg. 2016 Aug; 69(8):e168-73.

Hudson AS, et al. Reduction mammaplasty for macromastia in adolescents: A systematic review and pooled analysis. Plast Reconstr Surg. 2021 Jul 1;148(1):31-43.

Kerrigan CL, et al. Reduction mammaplasty: defining medical necessity. Med Decis Making. 2002;22(3):208-17.

Lin Y, et al. Postoperative health-related quality of life in reduction mammaplasty: a systematic review and meta-analysis. Ann Plast Surg. 2021 Jul;87(1):107-112.

Morrison KA, et al. Quantifying surgical complications for reduction mammaplasty in adolescents. Plast Reconstr Surg. 2023 Mar 1;151(3):376e-383e. Epub 2022 Nov 19.

New York State Consolidated Insurance (ISC) Laws [Internet]. Chapter 28, Article 32. Policy provisions. Section § 3216 (18) (A). 2025 Feb 28 [accessed 2026 Jun 18] Available from: https://www.nysenate.gov/legislation/laws/ISC/3216

New York State Consolidated Insurance (ISC) Laws [Internet]. Chapter 28, Article 32. Standard provisions. Section § 3221 (10) (A)(ii). 2025 Feb 21 [accessed 2026 Jun 18] Available from: https://www.nysenate.gov/legislation/laws/ISC/3221

New York State Consolidated Insurance (ISC) Laws [Internet]. Chapter 28, Article 43. Benefits. Section § 4303 (x)(1)(B). 2025 Feb 21 [accessed 2026 Jun 18] Available from: https://www.nysenate.gov/legislation/laws/ISC/4303

Nuzzi LC, et al. Complications and quality of life following reduction mammaplasty in adolescents and young women. Plastic and Reconstructive Surgery. 2019;144(3):572-581.

Nuzzi LC, et al. Optimal timing for reduction mammaplasty in adolescents. Plast Reconstr Surg. 2020 Dec;146(6):1213-1220.

Nuzzi LC, et al. The effect of reduction mammaplasty on quality of life in adolescents with macromastia. Pediatrics. 2017 Nov;140(5):e20171103.

Payne SH, et al. Short-term satisfaction, psychosocial impact, and complication profile of reduction mammaplasty during adolescence. Aesthet Surg J. 2023 Jun 14;43(7):NP484-NP491.

Perdikis G, et al. American Society of Plastic Surgeons evidence-based clinical practice guideline revision: reduction mammaplasty. Plast Reconstr Surg. 2022 Mar;149(3):392e-409e. Also available from: https://www.plasticsurgery.org/for-medical-professionals/quality/evidence-based-clinical-practice-guidelines [accessed 2026 May 26].

Pocock KS, et al. Enlarged breast size (macromastia) and associated neurologic risks: a scoping review. Neurology. 2024 Aug 13;103(3):e209660.

Schnur PL, et al. Reduction mammaplasty: cosmetic or reconstructive procedure? Ann Plast Surg. 1991 Sep;27(3):232-7.

Singh KA, Losken A. Additional benefits of reduction mammaplasty: a systematic review of the literature. Plast Reconstr Surg. 2012 Mar;129(3):562-570.

Torresetti M, et al. The effects of breast reduction on pulmonary functions: A systematic review. J

Plast Reconstr Aesthet Surg. Dec 2022; 75(12):4335-4346.

U.S. Department of Labor [Internet]. Women's Health and Cancer Rights Act. 1998 Oct 21 [accessed 2026 Jun 18]. Available from: https://www.dol.gov/general/topic/health-plans/womens

Wang AT, et al. Patient-reported outcomes after reduction mammoplasty using BREAST-Q: a systematic review and meta-analysis. Aesthet Surg J. 2023 Apr;43(4):NP231-NP241.

Wirthmann AE, et al. Reduction mammoplasty in adolescents and elderly: A ten-year case series analyzing age related outcome with focus on safety and complications. J Plast Reconstr Aesthet Surg. 2018;71(3):377-383.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Breast Reconstruction Following Mastectomy (NCD 140.2) [accessed 2026 Jun 18]

Reduction Mammaplasty (LCD L35001) [accessed 2026 Jun 18]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 1/01

Revised:05/02, 10/02, 03/05, 03/12, 11/12, 01/15, 07/15, 01/17, 01/18, 01/19, 11/19, 1/22, 3/22, 11/22, 1/23, 7/24, 3/25, 5/26

Reviewed: 9/03, 6/04, 2/06, 1/07, 12/07, 1/09, 1/10, 1/11, 1/12, 1/13, 1/14, 1/16, 1/20, 1/21, 1/24, 1/26, 9/26

Date	Summary of Changes

10/1/26	• Annual review; replaced <18 not medically necessary criteria with medically necessary criteria; minor editorial updates for clarity. • Policy edit to clarify "per breast" to the Schnur Sliding Scale content in the Policy Guidelines.
6/1/2026	• Transitioned Reduction Mammoplasty for Hypertrophic Breast policy, 1370/20.000254 to Lifetime Healthcare Companies policy template.
8/1/2024* *No change to effective date for this update	• Updated requirements for submitting medical photographs.
8/1/2024	• Added information regarding reduction mammoplasty or mastopexy being performed as a 2-stage procedure for a nipple sparing mastectomy.
2/1/2023	• Removed the following requirement under Policy Considerations: Letter of medical necessity from the treating physician stating a belief that the benefits of breast reduction surgery outweigh the increased risk for infection following such surgery for an enrollee with a BMI > 25.
12/1/22* *No change to effective date of policy	Added language to require original photographs.
4/1/2022	Under the position statement for reduction mammoplasty to achieve symmetry, updated the requirement from "cancer surgery/indications" to "mastectomy or partial mastectomy".
1/1/2022	Added reference to Gender Dysphoria Therapies policy under the Exclusions section for exceptions.
1/1/2020	Moved all coverage criteria from Medicare section to the Application section. Removed reference that breast reconstruction surgery would only be covered for a breast cancer diagnosis to indicate that it would be covered regardless of diagnosis following any medically necessary mastectomy or partial mastectomy.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: REMOTE PATIENT MONITORING (RPM) AND REMOTE THERAPEUTIC MONITORING (RTM)

POLICY EFFECTIVE DATE:	7/1/2026
Policy Control #:	1370/20.000521
Next Annual Review:	September, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

RPM codes: 99091, 99445, 99453, 99454, 99457, 99458, 99470

RTM codes: 98975, 98976, 98977, 98978, 98979, 98980, 98981, 98984, 98985, 98986

DESCRIPTIONS

Remote patient monitoring (RPM) refers to the monitoring of physiological data, such as, weight, blood pressure, pulse oximetry, respiratory rate by means of digital technology.

Remote therapeutic monitoring (RTM) refers to the monitoring and collection of non-physiological data, such as, medication and therapy adherence and response by means of digital technology.

RELATED POLICIES/DOCUMENTS

POSITION STATEMENT

CDPHP considers RPM medically necessary when all the indications outlined below are met:

POLICY NAME: REMOTE PATIENT MONITORING (RPM) AND REMOTE THERAPEUTIC MONITORING (RTM)

- Services must monitor one of the below acute care or chronic conditions and the member is at risk of clinically significant changes in medical status which warrant enhanced monitoring based on current status and instability of the underlying clinical condition:
  - Congestive heart failure (CHF)
  - Chronic obstructive pulmonary disease (COPD)
  - Uncontrolled diabetes (DM)

    AND
- Hospitalization(s) or emergency department visits within one year with a primary diagnosis of CHF/COPD/Diabetes

Authorizations will be allowed for one year at a time. For continued services, following the one-year approvals, documentation must include patient adherence and documentation from the treating provider attesting that the patient has benefited from this monitoring and continuation is medically necessary.

POLICY CONSIDERATIONS

The use of information technology for RPM must meet the following:

- The device used to collect and transmit the data must meet the definition of a medical device as defined by the FDA
- Data is being assessed to detect acute changes in clinical status and prompt intervention
- Physiologic data must be electronically collected and automatically uploaded to the secure location where the data is available for analysis and interpretation by the billing practitioner
- Remote physiologic monitoring data must be collected for 2–15 or 16+ days out of 30 days, depending on the code descriptor.

EXCLUSIONS

- RPM for conditions other than uncontrolled DM, COPD, or CHF are considered not medically necessary.
- RPM for the convenience of the individual, physician, caregiver, or other health care provider are considered not medically necessary.
- Remote therapeutic monitoring (RTM) (98975, 98976, 98977, 98978, 98979, 98980, 98981, 98984, 98985, 98986) are considered experimental/investigational.

POLICY NAME: REMOTE PATIENT MONITORING (RPM) AND REMOTE THERAPEUTIC MONITORING (RTM)

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP:	Medical conditions that may be treated/monitored by means of RPM include, but are not limited to, congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), wound care, polypharmacy, mental or behavioral problems, and technology-dependent care such as continuous oxygen, ventilator care, total parenteral nutrition, or enteral feeding. RPM may be used during pregnancy and postpartum as well. Telehealth services provided by means of RPM should be billed using CPT code "99091" [collection and interpretation of physiologic data (e.g., Electrocardiography (ECG), blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training and licensure/regulation (when applicable) requiring a minimum of 30 minutes of time. RPM services may be delivered by clinical staff; however, the service must be ordered by a physician or other qualified health care professional. Clinical staff includes individuals under the direction of a physician or qualified health care professional who do not independently bill professional services, such as pharmacists and some registered dieticians. Providers delivering RPM services must confirm that they operate within their scope of practice. Clinical staff may not order nor modify prescriptions. This service is not intended for retail pharmacists. CPT code "**99457**" requires a live, interactive communication with

the patient/caregiver. The interactive communication contributes to the cumulative time, but it does not need to represent the entire cumulative reported time of the treatment management services. Providers are not to bill CPT code "**99457**" more than one time per New York State (NYS) Medicaid member, per 30-day period.

CPT code **"99470"** is a companion code to **"99457"** that allows providers to bill for a lower duration of 10 to 19 minutes of clinical time. Do not report **"99470"** in the same 30-day period as **"99457"**. In each calendar month, providers may report:

- **"99470"** for 10 to 19 minutes of treatment management services; *or*
- **"99457"** for at least 20 minutes of treatment management services.

Maternity RPM services:
In an effort to reduce maternal and infant morbidity and mortality, an additional allowance may be reimbursable for RPM equipment provided by enrolled providers to pregnant and postpartum members using CPT codes "99453" and "99454" with "HD" modifier.

NYS Medicaid reimburses an additional allowance for RPM during pregnancy and up to 84 days postpartum using CPT code **"99453"** for set-up and patient education and CPT code **"99454"** for monitoring. CPT code **"99445"** is now part of a duration-based series with CPT code **"99454"**. Do not report CPT code **"99445"** in the same 30-day period as CPT code **"99454"**. For each 30-day period of RPM for prenatal and postpartum services, providers may report:

- CPT code **"99445"** for two days up to 15 days of monitoring; *or*
- CPT code **"99454"** for at least 16 days up to 30 days of monitoring.

Please note that 99091 and 99454 are both intended to be billed once monthly but cannot be billed on the same day.

SOURCES

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POLICY NAME: REMOTE PATIENT MONITORING (RPM) AND REMOTE THERAPEUTIC MONITORING (RTM)

1. Other payers
2. CMS Manual
3. New York State Medicaid Update - January 2023 Volume 39 - Number 2
4. NYS Medicaid - Telehealth Policy Manual

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POLICY APPROVAL DATES

New: 9/24

Revised: 9/25, 3/26, 7/26

Reviewed: 9/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
7/1/2026	Under Medicaid, added information pertinent to the expansion of RPM services effective 3/1/2026. Under Policy Considerations, updated timeframe for RPM services.
1/1/2026	Added new 1/1/2026 CPT codes. Under Medicaid section added billing guidelines for codes 99091 and 99454 per Medicaid Telehealth Policy Manual updates.
5/1/2025* *No change to effective date for this update	Revised Select Plan/HARP section to clarify who can order and deliver RPM services and added information on code 99457.
5/1/2025	Effective date of policy extended to 5/1/2025
1/1/2025	New Policy

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BEHAVIORAL HEALTH RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
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POLICY NAME: RESIDENTIAL TREATMENT FACILITIES FOR MENTAL HEALTH AND SUBSTANCE USE DISORDERS

POLICY EFFECTIVE DATE:	4/1/2023
Policy Control #:	1370/20.000482
Next Annual Review:	7/2025

DISCLAIMER

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If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

REVENUE CODES

1001 = Behavioral Health Accommodations, Residential – Psychiatric
1002 = Behavioral Health Accommodations, Residential – Chemical Dependency

DESCRIPTION

Residential Treatment Services (RTS) are provided to individuals who require 24-hour treatment and supervision in a safe therapeutic environment. RTS is a 24- hour a day/seven day a week facility-based level of care. RTS provides individuals with severe and persistent psychiatric and/or substance use disorders therapeutic intervention and specialized programming in a controlled environment with a high degree of supervision and structure. RTS addresses the identified problems through a wide range of diagnostic and treatment services, as well as through training in basic skills, such as social skills and activities of daily living needed to transition to community living. The services are provided in the context of a comprehensive, multidisciplinary, and individualized treatment plan that is frequently reviewed and updated based on the individual's clinical status and response to treatment. This treatment primarily provides social, psychosocial rehabilitative training, and a focus on family or caregiver support. Active involvement of family/significant other through family therapy is a key element of

treatment and is strongly encouraged unless contraindicated.

RELATED POLICIES/DOCUMENTS

Refer to the following related resource coordination policies and guideline:

- Concurrent Review, 1370/20.000174
- Review Process for Resource Coordination, 1370/20.000213
- Concurrent Review Guideline

POSITION STATEMENT

CDPHP utilizes New York State Level of Care for Alcohol and Drug Treatment Referral 3.0 for substance use disorders and InterQual for determining medical necessity criteria relating to residential behavioral health level of care for eating and mental health disorders, in addition to general requirements outlined below.

General Requirements

- For treatment of mental, nervous, and emotional disorders, the residential facility must be established and operating in accordance with the standards pursuant to regulations of the New York Commissioner of Mental Health as defined by sub division 10 of section 1.03(33) of the Mental Hygiene Law or be part of a comprehensive care center for eating disorders pursuant to Article 27-J of the Public Health Law and, in other states, to facilities that are licensed or certified to provide the same level of treatment.
- For treatment of alcoholism, substance use, and dependency, coverage of services is limited to OASAS-certified facilities defined in 14 NYCRR 819.2(a)(1) and that are certified by OASAS and, in other states, those facilities that are licensed or certified by a similar state agency and which are accredited by the Joint Commission as alcoholism, substance use disorder, or chemical dependence programs.
- The services are essential health needs of the member and provided in the context of a comprehensive, multidisciplinary, and individualized treatment plan that is frequently reviewed and updated based on the individual's clinical status and response to treatment. Services include psychiatric and health care services, in addition to educational, social, and vocational services as needed, and are treatments based in guidelines as determined by medical research and/or expert consensus.
- Services must be required for purposes other than for the convenience of the provider or comfort of the patient.
- Discharge planning is documented and must begin at admission, including plans for reintegration into the home and community. If discharge to a home/family is not an option, alternative placement must be rapidly identified and there must be regular documentation of active efforts to secure such placement.

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- Staff monitoring is provided 24 hours a day/seven days per week.
- This level of care requires at least weekly physician visits.
- Three meals are made available to furnish sufficient nutrients and calories to meet normal needs, as well as the special needs of persons in recovery.

Mental Health

1. A mental health disorder is present (DSM-5 code related diagnosis) that requires, and can reasonably be expected to respond to, therapeutic intervention.

2. The individual is experiencing emotional or behavioral problems in the home, community, and/or treatment setting and is not sufficiently stable, either emotionally or behaviorally, to be treated outside of a highly structured 24-hour therapeutic environment.

3. The individual demonstrates a capacity to respond favorably to rehabilitative counseling and training in areas such as problem solving, life skills development, medication adherence, and independent or semi-independent living as appropriate.

4. The individual may have a history of multiple hospitalizations or other treatment episodes at other levels of care and/or a recent inpatient stay with a history of poor treatment adherence or outcome.

5. The individual lacks community/primary supports sufficient to maintain him/her in the community with treatment at a lower level.

Substance Use Disorders

1. A substance use disorder (SUD) is present (DSM-5 code-related diagnosis) that requires and can reasonably be expected to respond to therapeutic intervention at this level of care.

2. The individual has minimal to no withdrawal symptoms or is stable enough that any withdrawal can be safely managed at this level of care.

3. The individual lacks community/primary supports sufficient to maintain him/her in the community with treatment at a lower level.

4. Despite repeated attempts by the individual to refrain from substances, the individual has displayed an inability to maintain abstinence outside a structured residential setting.

5. The individual is not experiencing behavioral or biomedical problems severe enough to preclude treatment outside of a highly structured 24-hour therapeutic environment.

POLICY CONSIDERATIONS

Residential treatment for mental health or substance use disorders is considered equivalent to treatment rendered in skilled nursing facilities or rehabilitation hospitals.

Coverage for inpatient admission for substance use disorder treatment at an OASAS-licensed facility that participates in the CDPHP network is not subject to preauthorization. Coverage will be subject to concurrent review on day 29 of the inpatient admission if the OASAS-licensed facility notifies CDPHP of both the admission and the initial treatment plan within two business days of admission. The entire stay may be reviewed, including the initial 28-day period, to determine whether the admission and treatment is medically necessary. Care for members discharged prior to day 29 will be reviewed retrospectively. Facilities are required to notify CDPHP of discharge within 24 hours of the discharge date and retrospective review may begin when CDPHP is notified of the discharge. The facilities must hold members harmless for any denial of stay based upon retrospective review. *Applies to member contracts issued or renewed on or after 1/1/17. Self-insured, FEHB, and Medicare Choices products are excluded from this consideration and will follow standard prior authorization requirements.

EXCLUSIONS

The following criteria are not considered appropriate for treatment in residential level of care:

- The individual exhibits severe suicidal, homicidal, or acute mood symptoms/thought disorder that, require a more intensive level of care.
- The individual or parent/guardian does not voluntarily consent to admission or treatment.
- The individual can be safely maintained and effectively treated at a less intensive level of care.
- The individual has medical conditions or impairments that would prevent beneficial utilization of services, or is not stabilized on medications.
- The primary problem is social, legal, economic (e.g., housing, family, conflict, etc.), or admission is being used as an alternative to incarceration.
- The primary problem is academic or the residential setting is licensed/accredited only by the state Department of Education. Admission to a therapeutic boarding school is excluded from coverage and educational services should be arranged through the school district and/or the state Department of Education.

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POLICY NAME: RESIDENTIAL TREATMENT FACILITIES FOR MENTAL HEALTH AND SUBSTANCE USE DISORDERS

- Residential services for the primary treatment of developmental disabilities including Autism Spectrum Disorder: such services are available through the NYS Office for People with Developmental Disabilities.
- Services provided in NYS Licensed Residential/Housing Programs as defined in section 31.02 of the Mental Hygiene Law and various sections of 14 NYCRR, including but not limited to: Apartment, Support Community Residence; Apartment, Treatment Community Residence; Children and Youth Community Residence; Congregate, Support Community Residence; Congregate, Treatment Community Residence; Teaching Family Home; Service Enriched Single Room Occupancy; and Residential Treatment Facility for Youth and Children, are excluded from coverage. These services are available through NYS Office of Mental Health.
- Residential services for individuals who are incarcerated, confined, or committed to a local correctional facility or prison, or a custodial facility for youth operated by the NYS Office of Children and Family Services are subject to review of NYS legislation in effect at the time of the request for the service.
- Except for Select Plan/HARP, residential services solely because they are ordered by a court.
- Wilderness therapy programs are not considered residential treatment programs.
- Residential programs that utilize interventions that are not Evidence-based Programs and Practices.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	Coverage for residential treatment services for mental health is not included in the Child Health Plus benefit package. Eff 4/1/2023: Residential Rehabilitation Services for Youth (RRSY) for the treatment of substance use disorders is covered when rendered in a Part 817 OASAS certified program. • This includes all services provided by the RRSY, as described in OASAS Part 817. These services include, but are not limited to, clinical services, recovery support services, educational and vocational assessments and services, Medication for Addiction Treatment (MAT) and food and nutrition services. Clinical services include individual, group, and family counseling, assessment and referral services for patients and significant others (e.g., parent/guardian(s), sibling(s), partner(s), etc.), medical and psychiatric consultation, and HIV and AIDS, hepatitis C, tuberculosis, and other communicable diseases education, risk assessment, supportive counseling and referral. • Services must be clinically indicated and specified in the

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	individualized treatment/recovery plan and/or progress notes. Please see https://oasas.ny.gov/system/files/documents/2022/09/part817.pdf for specific RRSY program regulations
MEDICARE ADVANTAGE:	Coverage for residential treatment services for mental health or substance use disorders is not included in the Medicare benefit package.
SELECT PLAN/HARP:	Coverage for residential treatment services for mental health is not a covered benefit. Coverage is not available for treatment services for substance use disorder rendered in a Part 819 residential program. Coverage for treatment services for substance use disorder rendered to an enrollee in a Part 820 OASAS certified residential program is covered (excluding room and board). ○ LOCADTR 3.0 is utilized exclusively for all substance use disorder level of care decisions. Court ordered residential treatment for substance use disorder is a covered benefit.

SOURCES

1. American Psychiatric Association (2013). *Diagnostic and Statistical Manual of Mental Disorders* (Fifth Edition.). Arlington, VA: American Psychiatric Publishing.
2. American Society of Addiction Medicine Placement Criteria for the Treatment of Substance-Related Disorders (ASAM PPC-2R), 2nd Edition, 2001.
3. InterQual® (Version 2023) Substance Use Disorders, Residential Treatment Center Level of Care
4. InterQual® (Version 2023) Adult and Geriatric Psychiatry, Residential Treatment Center Level of Care
5. InterQual® (Version 2023) Child and Adolescent Psychiatry, Residential Treatment Center Level of Care
6. Member contract language.
7. New York State Mental Hygiene Law, Section 1.03(33).
8. New York State Public Health law, Article 27-J: Comprehensive Care Centers for Eating Disorders.
9. Other payers.
10. Value Options Clinical Criteria Guidelines: Residential Treatment Services.
11. Transition of Behavioral Health Benefit into Medicaid Managed Care and Health and Recovery Program Implementation, October 2015, NYS DOH OMH OASAS.

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POLICY NAME: RESIDENTIAL TREATMENT FACILITIES FOR MENTAL HEALTH AND SUBSTANCE USE DISORDERS

Vanessa Bobb, MD, PhD, FAPA Date
VP, Behavioral Health and Medical Integration

POLICY APPROVAL DATES

New:	07/14
Revised:	07/15, 01/16, 05/16, 07/16, 03/17, 05/17, 07/17, 07/18, 07/19, 09/20; 4/21, 10/21, 9/22, 5/23, 6/24, 10/24
Reviewed:	07/21, 07/22, 7/23

BEHAVIORAL HEALTH
RESOURCE COORDINATION POLICY

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POLICY NAME: RESIDENTIAL TREATMENT FACILITIES FOR MENTAL HEALTH AND SUBSTANCE USE DISORDERS

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
4/1/2023	Added RRSY coverage language to CHP Product Variation section.
1/1/2022	CDPHP replaced MCG with InterQual as a utilization review tool
11/1/2022	Updated exclusions section

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MEDICAL POLICY

Medical Policy Title	**Responsive Neurostimulation for the Treatment of Refractory Focal Epilepsy**
Policy Number	**7.01.103**
Current Effective Date	**September 1, 2026**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Responsive neurostimulation (RNS) is **medically appropriate** for an individual with refractory focal epilepsy who meet **ALL** of the following criteria:

   A. 18 years or older;

   B. Diagnosed with focal seizures with one (1) or two (2) well-localized seizure foci identified;

   C. Have had an average of three (3) or more disabling seizures (e.g., motor focal seizures, complex focal seizures, or secondary generalized seizures) per month over the prior three (3) months;

   D. Refractory to medical therapy (unsuccessful treatment with two (2) or more-appropriate antiepileptic medications at therapeutic doses);

   E. Not a candidate for focal resective epilepsy surgery (e.g., have an epileptic focus near the eloquent cerebral cortex; have bilateral temporal epilepsy);

   F. Does not have **ANY** of the following contraindications for responsive neurostimulation device placement:

      1. have three (3) or more specific seizure foci;
      2. have primary generalized epilepsy;
      3. have a rapidly progressive neurologic disorder;
      4. have one (1) or more implanted medical devices that delivers electrical energy to the brain;
      5. are unable or do not have the necessary assistance to properly operate the device or magnet; **or**
      6. are high risk for surgical complications (e.g., active systemic infection or coagulation disorders [e.g., use of antithrombotic therapies or platelet count below 50,000]).

II. RNS is **investigational** for all other indications.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Device Replacement

III. Replacement of a medically necessary RNS or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

   A. The device is no longer functioning adequately and has been determined to be non-repairable or the cost of the repair is in excess of the replacement cost; **or**

   B. There is documentation that a change in the individual's condition makes the present unit non-functional and improvement is expected with a replacement unit.

IV. The replacement of a properly functioning RNS, its components or accessories is considered **not medically necessary.** This includes, but is not limited to, replacement desired due to advanced technology or to make the device more aesthetically pleasing.

V. The replacement of equipment damaged or lost due to individual neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage.**

VI. Accessories or components for RNS that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

7.01.23 Deep Brain Stimulation

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Seizures have been defined as paroxysmal disorders of the central nervous system characterized by abnormal cerebral neuronal discharge with or without loss of consciousness. Medically refractory seizures are defined as seizures that occur despite therapeutic levels of antiepileptic drugs or seizures that cannot be treated with therapeutic levels of antiepileptic drugs because of intolerable adverse effects of these drugs.

The goal of epilepsy surgery is to either remove the seizure-producing area of the brain or to limit the spread of seizure activity. Surgical results can be considered curative (stopping the seizures) or palliative (restricting the spread of the seizure). The type of surgery performed is dependent on the

type of seizure and where the seizures begin in the brain. Curative procedures (e.g., temporal lobectomy, cortical excision, hemispherectomy) are performed when tests consistently point to a specific area of the brain where the seizures begin. Palliative procedures (e.g., corpus callosotomy, subpial transections) are performed when a seizure focus cannot be determined, or there are multiple seizure foci, or the seizure onset zone overlaps brain areas critical for speech, movement, or vision.

Responsive neurostimulation (RNS, NeuroPace Inc., Mountain View, CA) is considered a palliative option in individuals for whom resective surgery is not possible (e.g., two seizure foci, focus on the eloquent cortex) but whose seizure focus, or foci can be identified. The NeuroPace RNS System is an implantable therapeutic device that continuously monitors brain electrical activity, detects abnormal electrical activity, and responds by delivering electrical stimulation of up to two epileptic focus areas, to normalize that activity before an individual experiences a seizure. The NeuroPace RNS System includes a cranially implanted programmable neurostimulator, which is connected to one or two depth and/or subdural cortical strip leads that are surgically placed in or on the brain at the seizure focus. The implant procedure typically takes place during one inpatient stay. Battery life is about eight years, and revision is typically a same-day procedure. The RNS Neurostimulator model RNS320 is considered magnetic resonance (MR) conditional. MR imaging may be performed safely on individuals implanted with the RNS320 system only under very strict, specific conditions defined in their magnetic resonance imaging (MRI) Guidelines manual.

There are some key differences between the RNS System and other neurostimulators. Open-loop stimulations, such as deep brain stimulation (DBS), deliver scheduled intermittent stimulations for a pre-set duration and may not necessarily be applied during an ictal period. The RNS System is a closed-loop stimulator and only provides stimulation when abnormal electrical activity is detected. After the first stimulation, if seizure activity is redetected, it will deliver up to a maximum of five consecutive stimulations. The RNS System depth electrodes or subdural cortical strip leads also act as recording instruments, which continuously monitor brain electrical activity and store electrocorticograms (ECoG) for later review. This information is used by practitioners to optimize programming of the RNS System neurostimulator, to reduce seizure frequency, make informed decisions regarding the individual's progress, and diagnose any changes in the epileptiform discharges. Due to the limited number of ECoGs that can be stored on the device, individuals or caregivers must be able to regularly record and download data.

SUPPORTIVE LITERATURE

The RNS System has demonstrated safety and effectiveness in individuals who average three or more disabling seizures per month over the three most recent months (with no fewer than two seizures in any month) but has not been evaluated in individuals with less frequent seizures. Individuals who are not candidates for resective epilepsy surgery and have few treatment options may benefit from the RNS System. The evidence includes an industry-sponsored RCT, as well as a long-term, open-label study, and is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

The RNS System Pivotal Trial (Morrell 2011) was a multicenter, double-blinded, sham-controlled trial

in which 191 patients with medically intractable focal epilepsy were implanted with the RNS System device and randomized to treatment or sham control one month after device implantation. Eligible patients were adults with focal seizures whose epilepsy had not been controlled with at least two trials of antiepileptic drugs (AEDs), who had at least three disabling seizures (motor focal seizures, complex focal seizures, or secondary generalized seizures) per month, on average, and who had standard diagnostic testing that localized one or two epileptogenic foci. Patients were randomized to active stimulation (n=97) or sham stimulation (n=94). After the four-week post-operative period, patients received either sham or active stimulation, according to group assignment. There was a four-week stimulation optimization period, followed by a three-month blinded evaluation period. In the evaluation period, all outcome data were gathered by a physician blinded to group assignment, and the neurostimulator was managed by a nonblinded physician. One patient in each group did not complete the stimulus optimization period (one due to subject preference in the active stimulation group; one due to death in the sham stimulation group). An additional patient in each group did not complete the blinded evaluation phase due to emergent explant of the device. After the three-month blinded evaluation period, all patients received active stimulation during an open-label follow-up period. At the time of the Morrell publication, 98 subjects had completed the open-label period, and 78 had not. Eleven patients did not complete the open-label follow-up period (five due to death, two to emergent explant, four to study withdrawal). The trial's primary effectiveness objective was to demonstrate a significantly greater reduction in the frequency of total disabling seizures in the treatment group, compared with the sham group, during the blinded evaluation period relative to baseline (pre-implant). The mean pre-implant seizure frequency per month in the treatment group was 33.5 (range, 3-295) and 34.9 (range, 3-338) in the sham group. Mean seizure frequency modeled using generalized estimating equations was significantly reduced in the treatment group, compared with the sham group (p=0.012). During the blinded evaluation period, the mean seizure frequency in the treatment group was 22.4 (range, 0.0-226.8) and 29.8 (range, 0.3-44.46) in the sham group. The treatment group experienced a -37.9% change in seizure frequency (95% confidence interval [CI], -6.7% to -27.7%), while the sham group experienced a -17.3% change in seizure frequency (95% CI, -29.9% to -2.3%). By the third month of the blinded evaluation period, the treatment group had 27% fewer days with seizures, while the sham group experienced 16% fewer days (p=0.048). There were no significant differences between groups over the blinded evaluation period for secondary end points of responder rate (proportion of subjects who experienced at least a 50% reduction in mean disabling seizure frequency versus the pre-implant period), change in average frequency of disabling seizures, or change in seizure severity. During the open-label period, subjects in the sham group demonstrated significant improvements in mean seizure frequency compared with the preimplant period (p=0.04). For all subjects (treatment and sham control), the responder rate at one-year post-implant was 43%. Overall quality of life scores improved for both groups, compared with baseline at one year (p=0.001) and two years post-implant (p=0.016). For the study's primary safety end point, the significant adverse event rate over the first 28 days post-implant was 12%, which did not differ significantly from the prespecified, literature-derived comparator of 15% for implantation of intracranial electrodes for seizure localization and epilepsy surgery. During the implant period and the blinded evaluation period, the significant adverse

event rate was 18.3%, which did not differ significantly from the prespecified, literature-derived comparator of 36% for implantation and treatment with deep brain stimulation for Parkinson disease. The treatment and sham groups did not differ significantly in terms of mild or serious adverse events during the blinded evaluation period. Intracranial hemorrhage occurred in nine (4.7%) of 191 subjects; implant or incision site infection occurred in 10 (5.2%) of 191 subjects, and the devices were explanted from four of these subjects. The authors concluded responsive cortical stimulation may provide another treatment option for persons with medically intractable partial seizures. This study was funded by NeuroPace, Inc.

In a follow-up to the RNS System Pivotal Trial, Heck et al (2014) compared outcomes at one- and two-years post-implant, with baseline for patients in both groups (sham and control) who had the RNS stimulation device implanted during the RNS System Pivotal Trial. Of the 191 subjects implanted, 182 subjects completed follow-up to one-year post-implant, and 175 subjects completed follow-up to two years post-implant. Six patients withdrew from the trial, four underwent device explantation due to infection, and six subjects died. Four deaths were attributed to possible or definite sudden, unexplained death in epilepsy (SUDEP); one of these subjects was randomized to the sham group and did not have stimulation enabled. One subject died of lymphoma and one of suicide. The subject who died of suicide had a preexisting history of depression but was clinically stable at the time of enrollment. During the open-label period, at two years of follow-up, median percent reduction in seizures was 53%, compared with the pre-implant baseline ($p<0.001$), and the responder rate (percentage of subjects with a 50% or more reduction in seizures) was 55%.

Loring et al (2015) analyzed one of the trial's pre-specified safety end points (neuropsychologic function) during the Pivotal trial's open-label period. Neuropsychological testing focused on language and verbal memory, measured by the Boston Naming Test and the Rey Auditory Verbal Learning Test. A total of 175 patients had cognitive assessment scores at baseline and at one or two (or both) years and were included in this analysis. The authors used reliable change indices (RCIs) to identify patients with changes in test scores beyond that attributed to practice effects or measurement error in the test-retest setting, with 90% RCIs used for classification. Overall, no significant group-level declines in any neuropsychological outcomes were detected. On the Boston Naming Test, 23.5% of subjects demonstrated RCI improvements, while 6.7% had declines; on the Rey Auditory Verbal Learning Test, 6.9% of subjects demonstrated RCI improvements, and 1.4% demonstrated declines.

Meador et al (2015) reported on quality of life and mood outcomes for individuals in the RNS pivotal trial. At the end of the blinded study period, both groups reported improvements in Quality of Life in Epilepsy Inventory-89 (QOLIE-89) scores, with no statistically significant differences between groups. In analysis of those with follow-up to two years post-enrollment, implanted patients had statistically significant improvements in QOLIE-89 scores from enrollment to one- and two-year follow-up. Mood, as assessed by the Beck Depression Inventory and the Profile of Mood States, did not worsen over time.

The Long-Term Treatment (LTT) Study was a seven-year, multicenter, prospective, open-label study to evaluate the RNS System's long-term efficacy and safety in individuals who participated in the device's feasibility or pivotal trials. Bergey et al (2015) reported on follow-up for 191 subjects who

participated in a two-year randomized, blinded, controlled study and 65 subjects who completed a two-year open label safety study (n=230) for a median 5.4 years. A total of 39 participants discontinued participation in the LTT Study, resulting in 191 active participants. For follow-up at years three and six, the median percent reductions in seizures were 60% and 66%, respectively. Responder rates were 58% and 59% for year three and year six, respectively. Statistically significant quality of life improved at four years, with a trend toward improvement at five years. After five years, the sample sizes were not sufficient to reliably assess statistical significance. The most common adverse events were implant site infection (n=24 [9.4%]) and increase in complex focal seizures (n=20 [7.8%]). There were 11 deaths, seven of which were attributed to possible, probable, or definite SUDEP. The authors stated that the frequency of deaths, including deaths by SUDEP, was not greater than expected in patients with medically intractable partial onset seizures.

Nair et al (2020) conducted a long-term, prospective, open-label study that included patients who participated in the two-year feasibility or pivotal studies of the RNS System between 2004 and 2018. Patients were followed up for an additional seven years. Overall, 230 patients enrolled in the study, and 162 completed all nine years of follow-up, providing a total of 1895 patient-implantation years. Among 68 patients who discontinued the study, 4 experienced emergent explants, five were lost to follow-up, nine were deceased, and 50 withdrew. The mean follow-up period was 7.5 years. At nine years, the median percent reduction in seizure frequency was 75% ($p<0.0001$), 73% of patients were considered responders, and 35% had at least 90% reduction in seizure frequency. Overall, 18.4% of patients experienced at least one year free of seizures. Overall scores for quality of life and epilepsy-targeted and cognitive domains of the Quality of Life in Epilepsy-89 inventory remained significantly improved at year 9 ($p<0.05$). The only device-related serious adverse events that were reported in at least 5% of patients were implantation site infection and elective explantation of the neurostimulator, leads, or both. Overall, serious device-related implantation site infection occurred in 12.1% of patients. No serious adverse events occurred related to stimulation.

Skrehot et al (2023) conducted a systematic review and meta-analysis of prospective and retrospective studies comparing the efficacy of different neurostimulation modalities, that included vagus nerve stimulation (VNS), responsive neurostimulation (RNS), and deep brain stimulation (DBS) for focal epilepsy. Data was available for analysis at one year follow up, seizure reductions observed were 66.3% for RNS (N=372; 5 studies) and 32.9% for VNS (N=61; 5 studies) and 58.4% for DBS (N=209;10 studies). At 2 years follow-up, seizure reductions observed were 56.0% for RNS (N=280; 4 studies), 44.4% for VNS (N=42; 3 studies), and 57.5% for DBS (N=158;6 studies). At 3 years follow-up, seizure reductions observed were 68.4% for RNS (N=261; 4 studies), 53.5% for VNS (N=13; 1 study), and 63.8% for DBS (N=111;5 studies). The authors noted RNS studies had high heterogeneity and VNS studies had low heterogeneity. RNS and DBS have similar seizure reduction efficacy and had greater seizure reductions compared to VNS in the first-year post implantation, with the differences diminishing with longer term follow up. Authors noted that many of the studies were observational, non-randomized, or retrospective in nature, reducing the reliability of their results. The evidence suggests seizure reductions were greater for RNS compared to VNS at one-year post-implantation with diminishing differences in longer-term follow-up.

Pediatrics

RNS is not FDA approved for patients younger than 18 years of age and published literature on children is limited. RNS has been used on an off-label basis in pediatric patients.

In 2023, the Pediatric Epilepsy Research Consortium (PERC) published findings (Hansen 2024) from a multicenter, prospective, case series including data from 22 collaborating US pediatric epilepsy centers. Of 1,426 patients included in the comprehensive PERC surgery database at the time of analysis, 56 unique patients from 12 centers received RNS for focal drug-resistant epilepsy not considered candidates for resective surgery. The mean age at RNS implantation was 14.9 years (range, 5.6 to 19.5 years; S.D., 3.7) with mean duration of epilepsy at the time of implantation of 8.1 years (range, 0.8 to 16.9 years; S.D., 3.9). Surgical complications occurred in three individual patients (5.3%) including one patient with a malpositioned lead and transient weakness and two patients who had transient weakness in relation to resection or subdural grid placement, not related to RNS placement. With a mean duration of follow-up of one year, 65% of the patients with RNS enabled experienced a >50% seizure reduction. The authors acknowledged that there are important limitations in generalizing the findings from this study and that randomized controlled studies of RNS in children are necessary to understand the efficacy and safety in this vulnerable population.

PROFESSIONAL GUIDELINE(S)

Professional societies do not provide specific published practice guidelines for RNS as they do for other treatments such as medical guidelines or position statements. However, these societies offer recommendations and guidance through various channels including articles, clinical reviews and guidelines from related fields as well as supporting documents from organizations like the American Epilepsy Society.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates the RNS Systems as medical devices. All RNS Systems including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Apr 02]

The U.S. Food and Drug Administration (FDA) approved the NeuroPace RNS System in 2013 (P100026) for the adjunctive treatment of medically intractable focal epilepsy in adults with frequent and disabling seizures (motor partial seizures, complex partial seizures, and/or secondarily generalized seizures), who have undergone diagnostic testing that localized no more than two epileptogenic foci and are refractory to two or more antiepileptic medications.

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Apr 02]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
61850	Twist drill or burr hole(s) for implantation of neurostimulator electrodes, cortical
61860	Craniectomy or craniotomy for implantation of neurostimulator electrodes, cerebral, cortical
61863	Twist drill, burr hole, craniotomy or craniectomy with stereotactic implantation of neurostimulator electrode array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray), without use of intraoperative microelectrode recording; first array
61864	each additional array
61880	Revision or removal of intracranial neurostimulator electrodes
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to single electrode array
61886	with connection to 2 or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
61889	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)
61891	Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)
61892	Removal of skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed
95836	Electrocorticogram from an implanted brain neurostimulator pulse generator/transmitter, including recording, with interpretation and written report, up to 30 days
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with

Code	Description
	brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95971	Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
95983	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact groups[s], interleaving, amplitude, pulse width, frequency [HZ], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain neurostimulator pulse generator/transmitter programming, first 15 minutes face-to-face time with physician or other qualified health care professional
95984	each additional 15 minutes face-to-face time with physician or other qualified health care professional (list separately in addition to code for primary procedure)

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HCPCS Codes

Code	Description
C1767	Generator, neurostimulator (implantable), nonrechargeable
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non- rechargeable, includes extension

ICD10 Codes

Code	Description
G40.011 - G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable (code range)
G40.111 - G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable (code range)
G40.211 - G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable (code range)

Code	Description
Investigational Codes:	
All other ICD10 diagnosis codes are considered investigational.	

REFERENCES

Bercu M, et al. Responsive neurostimulation for refractory epilepsy in the pediatric population: A single-center experience. Epilepsy Behav. 2020 Nov;112:107389).

Bergey GK, et al. Long-term treatment with responsive brain stimulation in adults with refractory partial seizures. Neurology. 2015 Feb 24;84(8):810-7.

Hansen D, et al. A multi-center comparison of surgical techniques for corpus Callosotomy in pediatric drug-resistant epilepsy. Epilepsia. 2024 Feb;65(2):422-429.

Heck CN, et al. Two-year seizure reduction in adults with medically intractable partial onset epilepsy treated with responsive neurostimulation: final results of the RNS System Pivotal trial. Epilepsia. 2014 Mar;55(3):432-41.

Kerezoudis P, et al. Safety and efficacy of responsive neurostimulation in the pediatric population: Evidence from institutional review and patient-level meta-analysis. Epilepsy Behav. 2022 Apr;129:108646

Loring DW, et al. Differential neuropsychological outcomes following targeted responsive neurostimulation for partial-onset epilepsy. Epilepsia. 2015 Nov;56(11):1836-44.

Ma BB, et al. Responsive neurostimulation for regional neocortical epilepsy. Epilepsia. 2020 Jan;61(1):96-106**.**

Meador KJ, et al. RNS System Pivotal Trial Investigators. Quality of life and mood in patients with medically intractable epilepsy treated with targeted responsive neurostimulation. Epilepsy Behav. 2015 Apr;45:242-7.

Morrell MJ, et al. Responsive cortical stimulation for the treatment of medically intractable partial epilepsy. Neurology. 2011 Sep 27;77(13):1295-304.

Nair D, et al. Nine-year prospective efficacy and safety of brain-responsive neurostimulation for focal epilepsy. Neurology. 2020 Sep 1;95(9):e1244-e1256.

Singh RK, et al. Responsive Neurostimulation in Drug-Resistant Pediatric Epilepsy: Findings From the Epilepsy Surgery Subgroup of the Pediatric Epilepsy Research Consortium. Pediatr Neurol. 2023 Jun;143:106-112.

Skrehot HC, et al Neuro-stimulation in focal epilepsy: A systematic review and meta-analysis. Epilepsy Behav. 2023 May;142:109182.

U.S. Food and Drug Administration. [Internet] Premarket Approval (PMA) Neuropace RNS System – P100026. [Updated 2025 Mar 31; accessed 2026 Mar 31]. Available from: [https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100026]

U.S. Food and Drug Administration. [Internet] RNS System. Summary of Safety and Effectiveness Data (SSED). [Updated 2013 Nov 14;accessed 2026 Mar 31]. Available from: [https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100026b.pdf]

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Responsive neurostimulation is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 5/26

Revised:

Reviewed:

Date	Summary of Changes
9/1/2026	• New

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: REVIEW PROCESS FOR RESOURCE COORDINATION

POLICY EFFECTIVE DATE:	1/1/2026
Policy Control #:	1370/20.000213
Next Annual Review:	July, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

DESCRIPTION

Process utilized by resource coordination to render timely decisions on all requests for services, to review and determine whether health care services that have been provided, are being provided, or are proposed to be provided to an enrollee, whether undertaken prior to, concurrent with, or subsequent to the delivery of such service are medically necessary.

POSITION STATEMENT

Resource Coordination Policies:

- Medically Fragile Children, 1370/20.000514

POSITION STATEMENT

The CDPHP resource coordination department provides complete and timely review of and notification of determination on all requests for services received according to the process outlined below.

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: REVIEW PROCESS FOR RESOURCE COORDINATION

Coverage determinations for behavioral health services are made in a manner consistent with accepted medical practices and Federal and State behavioral health parity laws.

The review process for behavioral health services includes application of criteria that are no more stringent than criteria used in the review of medical services and the review process itself is comparable to and no more stringent than the process for reviewing medical services.

1. **Request for service is received in the resource coordination department.**

   - CDPHP enrollee's contract and resource coordination prior authorization guideline outline those services that require prior authorization.
   - If a request for service is received and no authorization is required, the enrollee, enrollee's duly authorized representative, physician, referral specialist, or vendor is notified by a CDPHP staff member.
   - Request may be received via phone, fax, email, or standard mail.
   - Request may be from the enrollee, enrollee's duly authorized representative, physician, referral specialist, or vendor.
   - If anyone other than a physician initiates the request, the physician may be contacted for informational purposes.

2. **Request is date stamped.**

   - The Document Management staff date stamp all incoming mail based on the date received at CDPHP.
   - Faxes are received electronically, generating notification page indicating the date/time received.
   - Requests received by telephone are documented in Facets, which automatically dates each entry.
   - Requests received by email are automatically date/time stamped by the server and saved to member's Macess folder by the clinical reviewer.

3. **Request is received by or is forwarded to a clinical reviewer.**

   - Administrative personnel trained in the principles and procedures of intake screening and data collection, review request submission, and prepare the case to forward to clinical reviewer. Administrative personnel are supervised by a licensed health care professional.
   - All requests for medical services are reviewed by a registered nurse (RN) or licensed practical nurse (LPN).
   - All requests for behavioral health services are reviewed by a licensed mastered social worker (LMSW), licensed clinical social worker (LCSW), licensed mental health counselor (LMHC), or registered nurse (RN).

4. **Requests are documented in Facets.**

    - Facets/Salesforce is updated by the clinical reviewer throughout the review process as per department procedure.

5. **Enrollee eligibility is confirmed by the reviewer.**

    - Enrollee name and identification number are required. Gender and date of birth may be required if multiple enrollees have the same name. Effective dates as well as any contract or rider-specific limitations are reviewed. Reviewer verifies that the request is not a duplicate or an appeal.

6. **Resource coordination staff identify themselves by name, title, and organization when initiating or returning calls regarding utilization management issues**.

    - Routine inbound/outbound communication regarding utilization management determinations, including questions regarding the UM process, takes place during regular business hours (Monday through Friday, 8 a.m. to 5 p.m. On-call staff is available for urgent issues after-hours, weekends, and holidays by calling the resource coordination department at 1-800-274-2332 or the behavioral health department at 1-888-320-9584.

7. **Clinical information is obtained to support the medical necessity of the request, or in the case of a contractual review, enrollee-specific contract is reviewed.**

    - The reviewer is responsible for obtaining the following information for all case reviews:
        - Name
        - Date of birth (age)
        - Service requested
        - Enrollee's diagnosis, including comorbidities
        - Clinical information supporting the requested service
        - Supporting literature for any request for new technology
        - Information obtained is the minimum needed to make an informed determination. No undue burden is placed on the practitioner.
        - Enrollee-specific contract is reviewed to determine coverage availability.

8. **Claims history is reviewed by the clinical reviewer for any service that is monitored.**

    - Each contract may have different services that have calendar year or lifetime maximums.

9. **The reviewer requests additional information when all or part of the information is**

incomplete.

- Additional clinical information is requested from the practitioner via telephone and/or in writing.

10. **Complete clinical information is reviewed against established criteria, including the state's guidance on care for medically-fragile children as applicable. In the case of a contractual review, the enrollee-specific contract is reviewed.**

- The reviewer utilizes InterQual® for admission, concurrent, and discharge review, as well as procedure-specific authorization (Information relating to these guidelines may be accessed at https://www.changehealthcare.com/clinical-decision-support/interqual for medical and behavioral health services. InterQual® provides nationally recognized, evidence-based criteria. CDPHP resource coordination policies are utilized for coverage guidelines of medical technologies and new uses of existing technologies; the enrollee's contracts and riders are utilized to determine if a service is covered or excluded. Reviewers utilize evidence-based and peer reviewed clinical review criteria that are appropriate to the age of the patient.
- In addition, for services related to the treatment of substance use disorders, the reviewer utilizes LOCADTR-3 patient placement tool, which takes into consideration the strengths and needs of the individual.
- In addition to reviewing against established criteria, the reviewer reviews and/or investigates both the participating delivery system and community resources to identify available resources to meet the enrollee's needs.
- Out-of-network services will be approved if the reviewer determines its panel or network does not have a health care provider with appropriate training and experience to meet the needs of the enrollee or the requested service is determined to be materially different from an available in-network health service and cannot be provided through the CDPHP participating provider network.
- For behavioral health services, in situations where the medically necessary level of care does not exist (e.g., rural location), the health plan may make available the proper level of care in another location, or authorize a higher than otherwise needed level of care, to ensure that services will meet the member's essential needs for safe and effective treatment.

11. **Resource coordination decision-making is based only on appropriateness of care and service.**

- Utilization decision-making is based only on appropriateness of care and service and existence of coverage. Staff who make utilization-related decisions should be particularly aware of the special concern about the risks of underutilization.
- CDPHP does not specifically reward practitioners or other individuals for issuing denials of coverage or care.

- Financial incentives for resource coordination decision-makers do not encourage decisions that result in underutilization. CDPHP does not use incentives to reward restrictions of care.
- An adverse determination will not be based on:
  - Enrollee's refusal to consent to observing any health care service.
  - Lack of reasonable access to a health care provider's medical or treatment record, unless the reviewer has provided reasonable notice to the enrollee, enrollee's designee, or enrollee's health care provider, of medical/treatment records needed. CDPHP works collaboratively with practitioners and facilities to obtain all information necessary to complete review.

12. **CDPHP considers information obtained through review activities as strictly confidential.**

- Refer to CDPHP "Standards of Conduct".

13. **Requests that meet the established criteria are approved by the clinical reviewer.**

- Clinical reviewers (registered nurse (RN) or licensed practical nurse (LPN)) who make medical UM decisions are supervised by an RN with an active New York state license.
- Clinical reviewers (licensed mastered social worker (LMSW), licensed clinical social worker (LCSW), licensed mental health counselor (LMHC), or registered nurse (RN)) who make behavioral health UM decisions are supervised by an appropriately licensed and qualified behavioral health professional.
- Upon approval, the practitioner and the enrollee, or enrollee's designee, are notified via telephone and in writing.

14. **Requests that do not meet the established criteria are forwarded to a medical director by the clinical reviewer.**

- The medical director (board certified medical or behavioral health physician) reviews the individual enrollee circumstances, available practice guidelines, applicable contract benefits, the capacity of the CDPHP participating practitioner and provider delivery system and supporting resource coordination policies and procedures to render a determination.
  - **Medicare Advantage:** Medical director also reviews Centers for Medicare & Medicaid Services local and national medical review policies.
- Out-of-network services will be approved if the reviewer determines its panel or network does not have a health care provider with appropriate training and experience to meet the needs of the enrollee or the requested service is determined to be materially different from an available in- network health service and cannot be provided through the CDPHP participating provider network.
- When the clinical judgment necessary to render a determination on a specific case is

outside the expertise of the medical director, a clinical peer reviewer will be utilized as outlined in Resource Coordination Policy: *Clinical Peer Reviewers*, # 1370/20.000270.
- The medical director or clinical peer reviewer may also speak with the requesting provider.

15. **The medical director will approve or deny service request.**

- The medical director will document the following information on all determinations:
  - The specific reason(s) for the determination;
  - Reference to the specific contract provision(s) on which the determination is based;
  - If any internal rule, guideline, protocol, policy, or other similar criterion was relied upon in making the determination, a statement of what specific criterion was relied upon; and
  - If the determination is based on medical necessity, experimental treatment or similar exclusion or limit, an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the enrollee's medical circumstances.
- The clinical reviewer will notify the practitioner and the enrollee via telephone followed in writing. The denial determination, including the clinical rationale, will be communicated both verbally and in writing as documented by the medical director.
- The clinical reviewer will notify the practitioner or their office staff that the medical director is available to discuss the denial determination by calling the resource coordination department at (518) 641-4100 or 1-800-274-2332. The clinical reviewer will document the time and date of this notification and with whom he/she spoke.

16. **The requesting practitioner may request a reconsideration (peer-to-peer review) of an adverse determination when they have not had the opportunity to speak with the medical director who rendered the determination or a clinical peer representative.**
- Reconsideration review is not applicable to a determination made as a result of retrospective review or contractual denial.
- CDPHP allows 14 calendar days from the date of the initial adverse determination for the ordering/attending practitioner/provider to request reconsideration. If the request for reconsideration is made after the 14 days have passed, the case would be processed as an enrollee appeal once the provider obtains sign off from the enrollee and submits the provider designation form. If the request is concurrent in nature, the practitioner has individual rights to appeal and would not require sign-off from the enrollee.
- All reconsiderations will take place within one business day of receipt of the request from the practitioner/provider. If the ordering/attending physician/provider requests that reconsideration be done on a specific day, we will allow the review, if it is within 14 calendar days of the decision. The final decision will be made within one business day of the discussion.
- A reconsideration will be considered closed if the physician/provider has not contacted the CDPHP medical director within 14 calendar days of the original decision.

- Verbal and written notification of the reconsideration determination will be provided.
- In the event the adverse determination is upheld after reconsideration, the enrollee, enrollee's designee, or the enrollee's health care provider may appeal the determination and are notified verbally, and in writing, on how to initiate the appeal process. Notice of an adverse determination includes:
  - The reason(s) for the determination including the clinical rationale, if any;
  - Instructions on how to initiate the appeals process;
  - Notice of the availability, upon request of the enrollee, enrollee's designee, or enrollee's health care provider, of the clinical review criteria relied upon to make the determination; and
  - Specify what, if any, additional necessary information to be provided to, or obtained by, CDPHP in order to render a decision on the appeal.
- Medicare Advantage: Reconsideration of an adverse determination is not applicable to the Medicare Advantage Plans. Members are to follow the standard appeals process as outlined in the Evidence of Coverage for responding to an adverse determination.

17. **The clinical reviewer educates the enrollee regarding alternatives for continuing and/or obtaining services when available on all denials, with special attention given to benefit exhaustion.**

- The clinical reviewer educates the enrollee regarding local, state, and federal programs available to meet their health care needs when such a program exists.
- The clinical reviewer assists the enrollee with obtaining such services to ensure a smooth and timely transition of care.

18. **All determinations must be made in a timely manner.**

- CDPHP utilizes the following standards for timeliness (refer to the following product-specific attachments):
  - Attachment A: Commercial (Large & Small Group/Individual)
  - Attachment B: Medicare Advantage
  - Attachment C: Select Plan/HARP and Child Health Plus
-

19. **Utilization review is not conducted more frequently than is reasonably required to assess whether the health care services under review are medically necessary**.

- There is no requirement for prior authorizations for admissions to inpatient mental health care for adults or children presenting in hospital emergency departments and determined by an emergency department physician to need inpatient care to stabilize and treat an emergency condition.

POLICY NAME: REVIEW PROCESS FOR RESOURCE COORDINATION

- Refer to Resource Coordination Policy: *Prior Authorization Guideline*, # 1370/20.000425

- There is no requirement that providers demonstrate evidence that an adult or child presents an imminent danger to self or others for clinical reviewers to approve admission to or continued inpatient mental health care.

- There is no requirement that providers demonstrate evidence of the adult or child's active participation in treatment and/or benefit from treatment for authorization of continued mental health care.

- There is no requirement that all inpatient mental health care is subject to concurrent utilization review.
  - Inpatient mental health treatment may be subject to concurrent review only when specific quality or clinical triggers are met.
  - Clinical reviewers offer coordination of care to all enrollees who are admitted for inpatient mental health and substance use treatment regardless of whether or not utilization review or a coverage determination is required.

20. **Criteria utilized to render a resource coordination determination are available to the enrollee or practitioner upon request.**

- Enrollees and practitioners may request clinical guidelines and/or policies used in making resource coordination determinations by contacting the resource coordination department as outlined in the resource coordination determination letter.

21. UM Information Integrity

The medical and behavioral health utilization review teams, in coordination with the Plan's corporate security oversight team, maintains and audits the process for ensuring the integrity of UM information used in the processing of denials, this includes but is not limited to the dates the requests were received, the appropriate practitioner review, collection of clinical information, documentation of the final decision, the date of the decision notification and the denial notice. Utilization management decisions are documented in the Plan's system of record, Facets.

CDPHP considers date of receipt, the date that a request was received. All requests for medical or behavioral health utilization review are date stamped upon receipt as follows:

- The date and time the request was received by CDPHP (user field 1 in Facets) is manually documented within the record based on the date stamp described below:
- The Document Management staff of the Plan will date stamp all incoming mail with the date the mail was received by CDPHP. CDPHP receives mail on business days only.
- Faxes and emails are received electronically, indicating the date/time received into any department of CDPHP.

- Requests received by telephone are documented in the Facets system of the Plan which automatically dates each entry.

Facets is updated by the clinical reviewer throughout the review process as per department procedure which includes but is not limited to the following documentation:

- The date and time the request was received by CDPHP (user field 1)
- The written notification is defined as the date the letter is generated to the member/provider
    - Denial letters generated up until 2:00 p.m. will be mailed on the same business day. Letters generated after 2:00 p.m. will be mailed on the next business day.
    - The date and time of Facets-generated letters can be viewed in the attachments tab of the Prospective UM module.
    - The date and time of Macess-generated letters is evidenced by the date and time stamp of the "letter generated" note in Facets entered by the user in the related authorization.
    - The "letter generated" note is not modifiable. The letter is saved in Macess with the date it was generated which is also not modifiable.
- Only Utilization Review Nurses/Behavioral Health Clinical Reviewers, including Supervisors and Managers, and Clinical Support Specialists that are involved in the prior authorization process are authorized to correct dates/times in user fields and only if a key stroke error was made. If such a correction is done, a note will be added in the note field of the authorization to document the reason for the correction, describe the change which was made, the date/time of the correction and who made the correction. This note is given a system-generated date and time stamp that is unmodifiable. Facets will also show the user who last updated the user field.
- CDPHP defines the following as inappropriate modifications to a UM case:
    - Falsifying UM dates (received date, decision date, notification date)
    - Creating documents without performing the required activities
    - Fraudulently altering existing documents (clinical received from providers, board certified consultant review, denial notices)
    - Attributing review to someone who did not perform the activity
    - Updates to information within a UM case by an unauthorized individual
- Corrections for dates on verbal or written notifications cannot be made by any CDPHP utilization review staff. A new note will be added to the auth to explain any errors in the documentation of verbal notifications or regeneration of written notifications if necessary.
- All written notifications are stored in the CDPHP Macess system. Dates cannot be altered within this system. Written notifications that need to be corrected before they have been mailed, will be removed from Macess using the CDPHP Service Now process with a note entered on the authorization with the service now incident number of such.

22. UM Information Integrity Oversight

- A sample of 5% or up to 50 (whichever is less) medical and behavioral health

utilization management denials with modifications found will be selected to audit compliance with this policy annually. If 50 such cases with modifications are not identified, we will audit all records with modifications. The audit findings will be documented in a workbook which contains verification of the accuracy of the modified data entry of all dates captured within the authorization. If any modifications were made to one of these dates outside of the parameters of this policy, that will be documented.

- The audit workbook will contain any identified factors contributing to the non-compliance with this policy, any identified coaching and/or training needed, any process improvements that were made due to the audit findings and any disciplinary action taken from these findings, if necessary.
- If there are findings of modifications made in violation of this policy, audits will be changed to quarterly until 3 consecutive quarters of improvements in findings is realized.
- UM management will provide appropriate feedback/re-education to any staff members who through the audit have been found in non-compliance by making inappropriate modifications per the guidelines within this policy.
- If the UM leadership identifies fraud and misconduct this will be reported to NCQA
- A report will be generated from this sample review tracking to validate and analyze that the process described is being followed by all staff and to evaluate for opportunities to improve documentation for process improvement.
- Oversight of this audit process will be reported out annually to the Utilization Management Committee.
- Annually, the Plan's Identity and Access Management team reviews staff access to Facets and the functionality they are approved or to ensure access is still appropriate for each staff's job responsibilities.

23. UM Information Integrity Training

- Annual training will be provided to all UM staff on inappropriate documentation and updates to UM information as defined within this policy.
- The training will also inform UM staff of the organizations audits of staff documentation and updates within UM authorizations.
- UM staff will be made aware of the process for documenting and reporting inappropriate documentation to both the designated individuals when identified and NCQA when the organization identifies fraud and/or misconduct.

CDPHP has controls in place to protect data from unauthorized modification. Refer to the following policies:

- Corporate Information Security Policy
- Physical & Environmental Security
- User Registration and Management
- Password Policy

POLICY NAME: REVIEW PROCESS FOR RESOURCE COORDINATION

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy.

SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy in addition to the following:
	• All behavioral health decision-makers have clinical expertise in treating enrollee's condition, stratified by age.
	• Behavioral health denials are conducted by a peer with credentials at least equal to that of the recommending clinician.
	• All behavioral health admission and continued stay authorizations are under the direction of a CDPHP medical director with a minimum of three years' experience in a behavioral health setting.
	• For all inpatient behavioral health treatment denials, review will be completed by:
	  ○ A physician board certified in general psychiatry for inpatient psychiatric treatment.
	  ○ A physician board certified in child and adolescent psychiatry for inpatient psychiatric treatment for enrollees age 18 and under.
	  ○ A physician certified in addiction treatment for inpatient substance use disorder treatment.
	• LOCADTR 3 is utilized to determine level of care for inpatient and outpatient substance use disorder services.

SOURCES

1. Contract clarification.
2. The CDPHP Technology Assessment Team
3. Center for Medicare Advocacy, Grijalva v. Shalala, http://www.medicareadvocacy.org/Litigation_Archives.htm
4. Medicaid Managed care Contract, Appendix F:

5. Medicare Managed Care Manual, Chapter 13: Medicare Managed Care Beneficiary Grievances, Organization Determinations, and Appeals Applicable to Medicare Advantage Plans, Cost Plans, and Health Prepayment Plans, Section 90.3: Notice of Medicare Non-Coverage (NOMNC), 9/21/07.
6. Other Payers
7. www.cms.gov/regs/mplusc/1030FC-M.PDF
8. Regulatory requirements – NYS Department of Labor
9. National Committee for Quality Assurance (NCQA), MCO Standards and Guidelines, 2004/2005.
10. Transition of Behavioral Health Benefit into Medicaid Managed Care and Health and Recovery Program Implementation, October 2015, NYS DOH OMH OASAS.
11. Guiding Principles for the Review and Approval of Clinical Review Criteria for Mental Health Services, NYS OMH; October 2019

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POLICY APPROVAL DATES

New:	08/99
Revised:	09/00, 09/02, 01/03, 09/04, 05/05, 12/05 (Standards for timeliness updates implemented 10/1/05), 12/06, 12/07, 03/08, 07/08, 07/09, 11/09, 07/11, 09/11, 07/12, 05/13, 07/13, 09/13, 07/14, 11/14, 11/15, 01/16, 05/16, 11/16, 01/17, 05/17, 07/17, 11/17 (Regulatory requirement), 01/18, 03/18, 07/18, 03/19, 7/19, 7/20, 11/20, 01/21,11/21, 3/22, 11/22,7/23, 3/24, 9/24, 1/25, 7/25, 1/26
Reviewed:	07/10, 07/15, 7/21, 7/22, 7/24, 9/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update

POLICY NAME: REVIEW PROCESS FOR RESOURCE COORDINATION

1/1/2026	Updated required timeframe for Standard Preauthorization Review for Medicare in Attachment B and for Medicaid in Attachment C.
7/1/2025	NCQA standard for System Controls has changed to UM Information Integrity. Policy updates also completed on UM Information Integrity to support changes to the NCQA standard.
1/1/2025	Updated policy for Child Health Plus to mirror all Select Plan/HARP's rules/timeframes.
8/8/2024	Updates made to #19 regarding generation of denial letters.
3/1/2024	Updated the timeframe to close a reconsideration from 1 business day to within 14 calendar days of the original determination. Under attachment B updated timeframe for standard preauthorization review. Under attachment A & C updated verbiage for Inpatient Mental Health Admissions. Added additional information regarding notice of an adverse determination which was formerly housed in the obsolete Resource Coordination policy *1370/20.0000146 Reconsideration of Adverse Determination.*
7/1/2022* No change to effective date of policy	Removed reference to LOCUS OR CALOCUS for Behavioral Health services. Added detailed language explaining reviewer types to satisfy NCQA UM standards.
7/1/2022	System Control Oversight section updated for NCQA requirements.
4/01/2022	To meet new NCQA requirement, added section in regard to System Control Oversight.
1/1/2022	Removed MCG guideline references and replaced with InterQual.
12/1/21	Added verbiage to the member notification process: • A voicemail left for an enrollee will only consist of the name of the CDPHP employee calling, the phone number to return the call and a reference number to the case the call pertains to.
1/1/21* *No change to effective date	Added turnaround determination timeframes for inpatient or SNF members to go to an acute rehab facility in the Pre-Authorization and Concurrent Review sections in Att A and Att C.

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

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1/1/21	Changes made throughout policy regarding Behavioral Health as part of regulatory requirement issued by NYS Office of Mental Health (OMH).
11/1/20	Added section for System Control Standards.

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POLICY NAME: REVIEW PROCESS FOR RESOURCE COORDINATION

Attachment A

Commercial (Large & Small Group/Individual)
Timeframe Requirements

Preauthorization Reviews:

Standard Preauthorization Reviews

- If all necessary information is submitted with the request, CDPHP will make a determination, providing notice to the enrollee, or enrollee's designee, and the enrollee's provider, by telephone and in writing, within three business days of receipt of the request.

- Upon receipt of request for a member who is currently in an inpatient hospital or a skilled nursing facility to go to an acute rehabilitation facility, the turnaround time for this determination is one business day.

- If additional information is needed, it will be requested within the three business days of receipt of request. The enrollee, or enrollee's designee, or the enrollee's provider will have 45 calendar days to provide the necessary information. If requested information is received within 45 calendar days, CDPHP will make a determination and provide notice to the enrollee, or enrollee's designee, and the enrollee's provider, by telephone and in writing, within three business days of receipt of the information. If all necessary information is not received within 45 days, the plan will make a determination within 15 calendar days of the end of the 45-day period.

Urgent/Expedited Preauthorization Reviews

- Enrollee, or enrollee's designee, or practitioner may request an urgent care/expedited review. If requested by a practitioner, review must be expedited. If requested by enrollee, CDPHP can determine if expedited review is medically necessary.

- If all necessary information is submitted with the request, CDPHP will make a determination, providing notification to the enrollee, or enrollee's designee, and the provider by telephone within 72 hours of receipt of the request. Written notice will follow within three business days of receipt of request.

- If additional information is needed, it will be requested within 24 hours. The enrollee, or enrollee's designee, or the enrollee's provider will have 48 hours to submit this information. CDPHP will make a determination and provide notice to the enrollee, or enrollee's designee, and the enrollee's provider by telephone and in writing within 48 hours of the earlier of receipt of the requested information or the end of the 48-hour time period.

Court Ordered Treatment Reviews

- If all necessary documentation is submitted with the request, CDPHP will make a determination regarding a request for court ordered treatment relating to a mental health and /or substance use disorder and provide notice, by telephone, to the enrollee or enrollee's designee, and the enrollee's provider within 72 hours of receipt of the request. Written notification for elective court ordered admissions will be provided within three business days of receipt of the request. Where feasible, telephonic and written notification will also be provided to the court.

Concurrent Review

Standard Concurrent Reviews

- Decisions for services during the course of care (concurrent review) will be made, and notice provided to the enrollee, or enrollee's designee, and the enrollee's provider, by telephone and in writing, within one business day of receipt of all necessary information. Written notification includes number of extended services approved, the new total of approved services, date of onset of services and next review date.

- Upon receipt of request for a member who is currently in an inpatient hospital or a skilled nursing facility to go to an acute rehabilitation facility, the turnaround time for this determination is one business day.

- If additional information is needed, CDPHP will request it within one business day. The enrollee, or enrollee's designee, or the enrollee's provider will have 45 calendar days to provide the necessary information. CDPHP will make a determination and provide notice to the enrollee, or enrollee's designee, and the enrollee's provider, by telephone and in writing, within one business day of receipt of the requested information. If requested information is not received, notice is provided within 15 calendar days of the end of the 45-day time period.

Urgent/Expedited Concurrent Reviews

- For concurrent reviews that involve an extension of urgent care, if the request for coverage is made at least 24 hours prior to the expiration of a previously approved treatment, CDPHP will make a determination and provide notice to the enrollee, or enrollee's designee, and the enrollee's provider by telephone within 24 hours of receipt of the request. Written notice will be provided within one business day of receipt of the request for coverage if all necessary information was included or three calendar days from the verbal notification if all necessary information was not included. Written notification includes number of extended services approved, the new total of approved services, date of onset of services and next review date.

- If the request for coverage is not made at least 24 hours prior to the expiration of a previously approved treatment, and all information necessary to make a determination has

been received, CDPHP will make a determination and provide notice to the enrollee, or enrollee's designee, and the enrollee's provider within 72 hours or one business day from receipt of the request, whichever is earlier. If additional information is needed, we will request it within 24 hours. The enrollee, or enrollee's designee, or enrollee's provider will have 48 hours to submit the information. CDPHP will make a determination and provide written notice to the enrollee, or enrollee's designee, and enrollee's provider within one business day or 48 hours of receipt of the information, whichever is earlier or, if information is not received, within 48 hours of the end of the 48-hour period.

Inpatient Substance Use Disorder Treatment Reviews (Special conditions apply.)

- CDPHP will make a determination regarding a request for inpatient substance use disorder treatment submitted at least 24 hours prior to discharge from an inpatient admission within 24 hours of receipt of the request and will provide coverage for the inpatient substance use disorder treatment while determination is pending.
- Coverage for inpatient admission for substance use disorder treatment at an OASAS-licensed facility that participates in the CDPHP network is not subject to preauthorization. Coverage will be subject to concurrent review on day 29 of the inpatient admission if the OASAS-licensed facility notifies CDPHP of both the admission and the initial treatment plan within two business days of admission. If the facility fails to notify CDPHP of either the admission or the treatment plan within two business days of admission, CDPHP may begin concurrent review immediately upon learning of the admission. In either case, the entire stay may be reviewed, including the initial 28-day period, to determine whether the admission and treatment is medically necessary. Applies to member contracts issued, renewed, modified, or amended on or after 1/1/17. Self-insured, FEHB, and Medicare Choices products are excluded from this consideration and will follow standard prior authorization requirements.

Inpatient Mental Health Admissions (Special conditions apply.)

- Coverage for inpatient admission to a participating facility within New York State, for the treatment of a mental health condition, is not subject to preauthorization. For children under age 18, coverage may be subject to concurrent review on day 15 of the inpatient admission if the facility notifies CDPHP of both the admission and the initial treatment plan within two business days of admission. The entire stay may be reviewed, including the initial 14-day period, to determine whether the admission and treatment is medically necessary. Care for members discharged prior to day 15 may be reviewed retrospectively if one or more specific quality or clinical triggers are met. The specific trigger met will be documented by the reviewer. Facilities are required to notify CDPHP of discharge within 24 hours of the discharge date and retrospective review may begin when CDPHP is notified of the discharge. *Applies to member contracts issued or renewed on or after 1/1/20. This does not apply to self-funded (ASO) or Medicare Choices member contracts. Applies to members under age 18 at the time of their hospitalization.

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Retrospective Review

- If CDPHP has all necessary information to make a determination regarding a retrospective claim, CDPHP will make a determination and notify the enrollee, or the enrollee's designee, within 30 calendar days of receipt of the request. If additional information is needed, CDPHP will request it within 30 calendar days. The enrollee, or enrollee's designee, or the enrollee's provider will then have 45 calendar days to provide the information. CDPHP will make a determination and provide notice to the enrollee, or enrollee's designee, and enrollee's provider in writing, within 15 calendar days of the earlier of our receipt of the information or the end of the 45-day period.

- CDPHP will only reverse a prior authorized treatment, service, or procedure on retrospective review when:

    - The relevant medical information presented to us upon retrospective review is materially different from the information that was presented during the prior authorization review; and
    - The relevant medical information presented to us upon retrospective review existed at the time of the prior authorization but was withheld from or not made available to us; and
    - CDPHP was not aware of the existence of the information at the time of the prior authorization review; and

Had CDPHP been aware of such information, the treatment service or procedure being requested would not have been authorized. The determination is made using the same specific standards, criteria, or procedures as used during the preauthorization review.

Notification

- All notifications identified above, both verbal and written, are completed within the timeframes identified and in compliance with all other notification requirements found in applicable law.

    - **Telephonic notification** – the enrollee, or enrollee's designee, and the enrollee's provider are notified of the decision.
        - In the case of an initial adverse determination, at the time of telephonic notification, the enrollee, or enrollee's designee, and the enrollee's provider are notified of how to initiate the appeal process based on the enrollee's contract/Plan.
        - When notifying by telephone the clinical reviewer documents the date, time, and name of the person notified in the case record. A voicemail left for an enrollee will only consist of the name of the CDPHP employee calling, the phone number to return the call and a reference number to the case the call pertains to.

    - **Written notification** – The enrollee, or enrollee's designee, and the enrollee's provider receive written confirmation of the determination. A copy of the written confirmation is

scanned into the enrollee's computerized file.

- In the case of an initial adverse determination, the written notice includes, in addition to all other notification requirements found in applicable law:
  - That the notice constitutes the initial adverse determination, specifically identifying that requested service was not medically necessary or experimental/investigational and the clinical rationale for the decision.
  - How to initiate the standard and expedited appeals process based on the enrollee's contract/plan and specify what, if any, additional information must be provided to, or obtained by, CDPHP in order to render a decision on the appeal.
  - Instruction on filing an external appeal within four months of the final adverse determination letter or Plan letter agreeing to waive the internal appeal process.
  - Statement that CDPHP will not retaliate or take any discriminatory action against the enrollee, or enrollee's designee, because s/he filed an appeal.
  - If enrollee completes the expedited appeal process and CDPHP upholds the denial, the enrollee may file either a standard appeal or an external appeal.
  - If enrollee completes the standard appeal process and CDPHP upholds the denial, the enrollee may apply for an external appeal within 45 days of receipt of the final adverse determination notice.
  - The enrollee and CDPHP may jointly agree to waive the CDPHP appeal process, and the enrollee may apply for an external appeal within 45 days of this agreement.
  - Notice of availability, upon request, of the clinical review criteria relied upon to make such determination.

Attachment B
Medicare Timeframe Requirements

Standard Preauthorization Review

- CDPHP renders a determination and provides notification as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from receipt of the request. Request for additional information is made within three business days of receipt of the coverage request.

- CDPHP may extend the timeframe for up to an additional 14 calendar days if the enrollee, or enrollee's designee, requests the extension. CDPHP may also extend the timeframe for up to 14 calendar days for non-participating providers if they justify a need for additional information and how the extension is in the best interest of the enrollee. The enrollee, or enrollee's designee, must be notified in writing of any extension, including enrollee's right to file an expedited grievance if he/she disagrees with decision to grant an extension.

- CDPHP notifies the enrollee, or enrollee's designee, in writing as expeditiously as the enrollee's health condition requires, but no later than the expiration of any extension that occurs.

Expedited/Urgent Preauthorization Review

- Enrollee, or enrollee's designee, or practitioner may request an expedited review. If requested by a practitioner, review must be expedited. If requested by enrollee, or enrollee designee, CDPHP can determine if expedited review is medically necessary. If CDPHP denies enrollee's request for expedited review, enrollee, or enrollee's designee, is given prompt oral notice of the denial, advising request will be reviewed under the standard timeframe, identifying enrollee's right to file an expedited grievance if he/she disagrees with decision not to expedite, as well as right to resubmit request if physician support to expedite is obtained. Written notice is provided within three calendar days of the decision to not expedite review.

- If decision is made to approve request for expedited review, determination is made as expeditiously as the enrollee's health condition requires, but no later than 72 hours from receipt of the request. Enrollee, or enrollee's designee, and practitioner must be aware of the determination prior to the end of the 72-hour review period. Written notice is provided within three calendar days of the oral notification.

POLICY NAME: REVIEW PROCESS FOR RESOURCE COORDINATION

- If additional information is required from a *non-contract* provider to make a decision, CDPHP must request the necessary information from the *non-contract* provider within 24 hours of the initial request for an expedited organization determination.

- CDPHP may extend the timeframe for up to an additional 14 calendar days if the enrollee, or enrollee's designee, requests the extension. CDPHP may also extend the timeframe for up to 14 calendar days for non-participating providers if they justify a need for additional information and how the extension is in the best interest of the enrollee. The enrollee, or enrollee's designee, must be notified in writing of any extension, including enrollee's right to file an expedited grievance if he/she disagrees with decision to grant an extension.

- CDPHP notifies the enrollee, or enrollee's designee, in writing as expeditiously as the enrollee's health condition requires, but no later than the expiration of any extension that occurs.

Retrospective Review

- CDPHP renders a determination and provides written notification within 30 calendar days of obtaining the request. Up to a 30-day extension may be utilized when all necessary information has not been received within the initial 30 days, provided the enrollee, or enrollee's designee, is notified in writing prior to the expiration of the initial 30-day period of what additional information is needed and the date by which a determination will be rendered.

- CDPHP will only reverse a prior authorized treatment, service, or procedure on retrospective review when:
  - The relevant medical information presented to us upon retrospective review is materially different from the information that was presented during the prior authorization review; **and**
  - The relevant medical information presented to us upon retrospective review existed at the time of the prior authorization but was withheld from or not made available to us; and
  - CDPHP was not aware of the existence of the information at the time of the prior authorization review; **and**
  - Had CDPHP been aware of such information, the treatment service or procedure being requested would not have been authorized. The determination is made using the same specific standards, criteria, or procedures as used during the preauthorization review.

Notification

- All notifications identified above, both verbal and written, are completed within the timeframes identified and in compliance with all other notification requirements found in applicable law

  - **Telephonic notification** – The enrollee, or enrollee's designee, and the enrollee's

provider are notified of the decision.

- In the case of an initial adverse determination, at the time of telephonic notification, the enrollee, or enrollee's designee, and the enrollee's provider are notified of how to initiate the appeal process based on the enrollee's contract/Plan.
- When notifying by telephone the clinical reviewer documents the date, time, and name of the person notified in the case record. A voicemail left for an enrollee will only consist of the name of the CDPHP employee calling, the phone number to return the call and a reference number to the case the call pertains to.

- **Written notification** – The enrollee, or enrollee's designee, and the enrollee's provider receive written confirmation of the determination. A copy of the written confirmation is scanned into the enrollee's computerized file.
  - In the case of an initial adverse determination, the written notice includes how to initiate the standard and expedited appeals process based on the enrollee's contract/ plan and what additional information needs to be provided.
  - In accordance with guidelines from the Centers for Medicare & Medicaid Services (CMS), hospitals are responsible for issuing the Important Message (IM) to an enrollee or designee upon admission and no later than two days prior to discharge. In an enrollee initiates a QIO appeal, CDPHP will issue the Detailed Notice of Discharge. Hospitals will provide a copy of the Detailed Notice of Discharge to the enrollee and maintain a copy in the record.

POLICY NAME: REVIEW PROCESS FOR RESOURCE COORDINATION

Attachment C
Select Plan/HARP and Child Health Plus Timeframe Requirements

In all cases, determinations are made as fast as the enrollee's condition requires. The timeframes below are outside timeframes for determinations.

Preauthorization Reviews

Standard Preauthorization Reviews

- CDPHP renders a determination and provides notification within three business days of receipt of necessary information, but no later than 7 calendar days from receipt of the request. If additional information is needed, it will be requested within the three business days of receipt of request.

- Upon receipt of request for a member who is currently in an inpatient hospital or a skilled nursing facility to go to an acute rehabilitation facility, the turnaround time for this determination is one business day.

- This timeframe may be extended for up to 14 calendar days if the enrollee, enrollee's designee, or practitioner requests an extension, orally or in writing. Requests by enrollees, enrollee's designee, or their practitioners are presumed to be in the enrollee's best interest, thereby ensuring the extension of time for a determination is appropriate. CDPHP does not request an extension of the review period. CDPHP will make a determination and provide notice to the enrollee, or enrollee's designee, and practitioner, by telephone and in writing, as fast as the enrollee's condition requires and within three business days of receipt of necessary information, but no later than the date the extension expires.

Urgent/Expedited Preauthorization Reviews

- Enrollee, or enrollee's designee, or practitioner may request an urgent care/expedited review. If requested by a practitioner, or when determined necessary by CDPHP, review must be expedited. If requested by enrollee, or enrollee designee, CDPHP can determine if expedited review is medically necessary. If CDPHP denies enrollee's request for expedited review, the request will be handled under the standard review timeframes, with written notice to the enrollee, or the enrollee's designee, advising of this, including a description of the timeframes, and a statement that oral interpretation and alternate formats are available and how to access the alternate format.

- CDPHP renders a determination and provides notification as soon as possible, taking into account the medical condition of the enrollee, but no later than 72 hours from receipt of the request.

- This timeframe may be extended for up to 14 calendar days if the enrollee, enrollee's

designee, or practitioner requests an extension, orally or in writing. Requests by enrollees, enrollee's designee, or their practitioners are presumed to be in the enrollee's best interest, thereby ensuring the extension of time for a determination is appropriate. CDPHP does not request an extension of the review period. CDPHP will make a determination and provide notice to the enrollee, or enrollee's designee, and practitioner, by telephone and in writing, as fast as the enrollee's condition requires and within three business days of receipt of necessary information, but no later than the date the extension expires.

Concurrent Review

Standard Concurrent Reviews

- CDPHP renders a determination and provides notification within one business day of receipt of necessary information, but no more than 14 calendar days from receipt of the request. Written notification includes number of extended services approved, the new total of approved services, date of onset of services and next review date.

- Upon receipt of request for a member who is currently in an inpatient hospital or a skilled nursing facility to go to an acute rehabilitation facility, the turnaround time for this determination is one business day.

- This timeframe may be extended for up to 14 calendar days if the enrollee, enrollee's designee, or practitioner requests an extension, orally or in writing. Requests by enrollees, enrollee's designee, or their practitioners are presumed to be in the enrollee's best interest, thereby ensuring the extension of time for a determination is appropriate. CDPHP does not request an extension of the review period. CDPHP will make a determination and provide notice to the enrollee, or enrollee's designee, and practitioner, by telephone and in writing, as fast as the enrollee's condition requires and within one business day of receipt of necessary information, but no later than the date the extension expires.

Urgent/Expedited Concurrent Reviews

- CDPHP renders a determination and provides notification as soon as possible, taking into account the medical condition of the enrollee, but no later than one business day after receipt of necessary information, not to exceed 72 hours after receipt of the request. Written notification includes number of extended services approved, the new total of approved services, date of onset of services and next review date.

- This timeframe may be extended for up to 14 calendar days if the enrollee, enrollee's designee, or practitioner requests an extension, orally or in writing. Requests by enrollees, enrollee's designee, or their practitioners are presumed to be in the enrollee's best interest, thereby ensuring the extension of time for a determination is appropriate. CDPHP does not request an extension of the review period. CDPHP will make a determination and provide

notice to the enrollee, or enrollee's designee, and practitioner, by telephone and in writing, as fast as the enrollee's condition requires and within one business day of receipt of necessary information, but no later than the date the extension expires.

Inpatient Substance Use Disorder Treatment Reviews (Special conditions apply)

- CDPHP will make a determination regarding a request for inpatient substance use disorder treatment submitted at least 24 hours prior to discharge from an inpatient admission within 24 hours of receipt of the request and will provide coverage for the inpatient substance use disorder treatment while determination is pending.
- Coverage for inpatient admission for substance use disorder treatment at an OASAS-licensed facility that participates in the CDPHP network is not subject to preauthorization.

Inpatient Mental Health Admissions (Special conditions apply.)

- Coverage for inpatient admission to a participating facility within New York State, for the treatment of a mental health condition, is not subject to preauthorization. For children under age 18, coverage may be subject to concurrent review on day 15 of the inpatient admission if the facility notifies CDPHP of both the admission and the initial treatment plan within two business days of admission. The entire stay may be reviewed, including the initial 14-day period, to determine whether the admission and treatment is medically necessary. Care for members discharged prior to day 15 may be reviewed retrospectively if one or more specific quality or clinical triggers are met. The specific trigger met will be documented by the reviewer. Facilities are required to notify CDPHP of discharge within 24 hours of the discharge date and retrospective review may begin when CDPHP is notified of the discharge. *Applies to member contracts issued or renewed on or after 1/1/20. This does not apply to self-funded (ASO) or Medicare Choices member contracts. Applies to members under age 18 at the time of their hospitalization.

Timeframes for Actions Other Than Service Authorizations

Reductions/Terminations of Approved Care

- CDPHP will notify the enrollee, or the enrollee's designee, of any decision to reduce or end coverage of previously authorized service within an authorization period. CDPHP will provide written notice to the enrollee, or enrollee's designee, at least 10 days prior to the intended action, except:
  - The period of advance notice is shortened to five days in cases of confirmed enrollee fraud; **or**
  - The contractor may mail notice not later than date of the action for the following:
    - The death of the enrollee;

  - A signed written statement from the enrollee requesting service termination or giving information requiring termination or reduction of services (where the Enrollee understands that this must be the result of supplying the information);
  - The enrollee's admission to an institution where the enrollee is ineligible for further services;
  - The enrollee's address is unknown, and mail directed to the enrollee is returned stating that there is no forwarding address;
  - The enrollee has been accepted for Medicaid services by another jurisdiction; or
  - The enrollee's physician prescribes a change in the level of medical care.
- For long term services and supports, when CDPHP intends to reduce, suspend, or terminate a previously authorized service, or issue an authorization for a new period that is less in level or amount than previously authorized, CDPHP will not set the effective date of the action to fall on a non-business day.

Retrospective Review

- CDPHP renders a determination and provides notification within 30 calendar days of obtaining the request. Up to a 15-day extension may be utilized when all necessary information has not been received within the initial 30 days, provided the enrollee, or enrollee's designee, is notified in writing prior to the expiration of the initial 30-day period of what additional information is needed and the date by which a determination will be rendered. The enrollee, or enrollee's designee, is given 45 days from receipt of the extension notice to provide the necessary information.

- CDPHP will only reverse a prior authorized treatment, service, or procedure on retrospective review when:
  - The relevant medical information presented to us upon retrospective review is materially different from the information that was presented during the prior authorization review; and
  - The relevant medical information presented to us upon retrospective review existed at the time of the prior authorization but was withheld from or not made available to us; and
  - CDPHP was not aware of the existence of the information at the time of the prior authorization review; and
  - Had CDPHP been aware of such information, the treatment service or procedure being requested would not have been authorized. The determination is made using the same specific standards, criteria or procedures as used during the preauthorization review.

- In the case of a contractual denial, the written notice is generated on the day the determination is made.

Notification

POLICY NAME: REVIEW PROCESS FOR RESOURCE COORDINATION

- All notifications identified above, both verbal and written, are completed within the timeframes identified and in compliance with all other notification requirements found in applicable law.

- **Telephonic notification** – the enrollee, or enrollee's designee, and the enrollee's provider are notified of the decision. Verbal notification is not provided for retrospective.
  - In the case of an initial adverse determination, at the time of telephonic notification, the enrollee, or enrollee's designee, and the enrollee's provider are notified of how to initiate the appeal process based on the enrollee's contract/Plan.
  - When notifying by telephone the clinical reviewer documents the date, time, and name of the person notified in the case record. A voicemail left for an enrollee will only consist of the name of the CDPHP employee calling, the phone number to return the call and a reference number to the case the call pertains to.

- **Written notification** – The enrollee, or enrollee's designee, and the enrollee's provider receive written confirmation of the determination. The notice to the provider contains the same information as the notice given to the enrollee. A copy of the written confirmation is scanned into the enrollee's computerized file.
  - Notices are written in easily understood language and are accessible to non-English speaking and visually impaired enrollees.
  - Notice identifies that oral interpretation and alternate formats of written material for enrollee with special needs are available and how to access the alternate formats.
  - The right of the enrollee to contact the New York State Department of Health (NYSDOH) with his/her complaint, including the NYSDOH's toll-free number for complaints
  - In the case of an initial adverse determination, the written notice includes/identifies, in addition to all other notification requirements found in the New York State Department of Health action and grievance system requirements (Appendix F), the following:
    - That the notice constitutes the initial adverse determination.
    - For determinations that do not involve medical necessity or experimental/investigational service:
      - Description of action CDPHP has taken or intends to take;
      - Reasons for the action, including clinical rationale if applicable.
    - For determinations that involve medical necessity or experimental/investigational service, a statement of clinical rationale that identifies:
      - Enrollee and nature of his/her medical condition;
      - Medical service, treatment or procedure requested; and
      - The basis on which the reviewer determined that the service, treatment, or procedure is or was not medically necessary or experimental/investigational, which demonstrates that reviewer considered enrollee specific clinical information in the determination.
    - Statements of reasons and clinical rationale is sufficiently specific to enable enrollee, or the enrollee's designee, and enrollee's health care provider to

make an informed judgement regarding whether or not to appeal the adverse determination, and the grounds for such an appeal.

- Statement of what, if any, additional information must be provided to, or obtained by, CDPHP in order to render a decision on the appeal.
- Process and timeframes for filing appeal with CDPHP, including explanation that an expedited review of the appeal can be requested if a delay would significantly increase the risk to the enrollee's health, and a toll-free number for filing an oral appeal.
- Statement that CDPHP will not retaliate or take any discriminatory action against the enrollee, or enrollee's designee, because s/he filed an appeal.
- The right of the enrollee to designate a representative to file appeals on his/her behalf.
- Instruction on filing an external appeal within four months of the final adverse determination letter or plan letter agreeing to waive the internal appeal process.
- Timeframes within which the appeal determination must be made.
- If enrollee completes the expedited appeal process and CDPHP upholds the denial, the enrollee may file either a standard appeal or an external appeal.
- If enrollee completes the standard appeal process and CDPHP upholds the denial, the enrollee may apply for an external appeal within 45 days of receipt of the final adverse determination notice.
- The enrollee and CDPHP may jointly agree to waive the CDPHP appeal process, and the enrollee may apply for an external appeal within 45 days of this agreement.
- Notice of availability, upon request, of the clinical review criteria relied upon to make such determination.
- The notice entitled "Managed Care Action Taken" for denial of benefits or for termination or reduction in benefits, as applicable, containing the enrollee's fair hearing (does not apply to Child Health Plus) and aid continuing rights.

Policy/Procedure Name: Ryoncil (remestemcel-l-rknd) **Control Number: 1350/20.000570**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Ryoncil ™ (remestemcel-L) is an allogeneic bone marrow-derived mesenchymal stromal cell therapy indicated for the treatment of pediatric steroid-refractory acute graft-versus-host disease (SR-aGVHD) in patients 2 months ≤ 18 years of age. Ryoncil is administered via intravenous (IV) infusion, typically in a series of eight doses over four weeks.

The exact mechanism of action of Ryoncil is not fully understood; however, it is believed to function through immunomodulatory and anti-inflammatory effects. Clinical studies suggest that Ryoncil interacts with immune effector cells such as T cells and dendritic cells to reduce inflammatory cytokine production, support tissue repair, and promote immune homeostasis. These processes are the crux in the management of GVHD.

Acute GVHD is a serious and potentially life-threatening complication of allogeneic hematopoietic stem cell transplantation (HSCT) that can involve one or more organ systems (e.g., the skin, gastrointestinal tract, and liver). Steroids are the first-line treatment; however, up to 50% of pediatric patients do not adequately respond. These cases are considered steroid-refractory and are at high risk for morbidity and mortality.

Approval of Ryoncil was based on the results from a single-arm, phase III trial (MSB-GVHD001; NCT02336230) that included 54 pediatric patients with grade B-D SR-aGVHD after receiving allogeneic HSCT. The underlying reasons for allogeneic HSCT were hematologic malignancies (67%) and non-malignant disease (37%). The trial demonstrated an overall response rate of 70% (n = 38/54).

According to the National Comprehensive Cancer Network (NCCN) guidelines, treatment of SR-aGVHD involves consideration of several second-line agents. There is, however, no single standard approach. Options may include ruxolitinib, anti-thymocyte globulin, and extracorporeal photopheresis. Ryoncil has not yet been added to the NCCN guidelines.

Summary

Effective Date of Policy:	6/11/25
Indications	Steroid-refractory graft-versus-host-disease (SR-aGVHD)
ICD10 Diagnosis Codes:	D89.810
HCPCS Code	J3402
Availability:	Single-Use Vials: $25x10^6$ MSCs in 3.8mL
Duration:	4 weeks

Required Criteria for Approval

1. Must be prescribed by or in consultation with an oncologist, hematologist, BMT specialist, or other qualified health professionals experienced in the management of Steroid Refractory acute Graft versus Host Disease (SR-aGVHD) AND
2. Patient must be ≥ 2 months to 17 years of age AND
3. Must have a diagnosis of Steroid Refractory acute Graft versus Host Disease (SR-aGVHD) following receipt of allogeneic hematopoietic stem cell transplantation (HSCT) AND
4. Must have Grade B–D aGvHD as defined using the modified Glucksberg grading system or the International Blood and Marrow Transplantation Registry (IBMTR). Objective documentation must be submitted confirming grade (severity) of disease (including but not limited to skin involvement [BSA], serum bilirubin levels, and stool volume [mL/day])
    a. Grade III-IV (modified Glucksberg)/C-D (IBMTR) disease involving the skin, liver, or gastrointestinal (GI) tract OR
    b. Grade II (modified Glucksberg)/B (IBMTR) disease involving the liver or gastrointestinal (GI) tract with or without concomitant skin disease AND
5. Must have documentation of steroid refractory defined as progression within 3 days or no improvement within 7 days of consecutive treatment with 2 mg/kg/day methylprednisolone (or prednisone dose equivalent)
6. Must have a medical reason why Jakafi AND all NCCN Category 2A recommended alternative therapies for Steroid Refractory acute Graft versus Host Disease (SR-aGVHD) cannot be used (e.g., ECP, basiliximab, infliximab, ATG).

a. A letter of medical necessity must be submitted confirming that all alternative therapies including Jakafi and NCCN category 2A alternative therapies are not appropriate or suitable considering the specific organ involvement, severity of SR-aGVHD, prior treatment history, comorbidities, and the institutional experience. AND

7. Baseline documentation of all organ involvement, including unaffected organs at the time of diagnosis, will be required. Incomplete documentation may result in an inability to evaluate the patient's eligibility for additional or repeat treatment.
8. Treatment Response Evaluation
    a. Response should be evaluated
        i. 28 days after the first dose for Initial Treatment
        ii. 56 days after Continued Therapy (if applicable) AND
    b. Objective documentation must be submitted confirming the patient's response to therapy (including but not limited to skin involvement [BSA], serum bilirubin levels, and stool volume [mL/day]) AND
    c. Response must be assessed across all organ systems that were documented as baseline and will be identified as one of the following:
        i. Partial or Mixed Response
            1. Partial Response – defined as organ improvement of at least one stage without worsening of any other organ
            2. Mixed response – defined as improvement in at least on evaluable organ stage with worsening in another
        ii. Complete Response - defined as a resolution of acute GVHD in all involved organs
        iii. No Response - defined as no change in any organ stage in any organ system and no improvement in organ stage.
9. Requirements for Continued or Additional (Recurrence) Treatment
    a. For Continued Treatment, the patient must have had a Partial or Mixed Response (as defined in 8.c.i.) to Initial Treatment OR
    b. For Additional (Recurrence) Treatment, the patient must have achieved a Complete Response (as defined in 8.c.ii.) to treatment (Initial or Continued) AND
        i. The patient must have a return or worsening of SR-aGVHD symptoms consistent with the requirements in criteria 4 (above)
            1. a) Occurring more than 28 days after the first infusion of Initial Therapy OR
            2. b) Occurring more than 56 days after achieving Complete Response to continued therapy AND
        ii. The patient must have not initiated another systemic therapy for Steroid Refractory acute Graft versus Host Disease (SR-aGVHD)
    c. No Response: Additional treatment will not be authorized for patients who had No Response to the initial treatment course.
10. Approved Dosage:
    a. Initial Treatment: 2×10^6 mesenchymal stromal cells (MSC)/kg body weight per intravenous infusion given twice a week for 4 consecutive weeks for a total of 8 infusions
    b. Continued or Additional (Recurrence) Treatment
        i. For Partial or Mixed Response: 2×10^6 mesenchymal stromal cells (MSC)/kg body weight per intravenous infusion given once weekly for an additional 4 weeks for a total of 4 additional infusions (12 infusions total)
        ii. For recurrence of SR-aGVHD after Complete Response: 2×10^6 mesenchymal stromal cells (MSC)/kg body weight per intravenous infusion given twice a week for an additional 4 consecutive weeks for a total of 8 additional infusions (16 infusions total)
11. Approval Timeframes:
    a. Initial Treatment: 4 weeks (28-days)
    b. Repeated Administration
        i. For Partial or Mixed Response: 4 weeks (28-days)
        ii. For recurrence of SR-aGVHD after Complete Response: 4 weeks (28-days)
    c. The approved dosage (10a,b) are provided per lifetime
12. Ryoncil will not be approved for uses beyond FDA approved indications including but not limiting to the treatment of chronic GVHD, non-SR-aGVHD, SR-aGVHD not associated with allogeneic HSCT, concomitant use with other systemic first-line or second-line SR-aGVHD therapies, adult patients with SR-aGVHD.

Considerations

Prior authorization must be obtained through the CDPHP pharmacy department.

References

		Accessed
1	Rynocil [prescribing information]. New York, NY: Mesoblast, Inc.; 2025 Jan.	5/2025
2	Kurtzberg J, et al. A Phase 3, Single-Arm, Prospective Study of Remestemcel-L, Ex Vivo Culture-Expanded Adult Human Mesenchymal Stromal Cells for the Treatment of Pediatric Patients Who Failed to Respond to Steroid Treatment for Acute Graft-versus-Host Disease. Biol Blood Marrow Transplant. 2020 May;26(5):845-854. doi: 10.1016/j.bbmt.2020.01.018.	5/2025
3	National Comprehensive Cancer Network®. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Hematopoietic Cell Transplantation V1.2025. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed [May 20, 2025]. To view the most recent and complete version of the guideline, go online to NCCN.org.	5/2025

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE CHOICES: Subject to all terms and conditions noted in above application if administered under the medical benefit

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 5/14/2026

Date	Notes
6/2025	New Policy
5/2026	Reformatted policy

This Pharmacy Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI), and Capital District Physicians' Healthcare Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

Policy/Procedure Name: Ryplazim (plasminogen, human) **Control Number: 1350/20.000439**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

RYPLAZIM (plasminogen, human-tvmh) is plasma-derived human plasminogen indicated for the treatment of patients with plasminogen deficiency type 1 (hypoplasminogenemia).

Plasminogen deficiency (PLGD; hypoplasminogenemia [HPG]) is an autosomal recessive multisystem disorder characterized by formation of fibrinous pseudomembranes on mucous membranes throughout the body. Plasminogen is the precursor to plasmin, a serine protease that cleaves fibrin and other proteins to restore blood vessel patency and maintain the extracellular matrix following establishment of hemostasis. Plasmin is important for regulating the inflammatory response as well as wound healing and tissue remodeling. The spectrum of this disease is not comprehensively described and is thought to be underdiagnosed. A clinical distinction is made between PLG variants (The *PLG* gene encodes plasminogen) that cause hypoplasminogenemia (reduced levels of plasminogen, type I disease) versus those that cause a dysfunctional protein (type II disease).

Type I disease: reduced protein production (quantitative deficiency, hypoplasminogenemia), plasminogen levels and functional activity both reduced.

Type II disease (more common): dysfunctional protein (qualitative deficiency, dysplasminogenemia), plasminogen levels normal but activity is reduced.

The clinical presentation involves many different body systems and is quite varied. Ligneous conjunctivitis (pseudomembrane formation in the conjunctiva of the eye) is the most easily recognizable and the most common presentation (80-90% of those with PLGD and often presenting finding). Other common sites include the GI tract, ear, and mouth (gingiva, tonsils), and urogenital. Also, skin lesions have been reported in areas of sun exposure, with a specific rare condition noted including juvenile colloid milium. More serious body systems affected include the respiratory tract where both upper and lower lesions can occur, and results can be fatal (airway obstruction).

Evaluation for disease involves laboratory testing of both plasminogen activity and antigen levels. The normal range of plasminogen activity is 70-130 percent, activity levels of < 40-45 percent is consistent with deficiency. In terms of antigen levels, these are measured using an immunologic assay with a normal range of 6-25 mg/dL. It is to be noted that normal ranges are lower in neonates and infants, and one should reference age-specific normal ranges.

Ryplazim is made from purified human plasma and works to increase the level of plasminogen in the blood to temporarily correct the plasminogen deficiency and reduce or resolve lesions. In Ryplazim's Phase 2/3 clinical trial, all 14 patients achieved target trough plasminogen activity levels and saw improvement in the number and/or size of their lesions by Week 48. Ryplazim was well tolerated, with no deaths or serious adverse events observed in its clinical trials. The most commonly reported adverse effects in Ryplazim Trial 2 included headache (43%), nasopharyngitis (36%), abdominal pain (29%), nausea (29%), diarrhea (21%), rhinorrhea (21%), and cough (21%). Three patients in Ryplazim Trial 2 developed anti-plasminogen antibodies following treatment with Ryplazim; however, trough plasminogen activity levels suggested that these antibodies were not neutralizing antibodies (i.e., inhibitors) to plasminogen. Patients using Ryplazim should be monitored for a loss of clinical effect (new or recurrent lesions), and regular trough plasminogen activity levels should be obtained.

Other management concepts beyond Ryplazim or plasminogen replacement include Fresh Frozen Plasma (FFP), immunosuppressants (corticosteroids, azathioprine, cyclosporine A), hormone therapy (estrogens, gestagens, androgens), anticoagulants, among other therapies.

Summary

Effective Date of Policy:	2/12/2026
Indications	Plasminogen deficiency type 1 (hypoplasminogenemia)
ICD10 Diagnosis Codes	E88.02
HCPCS Code	J2998

Availability	*Single-dose 50-mL vial containing 68.8 mg of plasminogen as a lyophilized powder for reconstitution with 12.5 mL of Sterile Water for Injection. After reconstitution, each vial will contain 5.5 mg/mL of plasminogen.*
Duration	Initial: 3 months Continuation: 3-12 months

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy.

Specific Drug	Inclusion Criteria	Recommended Dosing
Indication Plasminogen deficiency type 1 (hypoplasminogenemia) (FDA approval) ICD10: E88.02	• Enrollee is at least 11 months of age. • Therapy is being requested by a hematologist, geneticist, pulmonologist, ophthalmologist, or prescriber specializing in plasminogen deficiency type 1 • Must have diagnosis of plasminogen deficiency type 1 AND • Must have baseline plasminogen activity level < 45% (Note: if the patient is receiving plasminogen supplementation with fresh frozen plasma, allow for a 7-day washout period before obtaining baseline plasminogen activity level.) • Must have documented history of lesions consistent with a diagnosis of congenital plasminogen deficiency (i.e., ligneous conjunctivitis, ligneous gingivitis, growths in the mucous membrane of the middle ear, respiratory tract, gastrointestinal tract) • Initial approval will be for 12 weeks o A quantity limit sufficient to allow for 6.6 mg/kg body weight administered every 2 days will be authorized for 12 weeks.	• 6.6 mg/kg body weight given every two to four days via intravenous infusion.

Continuation Criteria

Recertification after the initial 12-week approval will be reviewed as follows:

- Must provide documentation of the trough plasminogen activity level that was obtained approximately 72 hours after the initial dose of Ryplazim and prior to the second dose to confirm dosing frequency used in the initial 12-week approval period aligns with FDA-labeling
- Duration of continued approval will be dependent on the patient's initial 12-week response:
  - For patients who have documented resolution of lesions, approval will be authorized for 12 months. Quantity limit authorizations (dose and frequency) will be based on FDA-approved labeling
  - For patients who do not have resolution of lesions or have new or recurrent lesions, continued approval will be authorized for an additional 12-weeks along with request for additional quantity to optimize dosing frequency. A quantity limit sufficient to allow for 6.6 mg/kg body weight administered every 2 days will be authorized for this additional 12-week period.
    - If patient has a documented clinical efficacy after the additional 12 weeks (i.e., resolution of lesions, improvement in size/number of lesions, trough plasminogen activity level > 10% above baseline trough level), continued approval will be authorized for 12 months. Quantity limit authorizations (dose and frequency) will be based on FDA-approved labeling.
    - Ryplazim will not be authorized beyond 24 weeks of therapy if confirmed (repeat) trough plasminogen activity level is
- Yearly recertification requests will require:
  - Documentation that the patient has maintained a clinical response to treatment
  - Quantity limit authorizations (dose and frequency) will be based on FDA-approved labeling.

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.

References

		Updated	Accessed
1	Shapiro, AD. Plasminogen deficiency. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc.	8/2023	11/2023
2	Kizilocak H, et al. Treatment of plasminogen deficiency patients with fresh frozen plasma. Pediatr Blood Cancer. 2018;65:e26779.	2/2018	10/2023
3	Ryplazim [package insert]. Laval, Quebec, Canada: Prometic Bioproduction Inc; June 2021.	6/2021	10/2024
4	FDA News Release: FDA Approves First Treatment for Patients with Plasminogen Deficiency, a Rare Genetic Disorder. June 4, 2021. Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-patients-plasminogen-deficiency-rare-genetic-disorder	6/2021	10/2023
5	Ryplazim (Plasminogen, Human) Clinical Trial (NCT03642691). Available at: https://clinicaltrials.gov/ct2/show/NCT03642691	12/2022	10/2023
6	Ryplazim (Plasminogen, Human) Clinical Trial (NCT02690714). Available at: https://clinicaltrials.gov/ct2/show/NCT02690714	8/2021	10/2023
7	Rare Bleeding Disorders. Rare Coagulation Disorders. Plasminogen Deficiency. Available at: https://rarecoagulationdisorders.org/disorder/plasminogen-deficiency/medication-treatment/		10/2024
8	NORD Rare Disease Database: Congenital Plasminogen Deficiency. Available at: https://rarediseases.org/rare-diseases/congenital-plasminogen-deficiency/	1/2024	10/2024

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE CHOICES:	Subject to all terms and conditions noted in above application if administered under the medical benefit.
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 2/12/2026

New: 2/2022

Revised	Reviewed
2/2024, 2/2026	2/2023, 2/2025

Revision Date	Changes Made
2/2024	Removed criteria for corticosteroids and other immunosuppressants Added criteria for hepatitis vaccination
2/2026	Updated provider type from only hematologist to other specialties Removed trial of FFP, abnormally low plasminogen antigen plasma level < 6 mg/dL, HepA/B vaccination Updated recertification criteria Removed exclusion criteria section

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MEDICAL POLICY

Medical Policy Title	**Sacral Nerve Stimulation**
Policy Number	**7.01.10**
Current Effective Date	**September 1, 2026**
Next Review Date	**November 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Sacral Nerve Stimulation for the Treatment of Urinary Conditions

I. Sacral nerve stimulation is a **medically appropriate** treatment option for individuals ≥ 16 years who meet specific criteria for **BOTH** Trial Stimulation and Permanent Placement:

A. Trial Stimulation

1. Individual has a diagnosis of chronic, idiopathic, non-obstructive, urinary retention who meet **ANY** of the following criteria:
   a. Failed clean-self-catheterization; or
   b. Have not tolerated clean-self-catheterization;

   OR

2. Individual has a diagnosis of urgency-frequency syndrome, overactive bladder, or urge incontinence that is unrelated to a neurological condition, who meets the **ALL** of the following criteria:
   a. Symptoms have persisted for more than six (6) months; and
   b. Documentation supports the following:
      i. Failure of conventional treatments (e.g., pelvic floor exercises, lifestyle therapy, bladder training); **and**
      ii. Failure of **ONE** of the following pharmacologic treatments.
         a) Two (2) different anticholinergics; **or**
         b) One (1) anticholinergic and one (1) beta-3 adrenergic agonist;

AND

B. Permanent Placement

1. Trial demonstrated at least 50% improvement in voiding incontinence and urinary symptoms; **or**
2. Trial demonstrated a 50% decrease in residual urine volume.

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II. Sacral nerve stimulation is considered **investigational** for **ALL** other indications, including, but not limited to, the following:

A. Stress incontinence;

B. Urge incontinence due to a neurological condition (e.g., diabetic neuropathy, multiple sclerosis, spinal cord injury);

C. Other types of chronic voiding dysfunction.

Sacral Nerve Stimulation for the Treatment of Fecal Incontinence

III. Sacral nerve stimulation is a **medically appropriate** treatment option for individuals ≥ 16 years who have fecal incontinence, when **ALL** of the following indications are met:

A. Have demonstrated an appropriate response to trial stimulation. An appropriate response is defined as at least a 50% improvement in voiding/incontinence for fecal symptoms;

B. Chronic fecal incontinence of greater than two (2) episodes per week with a duration greater than six (6) months (or 12 months, if occurring after vaginal childbirth);

C. Documented failure of prescribed conservative therapies (e.g., pharmacologic treatments, dietary changes) performed for more than three (3) months;

D. Incontinence unrelated to an anorectal malformation, chronic inflammatory bowel disease, or neurologic condition such as peripheral neuropathy or complete spinal cord injury.

Device Repair

IV. Repair of a medically necessary sacral nerve stimulator or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** of the following:

1. Date of device implantation/initiation;
2. Manufacturer warranty information, if applicable;
3. Attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device;

B. The device is no longer functioning adequately; and **BOTH** of the following criteria are met:

1. Inadequate function interferes with activities of daily living; **and**
2. Repair is expected to make the equipment fully functional (as defined by manufacturer).

C. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

Device Replacement

V. Replacement of a medically necessary sacral nerve stimulator or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

   A. The device is no longer functioning adequately and has been determined to be non-repairable, or the cost of the repair is in excess of the replacement cost;

   B. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

VI. The replacement of a properly functioning sacral nerve stimulator, its components or accessories, is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing.

VII. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

VIII. Accessories or components for sacral nerve stimulators that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary** or **investigational** by the Health Plan.

IX. Sacral nerve stimulation is considered **investigational** for **ALL** other indications, including, but not limited to, the following:

   A. Stress incontinence;

   B. Urge incontinence due to a neurological condition (e.g., diabetic neuropathy, multiple sclerosis, spinal cord injury);

   C. Other types of chronic voiding dysfunction;

   D. Constipation;

   E. Chronic pelvic pain.

X. Bilateral sacral nerve stimulation is considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Urinary Incontinence

Urinary voiding dysfunction is usually defined as the inability to control urination. Urinary voiding disorders are generally divided into five (5) types, depending on the pathophysiology involved: urge incontinence (a subtype of which is urgency-frequency syndrome), overflow incontinence (also known as urinary retention), stress incontinence, mixed incontinence, and functional incontinence. Urge incontinence is defined as leakage of urine when there is a strong urge to void. Urgency-frequency is an uncontrollable urge to urinate, resulting in very frequent, small volumes. Urgency-frequency is a prominent symptom of interstitial cystitis. The term "overactive" bladder is frequently used when describing the symptoms of urgency-frequency and urge incontinence. Urinary retention is the inability to completely empty the bladder of urine.

Sacral nerve stimulation (SNS), or sacral neuromodulation (SNM), is defined as the implantation of a permanent device that modulates the neural pathways controlling bladder or rectal function. The SNS device consists of an implantable pulse generator that delivers controlled electrical impulses. This pulse generator is attached to wire leads that connect to the sacral nerves, most commonly the S3 nerve root. Two external components of the system help control the electrical stimulation. A control magnet is kept by the patient and can be used to turn the device on or off. A console programmer is kept by the physician and used to adjust the settings of the pulse generator.

Treatment using SNS is one of several alternative modalities for patients with urinary urge incontinence, significant symptoms of urgency-frequency, or non-obstructive urinary retention who have failed behavioral (e.g., prompted voiding) and/or pharmacologic therapies.

Before implantation of the permanent device, patients undergo an initial testing phase to estimate potential response to treatment. The first type of testing developed was percutaneous nerve evaluation (PNE). This procedure is done with the patient under local anesthesia, using a test needle to identify the appropriate sacral nerve(s). Once identified, a temporary wire lead is inserted through the test needle and left in place for four to seven days. This lead is connected to an external stimulator, which is carried in the patient's pocket or on the patient's belt. Patients who show a 50% or greater reduction in symptom frequency are deemed eligible for the permanent device. The second type of testing is a two-stage surgical procedure. In stage one, a quadripolar-tined lead is implanted and tested for as long as several weeks. Patients who show a 50% or greater reduction in symptom frequency can proceed to stage two of the surgery, which is the permanent implantation of the neuromodulation device. The two-stage surgical procedure has been used in various ways, including as an alternative to PNE, for patients who failed PNE, for patients with an inconclusive PNE, or to further refine patient selection for patients who had a successful PNE. Approximately 63% of patients have a successful testing phase. The permanent device is implanted under general anesthesia, with the pulse generator inserted in the upper gluteal region.

Fecal Incontinence

Fecal incontinence is defined as the uncontrolled passage of feces or gas for at least one month's duration, in an individual of at least four (4) years of age, who had previously achieved control. Severity may range from involuntary passage of flatus to complete loss of bowel control.

SUPPORTIVE LITERATURE

Urinary Incontinence

In 1999, the FDA approved clinical studies of the Medtronic InterStim System for sacral nerve stimulation, allowing a large multicenter, randomized clinical trial to evaluate the safety and effectiveness of SNS for treating urinary urgency/frequency. Patients underwent test stimulation, and those showing ≥ 50% improvement were randomized into treatment or control groups. For urinary retention, 83% of treated patients achieved successful outcomes at six (6) months, with sustained improvements observed at 12 and 18 months. Similarly, patients with urgency/frequency symptoms experienced significant reductions in daily voids, increased voided volumes, and reduced urgency, with 88% achieving clinical success at six (6) months. Safety data from 581 patients and 219 implants revealed that most adverse events were resolved, with a surgical revision rate of 33.3%. The therapy demonstrated reversible effects and did not compromise urologic function. Overall, the InterStim System was found to be safe and effective for patients who had failed or could not tolerate conservative treatments.

A study by Groen et al (2011) provided the longest follow-up data on SNM for women with refractory idiopathic urge urinary incontinence. In this longitudinal series, 60 patients were followed for at least five years after receiving the therapy. Treatment success was defined as a minimum 50% reduction in daily incontinent episodes or pad usage. At one (1) month, 87% of patients met this criterion, but the success rate declined to 62% by the five-year mark. Complete continence was achieved by 25% of patients at one (1) month and 15% at five (5) years. Despite the decrease in efficacy over time, 80% of the women continued using the device at five (5) years. Adverse events were reported in 53% of patients most commonly related to hardware issues or discomfort, and 15 patients required a total of 23 reoperations. Most pain-related complications were managed conservatively.

Schwarztuch et al (2024) evaluated the feasibility, safety, and efficacy of SNM in patients with neurogenic lower urinary tract dysfunction (NLUTD) and/or fecal incontinence (FI), comparing outcomes to those with non-neurogenic conditions. Conducted as a retrospective single center study from 2017 to 2022, 67 patients underwent two-stage implantation of the InterStim II device. Of these patients, 16 had underlying neurologic conditions such as multiple sclerosis, spinal stenosis, or Parkinson's disease. Clinical success was defined as a ≥ 50% improvement in catheterizations or incontinence episodes. Results showed comparable success rates between the neurogenic (50%) and non-neurogenic (56.9%) groups, with no significant differences in surgical duration, follow-up, or device removal rates. Predictors of success included a maximal cystometric capacity below 430 mL and detrusor contraction during voiding. SNM was well tolerated in neurogenic patients, with low adverse event rates and no infections reported. Limitations of the study include a small sample size, heterogeneous patient characteristics, and a mid-term follow-up duration. Overall, the study supports SNM as a viable treatment option for carefully selected neurogenic patients who are refractory to conservative therapies, demonstrating similar outcomes to non-neurogenic populations.

Fecal Incontinence (FI)

Wexner et al (2010) evaluated the safety and effectiveness of SNS in a large patient population under an FDA approved investigational protocol for individuals with fecal incontinence. Patients who experienced a ≥ 50% improvement during the test stimulation phase received permanent

implantation of the InterStim Therapy device (Medtronic, Minneapolis, MN). The primary efficacy endpoint was defined as achieving therapeutic success ≥ 50% reduction in weekly incontinent episodes at 12 months compared to baseline. Of the 133 patients who underwent test stimulation, 90% were successful. A total of 120 patients (110 female), with a mean age of 60.5 years and an average FI duration of 6.8 years, received permanent implants. The mean follow-up duration was 28 months (range: 2.2–69.5 months). At 12 months, 83% of subjects met the criteria for therapeutic success (95% CI: 74%–90%; P < 0.0001), with 41% achieving complete continence. At 24 months, the success rate increased to 85%. The average number of weekly incontinent episodes decreased from 9.4 at baseline to 1.9 at 12 months and 2.9 at 24 months. No unexpected adverse device effects were reported.

Bharucha and colleagues (2017) published an American Gastroenterological Association (AGA) clinical practice update expert review of best practices for the management of fecal incontinence using surgical interventions and device-aided therapy. They advised that SNS should be considered for patients with moderate-to-severe fecal incontinence in whom symptoms have not responded after a three-month or longer trial of conservative measures. In addition, the authors found no evidence that SNS improves bowel symptoms or rectal evacuation in defecatory disorders.

Vollebregt et al (2024) conducted a randomized, double-blind, multicenter crossover trial to evaluate the clinical efficacy and underlying mechanisms of subsensory SNM in adults with chronic fecal incontinence (FI) who had failed conservative treatment. The study included two 16-week treatment periods (active SNM vs. sham stimulation), followed by a 26-week open-label phase, totaling 58 weeks. A mechanistic sub-study using magnetoencephalography (MEG) assessed brain-anorectum connectivity. Due to COVID-19 disruptions, 39 participants were randomized, with 16 completing the primary outcome assessment. The primary endpoint reduction in FI episodes per week, showed a non-significant improvement with SNM compared to sham (−0.7 episodes/week; p = 0.06). However, sensitivity analysis suggested a potentially meaningful effect (−0.9 episodes/week; p = 0.04). Open-label follow-up revealed sustained symptom improvement, with FI episodes decreasing from 6.2 to 3.2 per week, along with marked reductions in urgency and loperamide use. Mechanistic findings showed no significant differences in cortical responses between SNM and sham stimulation or between patients and healthy controls. MEG data confirmed bilateral sensorimotor activation during anal stimulation and voluntary squeeze, but SNM did not produce measurable changes in brain activity.

PROFESSIONAL GUIDELINE(S)

The American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin for Urinary Incontinence in Women (2015) suggests consideration of sacral neuromodulation for patients with recalcitrant urinary urge incontinence who have failed other conservative measures.

The 2019 American Urological Association guidelines on the diagnosis and treatment of overactive bladder states that sacral neuromodulation may be offered as a third-line treatment in carefully selected individuals with severe refractory symptoms or in those who are not candidates for second-line therapy (e.g., oral antimuscarinics, oral β3-adrenoceptor agonists, transdermal oxybutynin) and are willing to undergo surgery (recommendation, evidence strength Grade C.

In 2020, the National Institute for Health and Care excellence (NICE) issued guidance on the Axonics sacral neuromodulation system for treating refractory overactive bladder. The guidance states that the Axonics system should be considered an option for people with refractory overactive bladder. Similar to the 2004 guidance it states that use of SNS for urge incontinence and symptoms of urgency or frequency is supported by evidence of efficacy and safety.

In 2016, the American Society of Colon and Rectal Surgeons (ASCRS) released a clinical practice guideline for the management of constipation. The guidelines states that sacral neuromodulation may be an effective treatment for individuals with chronic constipation and successful peripheral nerve evaluation test when conservative measures have failed. However, it is not currently approved by the U.S. FDA for this condition in the United States (Grade of Recommendation: Weak, based on moderate quality evidence, 2B).

In 2023, the ASCRS released an updated clinical practice guideline for the treatment of fecal incontinence. The guidelines state that sacral neuromodulation may be considered as a first-line surgical option for incontinent individuals with and without sphincter defects (strength of recommendation, conditional; GRADE quality of evidence is low).

REGULATORY STATUS

Medical Devices

The United States Food and Drug Administration (FDA) regulates medical devices including sacral nerve stimulators. All medical devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Oct 17]

SNS has been approved by the Food and Drug Administration (FDA) since 1997 for the treatment of urinary urge incontinence, and its indications were later expanded to include urinary retention and urgency/frequency symptoms. There are two SNS systems currently approved by the United States Food and Drug Administration (FDA) for use in the treatment of urge incontinence, urgency-frequency, non-obstructive urinary retention, and fecal incontinence. The Interstim Sacral Nerve Stimulation System from Medtronic received approval in 1997 for urge incontinence, in 1999 for urgency-frequency and nonobstructive urinary retention, and in 2011 for fecal incontinence. The Axonic Sacral Neuromodulation System from Axonics received FDA approval for the treatment of urge incontinence, urgency-frequency, and non-obstructive urinary retention, and received pre-market approval for fecal incontinence, in 2019.

Medtronic has since received FDA approval for different models of SNS devices, the Interstim Micro, a small rechargeable device with 15 years of battery life, and the Interstim X, a recharge-free device, offering more than 10 years of battery life without any need to recharge. Both devices utilize a programming device in the form of what looks like a smartphone so that patients can discreetly adjust their own settings. Both devices have magnetic resonance imaging (MRI) modes and allow for full body 1.5T and 3T MRI scans under certain conditions.

In 2023, the Virtis Sacral Neuromodulation System (Nuvectra) was approved by the FDA for treatment of urinary retention and symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency in individuals who have failed more conservative treatments.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
64561	Percutaneous implantation of neurostimulator electrode array, sacral nerve (transforaminal placement) including image guidance, if performed
64581	Open implantation of neurostimulator electrode array, sacral nerve (transforaminal placement)
64585	Revision or removal of peripheral neurostimulator electrode array
64590	Insertion or replacement of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver.
64595	Revision or removal of peripheral, sacral, or gastric neurostimulator pulse generator or receiver, with detachable connection to electrode array.
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group(s), interleaving, amplitude, pulse width, frequency (Hz), on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming).
95971	with simple spinal cord, or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95972	with complex spinal cord, or peripheral nerve (e.g., sacral nerve) neurostimulator pulse generator/ transmitter, programming by physician or

Code	Description
	other qualified health care professional
0786T	Insertion or replacement of percutaneous electrode array, sacral, with integrated neurostimulator, including imaging guidance, when performed
0787T	Revision or removal of neurostimulator electrode array, sacral, with integrated neurostimulator
0788T	Electronic analysis with simple programming of implanted integrated neurostimulation system (e.g., electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 1-3 parameters
0789T	Electronic analysis with complex programming of implanted integrated neurostimulation system (e.g., electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, spinal cord or sacral nerve, 4 or more parameters

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HCPCS Codes

Code	Description
A4290	Sacral nerve stimulation test lead, each
C1767	Generator, neurostimulator (implantable), non-rechargeable
C1787	Patient programmer; neurostimulator
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only

Code	Description
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8684	Radiofrequency transmitter (external) for use with implantable sacral root stimulator receiver for bowel and bladder management, replacement
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, non-rechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, non- rechargeable, includes extension
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

ICD10 Codes

Code	Description
N32.81	Overactive bladder
N39.41	Urge incontinence
R15.0-R15.9	Fecal incontinence (code range)
R33.0-R33.9	Retention of urine (code range)
R35.0	Frequency of micturition
K59.00-K59.09	Constipation (code range)
R10.2	Pelvic and perineal pain
N39.3	Stress incontinence (male or female)
N39.42	Incontinence without sensory awareness

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REFERENCES

American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin No. 155: Urinary Incontinence in Women. Obstet Gynecol. 2015 Nov;126(5):e66-81.

American College of Obstetricians and Gynecologists (ACOG). Practice Bulletin No. 210: Fecal Incontinence. Obstet Gynecol. 2019 Apr;133(4):e260-273.

Andy UU, et al. Sacral neuromodulation versus onabotulinumtoxin A for refractory urgency urinary incontinence: impact on fecal incontinence symptoms and sexual function. Am J Obstet Gynecol. 2019 Nov;221(5):513.e1-513.e15.

Bharucha AE, et al. Surgical interventions and the use of device-aided therapy for the treatment of fecal incontinence and defecatory disorders. Clin Gastroenterol Hepatol 2017 Dec;15(12):1844-1854.

Bordeianou, L. et al. The American Society of Colon and Rectal Surgeons' practice guidelines for the management of fecal incontinence. Diseases of the colon and rectum. 2023 May;66(5), 647-661.

Chi-Wen L, et al. Comparing the efficacy of OnabotulinumtoxinA, sacral neuromodulation, and peripheral tibial nerve stimulation as third line treatment for the management of overactive bladder symptoms in adults: Systematic review and network meta-analysis. Toxins. 2020 Feb.12(128)1-17.

Food and Drug Administration (FDA) [Internet]. Summary of safety and effectiveness: Medtronic Interstim System for Urinary Control. 1999 Apr 15. [accessed 2025 Oct 09]. Available from: http://www.accessdata.fda.gov/cdrh_docs/pdf/P970004S004b.pdf

Groen J, et al. Sacral neuromodulation as treatment for refractory idiopathic urge urinary incontinence: 5-year results of a longitudinal study in 60 women. J Urol. 2011 Sep;186(3):954-9.

Lightner DJ, et al. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults: AUA/SUFU Guideline amendment 2019. J Urol. 2019; 202: 558.

Medtronic, Inc. Premarket approval of the Interstim Sacral Nerve Stimulation (SNS) System - FDA Notice. Fed Regist. 1998 Jan 29;63(19):4457. PMID:10177327.

National Institute for Health and Care Excellence (NICE) [Internet]. Axonics sacral neuromodulation system for treating refractory overactive bladder [MTG50]. 2020 Sep 03 [accessed 2025 Oct 09]. Available from: https://www.nice.org.uk/guidance/mtg50

National Institute for Health and Care Excellence (NICE) [Internet]. Sacral nerve stimulation for urge incontinence and urgency-frequency. Interventional procedures IPG64. 2004 Jun 23 [accessed 2025 Oct 09]. Available from: https://www.nice.org.uk/guidance/ipg64

National Institute for Health and Care Excellence (NICE) [Internet]. Faecal incontinence in adults: management. Clinica guideline CG49. 2007 Jun 27. [updated 2018 June 21;accessed 2025 Oct 09].

Schwarztuch G, et al. Feasibility of sacral neuromodulation in patients with underlying neurologic lower urinary tract dysfunction and fecal incontinence. Urology. 2024 Jun;188:54-62.

Vollebregt PF, et al. Clinical effectiveness of subsensory sacral neuromodulation in adults with faecal incontinence: the SUBSoNIC crossover RCT and mechanistic study. Southampton (UK): National Institute for Health and Care Research. 2024 Nov;11(19).

Wexner SD, et al. Sacral nerve stimulation for fecal incontinence: results of a 120-patient prospective multicenter study. Ann Surg. 2010 Mar;251(3):441-9.

Wagner L, et al. Unilateral versus bilateral sacral neuromodulation test in the treatment of refractory idiopathic overactive bladder: A randomized controlled pilot trial. Neurology and Urodynamics. 2020 July;39:2230-2237.

Yiannakou Y, et al. A randomized double-blinded sham-controlled cross-over trial of tined-lead sacral nerve stimulation testing for chronic constipation. Eur J Gastroenterol Hepatol. 2019 Jun; 1(6):653-660.

SEARCH TERMS

Sacral nerve stimulation (SNS) therapy, Sacral neuromodulation (SNM) for urinary incontinence, SNS treatment outcomes, SNS for fecal incontinence

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Sacral Nerve Stimulation for Urinary Incontinence (NCD 230.18) [accessed 2025 Oct 14]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 5/26

Revised:

Reviewed:

Date	Summary of Changes

9/1/2026	• New

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Policy/Procedure Name: Scenesse (Afamelanotide) **Control Number: 1350/20.000491**

Disclaimer Notice

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Background

Erythropoietic protoporphyria (EPP) is a genetic disorder due to ferrochelatase enzyme (FECH) deficiency resulting in an accumulation of protoporphyrin IX in the skin and liver. Protophyrin IX reacts to visible light, including sunlight and some artificial light, and can cause anaphylactoid and phototoxic reactions in people with EPP. After exposure to light, the skin may become itchy and red. Affected individuals may also experience a burning sensation on their skin. The hands, arms, and face are the most commonly affected areas. Cumulative exposure to light, even just a few minutes daily, will eventually trigger these symptoms. Some patients with EPP may also have complications related to liver and gallbladder function. EPP can result either from mutations of the ferrochelatase gene (FECH), or less commonly the delta-aminolevulinic acid synthase-2 gene (ALAS2). When EPP is due to an ALAS2 mutation it is termed X-linked protoporphyria (XLP) because the ALAS2 gene is found on the X chromosome. XLP accounts for approximately 2 to 10% of EPP cases. EPP affects males and females in equal numbers. It is estimated that the disorder occurs in about 1 in about 74,300 individuals. The onset of symptoms affecting the skin usually occurs in infancy; however, in some cases, onset may not occur until adolescence or adulthood.

The diagnosis of EPP is established by finding an abnormally high level of total erythrocyte protoporphyrin and showing that this increase is mostly free protoporphyrin rather than zinc protoporphyrin. There is considerable confusion about which test to order. Sometimes laboratories have measured only zinc protoporphyrin and reported results incorrectly as "protoporphyrin" or "free erythrocyte protoporphyrin (FEP)". Laboratories that measure total erythrocyte protoporphyrin, free protoporphyrin and zinc protoporphyrin and report results reliably are Porphyria Laboratory and Center, University of Texas Medical Branch at Galveston, 1-409-772-4661 and Mayo Medical Laboratories, 1-800-533-1710. Porphyrins are almost always elevated in plasma in EPP but may be normal in mild cases. Genetic testing is also an important component in diagnosis.

Mainstay of therapy has been supportive care including light avoidance, sun protection (complete light blocking creams), clothing, and vitamin D supplementation to correct for deficiency. Some patients note increased tolerance to sunlight with beta-carotene (Lumitene), especially in the summer. In the largest case series with 133 patients, 22 reported no effect and 111 reported moderate to substantial improvement in sunlight tolerance. It is dosed at 30 to 300 mg (1 to 10 capsules) daily and titrated to maintain serum carotene levels in the range of 600 to 800 mcg/dL or a tolerable degree of yellowish skin pigmentation. If the patient is not experiencing reduced symptoms with an adequate carotene level after three months, the therapy may be discontinued, as most individuals notice a protective effect within one to three months.

Scenesse (afamelanotide) is FDA approved and indicated to increase pain free light exposure in adult patients with a history of phototoxic reactions from EPP. It acts by increasing the levels of eumelanin in the skin, shielding against UV radiation (UVR) and visible light, including sunlight. Afamelanotide is a synthetic form of a hormone called alpha-melanocyte stimulating hormone. Afamelanotide increasing skin cell production of eumelanin which in turn can help to reduce the sensitivity of the skin to sunlight and artificial UV light sources. It is administered by a proficient health care professional under the skin every two months. A total of 168 patients with EPP from Europe (74 patients) and the United States (94 patients) were included in phase 3, multicenter, randomized, double-blind, placebo-controlled trials. They received 16 mg of afamelanotide, implanted at intervals of 60 days (for as long as 120 days in the United States and as long as 240 days in Europe). The primary efficacy endpoint was duration of direct sunlight exposure between 10:00 a.m. and 3:00 p.m. (in EU trial) and 10:00 am and 6:00 p.m. (in U.S. trial) on days when no pain was experienced. In the U.S. study, the duration of pain-free time after six months was longer in the afamelanotide group (median, 69.4 hours, vs. 40.8 hours in the placebo group; P=0.04). In the European Union study, the duration of pain-free time after nine months was also longer in the afamelanotide group than in the placebo group (median, 6.0 hours vs. 0.8 hours; P=0.005), and the number of phototoxic reactions was lower in the afamelanotide group (77 vs. 146, P=0.04). Adverse events were mostly mild; serious adverse events were not thought to be related to the study drug.

In December 2023, the Journal of the American Academy of Dermatology (JAAD) published evidence-based consensus guidelines for the diagnosis and management of erythropoietic protoporphyria and X-linked protoporphyria. In this review, they recommended that afamelanotide, administered every two months, should be used for prevention of phototoxic symptoms in EPP, with skin exams occurring every six months by a dermatologist.

Summary

Effective Date of Policy:	9/10/2025
Indications	Increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP)
ICD10 Diagnosis Codes	E80.0

Availability	Implant: 16 mg of afamelanotide
J-Code	J7352
Duration	Initial: 6 months Continuation: 1 year
Limitations	Scenesse must be administered by a health care professional proficient in the subcutaneous implantation procedure; therefore, it is covered under the medical benefit.

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve Scenesse:

Indication	Inclusion Criteria	Recommended Dosing Regimen
Increase pain free light exposure in adult patients with a history of phototoxic reactions from erythropoietic protoporphyria (EPP) (FDA approval) ICD10: E80.0	• Enrollee is at least 18 years of age, or older • Prescribed by a dermatologist or hematologist or geneticist with expertise in the diagnosis and management of EPP • Definitive diagnosis of erythropoietic porphyria supported by: o A marked increase (5-50 times) in total erythrocyte protoporphyrin (300-5000 µg/dL erythrocytes, reference interval <80 µg/dL) determined by an accredited laboratory. **AND** Elevated erythrocyte metal-free protoporphyrin greater than or equal to 85% of the total erythrocyte protoporphyrin as determined by an accredited laboratory. Laboratory report should document total erythrocyte protoporphyrin/porphyrin; erythrocyte zinc protoporphyrin and erythrocyte metal-free (free) protoporphyrin **OR** o Identification of biallelic pathogenic variants in ferrochelatase (*FECH)* on molecular genetic testing • History of documented characteristic symptoms of phototoxicity due to EPP such as burning, itching, swelling, pain and redness of the skin during or after exposure to sunlight or fluorescent light causing reduced quality of life	• Standard dose is one 16 mg implant inserted subcutaneously above the supra-iliac crest every 2 months. • Administration more frequently than every 2 months (shorter dose interval) will not be covered.

Exclusion Criteria

- Personal history of melanoma or dysplastic nevus syndrome.
- Current Bowen's disease, basal cell carcinoma, squamous cell carcinoma, or other malignant or premalignant skin lesions.
- Non-erythropoietic protoporphyria (EPP) skin disorders such as xeroderma pigmentosum, epidermolysis bullosa, polymorphous light eruption (PLE), discoid light eruption (DLE), solar urticaria or due to other porphyrias such as porphyria cutanea tarda and congenital erythropoietic porphyria

Continuation Criteria

- Recertification timeframe after the initial approval will be for one year and will be limited to the total number of implants approved for that year. For example: recertification for one year with approval for a maximum of 3 implants to be administered every 2 months during the period of high sunlight exposure.
- Documentation of a positive response to treatment such as decreased frequency and severity of phototoxic reactions, increased duration of sun exposure, increased quality of life, AND
- Enrollee has been examined to monitor preexisting and new skin pigmentary lesions

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.
- A quantity limit of 3 implants per year during periods of high sunlight exposure will apply. Requests for more than 3 implants per year will be evaluated on a case-by-case basis with prescriber documentation of medical necessity.

References

		Updated	Accessed
1	Scenesse [package insert], Burlingame, CA: Clinuvel, Inc.	8/2024	7/2025
2	Mittal S. Anderson K. Erythropoietic protoporphyria and X-linked protoporphyria. In: UpToDate. Waltham, MA.	4/2024	7/2025
3	Stölzel, U., Doss, M. O., & Schuppan, D. (2019). Clinical Guide and Update on Porphyrias. *Gastroenterology*, *157*(2), 365–381.e4. https://doi.org/10.1053/j.gastro.2019.04.050	5/2019	7/2025
4	Langendonk JG, Balwani M, Anderson KE, et al. Afamelanotide for Erythropoietic Protoporphyria. N Engl J Med. 2015;373(1):48-59.	7/2015	7/2025
5	Balwani, M., Bloomer, J., Desnick, R., & Porphyrias Consortium of the NIH-Sponsored Rare Diseases Clinical Research Network. (2017). Erythropoietic Protoporphyria, Autosomal Recessive. In M. P. Adam (Eds.) et. al., *GeneReviews*®. University of Washington, Seattle.	9/2017	7/2025
6	Gou, E. W., Balwani, M., Bissell, D. M., Bloomer, J. R., Bonkovsky, H. L., Desnick, R. J., Naik, H., Phillips, J. D., Singal, A. K., Wang, B., Keel, S., & Anderson, K. E. (2015). Pitfalls in Erythrocyte Protoporphyrin Measurement for Diagnosis and Monitoring of Protoporphyrias. *Clinical chemistry*, *61*(12), 1453–1456. https://doi.org/10.1373/clinchem.2015.245456	12/2015	7/2025
7	Debby Wensink, Margreet A.E.M. Wagenmakers & Janneke G. Langendonk (2021) Afamelanotide for prevention of phototoxicity in erythropoietic protoporphyria, Expert Review of Clinical Pharmacology, 14:2, 151-160, DOI: 10.1080/17512433.2021.1879638	2/2021	7/2025
8	Leaf, R. K., & Dickey, A. K. (2023). How I treat erythropoietic protoporphyria and X-linked protoporphyria. *Blood*, *141*(24), 2921–2931. https://doi.org/10.1182/blood.2022018688	6/2023	7/2025
9	Dickey, A. K., Naik, H., Keel, S. et al. Porphyrias Consortium of the Rare Diseases Clinical Research Network (2023). Evidence-based consensus guidelines for the diagnosis and management of erythropoietic protoporphyria and X-linked protoporphyria. *Journal of the American Academy of Dermatology*, *89*(6), 1227–1237. https://doi.org/10.1016/j.jaad.2022.08.036	12/2023	7/2025

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE CHOICES: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 9/10/2025

New: 9/23

Revised	Reviewed
9/2025	9/2024

Revision Date	Changes Made
9/2025	Removed exclusion of patients with significant hepatic dysfunction Updated photo dermatosis conditions in exclusion Updated inclusion criteria for phototoxic reactions Updated continuation criteria and quantity limits

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: SECOND OPINIONS

POLICY EFFECTIVE DATE:	7/1/2025
Policy Control #:	1370/20.000159
Next Annual Review:	November, 2026

DISCLAIMER

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PROCEDURE CODES

99202-99205, 99212-99215, 99231-99233

DESCRIPTION

A second medical opinion is an opinion obtained from an additional health care professional, prior to the performance of a medical service or surgical procedure that is used to educate a member regarding treatment alternatives, and/or to determine medical necessity.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

- Out-of-Network Care, 1370/20.000145.
- Prior Authorization Guideline, 1370/20.000425

POSITION STATEMENT

CDPHP administers benefits for an enrollee to obtain a second opinion for the treatment of cancer, surgical procedure, or other instances as outlined below.

Second Cancer Opinion

CDPHP administers benefits for one second opinion by an appropriate specialist, including but

not limited to a specialist affiliated with a specialty care center, for the treatment of cancer in the event of a positive or negative diagnosis of cancer, or a recurrence of cancer, or a recommendation of a course of treatment for cancer.

The second opinion may be obtained from a non-participating specialist, including but not limited to a specialist affiliated with a specialty care center for the treatment of cancer, when such services are requested in writing by the attending physician and are determined medically appropriate by a CDPHP medical director.

- *This coverage applies to the out-of-network consultation only.* Requests for additional out-of-network testing or treatment is subject to benefit limitations stated in the enrollee's contract and will require prior authorization.

Second Surgical Opinion

CDPHP administers benefits for a second surgical opinion by a qualified physician on the need for surgery.

In some instances, CDPHP reserves the right to require a second surgical opinion prior to authorizing a surgical procedure.

- The second opinion must be provided by a board-certified specialist after a face-to-face examination.

Second Opinions in Other Cases

CDPHP administers benefits for a second medical opinion in instances where an enrollee does not agree with a provider's recommended course of treatment.

- Enrollees may request CDPHP designate another provider to render a second opinion.

POLICY CONSIDERATIONS

In instances above, where the second opinion differs from the original, a third opinion will be granted.

- Third opinion consultations are also subject to the terms and conditions stated in this policy.
- CDPHP will approve covered, medically necessary services that are supported by a majority of the providers that have reviewed the case.

The CDPHP resource coordination department will provide case management services to facilitate a timely transfer of appropriate medical records.

CDPHP will determine where the recommended treatment plan is to be provided.

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EXCLUSIONS

No benefits are available for patients to continue to obtain opinions, beyond those stated above.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Second opinion for the treatment of cancer must be obtained within the CDPHP participating provider network unless it is determined the network does not have a qualified health-care provider with appropriate training and expertise to render such an opinion.
SELECT PLAN/HARP	Second opinion for the treatment of cancer must be obtained within the CDPHP participating provider network unless it is determined the network does not have a qualified health-care provider with appropriate experience or expertise to render such an opinion. • Health care providers within New York State will be utilized whenever possible. Second Medical/Surgical Opinions- Medicaid /HARP enrollees may obtain second opinions for diagnosis of a condition, treatment, or surgical procedure by a qualified physician or appropriate specialist, including one affiliated with a specialty care center. In the event that CDPHP determines that it does not have a participating provider in its network with appropriate training and experience qualifying the participating provider to provide a second opinion, CDPHP shall make a referral to an appropriate non-participating provider. CDPHP shall pay for the cost of the services associated with obtaining a second opinion regarding medical or surgical care, including diagnostic and evaluation services, provided by the non-participating provider.

SOURCES

1. American Medical Association (AMA) Opinion 8.041 – Second Opinions, http://www.ama-assn.org
2. CDPHP Technology Assessment Team
3. Member Contract Language

4. Other Payors
5. Regulatory Compliance: NYS Insurance Law, Article 32, §3216, Individual accident and health insurance policy provision: http://public.leginfo.state.ny.us/LAWSSEAF.cgi?QUERYTYPE=LAWS+&QUERYDATA=$$ISC3216$$@TXISC03216+&LIST=LAW+&BROWSER=EXPLORER+&TOKEN=52494699+&TARGET=VIEW

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POLICY APPROVAL DATES

New:	12/97
Revised:	11/98, 08/99, 09/99, 11/00, 10/03, 08/04, 04/05, 03/06, 01/09, 01/11, 11/13, 11/18, 11/19, 7/25
Reviewed:	11/01, 01/03, 08/04, 02/07, 01/08, 11/09, 01/10, 01/12, 01/13, 11/14, 11/15, 11/16, 11/17, 11/20, 11/21, 11/22, 11/23, 11/24, 11/25

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
7/1/2025	Added additional coverage information in the Select Plan/HARP section regarding second surgical opinions which was previously housed in the Mandated Benefits for State Funded Programs payment policy, 1550/20.000188.
1/1/2020	Added reference to Prior Authorizations Guideline policy.

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: SECOND OPINIONS

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MEDICAL POLICY

Medical Policy Title	**Serum Antibodies for the Diagnosis of Inflammatory Bowel Disease**
Policy Number	**2.02.19**
Current Effective Date	**January 1, 2027**
Next Review Date	**November 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Serologic testing of biomarkers including, but not limited to anti-neutrophil cytoplasmic antibodies (ANCA) or anti-Saccharomyces cerevisiae (ASCA); antibodies of outer membrane porin C of the bacteria Eschericia coli (anti-OmpC); Pseudomonas fluorescens-associated sequence I2 (anti-I2); flagellin CBir1 (anti-cBir1); antichitobioside antibodies (ACCA IgA); antilaminaribioside antibodies (ALCA IgG); and antimannobioside antibodies (AMCA IgG) (e.g.; Prometheus IBD sgi Diagnostic testing), is considered **not medically necessary** for **ALL** indications including, but not limited to:

   A. To diagnose and monitor patients with inflammatory bowel disease (IBD);

   B. To distinguish ulcerative colitis (UC) from Crohn's disease (CD).

RELATED POLICIES

Not Applicable

POLICY GUIDELINE(S)

Laboratories performing clinical tests must be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

DESCRIPTION

Inflammatory bowel disease (IBD) is a chronic disease of the gastrointestinal tract that consists of two related diseases, ulcerative colitis (UC) and Crohn's disease (CD). Although UC and CD are generally considered distinctive forms of IBD, their clinical presentations commonly overlap. Furthermore, for approximately 10-15% of patients with IBD, the distinction between UC and CD cannot be made with certainty. These patients are given a diagnosis of indeterminate colitis (IC). A correct diagnosis of IBD, especially the differentiation between CD and UC is highly important in determining treatment and prognosis. The diagnostic work-up of patients with IBD is relatively complicated, and endoscopic exam and biopsy are currently crucial components of the diagnosis. Less invasive, accurate diagnostic tools to distinguish between UC, CD, and cases of indeterminate colitis are needed.

It has been proposed that serological markers for IBD can be utilized, both to differentiate UC from CD, and to define patient subgroups (e.g., location of the disease, such as proximal versus distal bowel involvement). Other potential uses include determination of disease severity, prediction of response to anti-tumor necrosis factor (TNF) therapy, and identification of the susceptibility to IBD among family members of an affected individual. Anti-neutrophil cytoplasmic antibodies (ANCA) and anti-Saccharomyces cerevisiae antibodies (ASCA) have been the most extensively studied serological markers for use in the diagnosis of IBD. ANCA are a group of antibodies, which are specific for granulocyte antigens. Anti-neutrophil cytoplasmic antibodies with perinuclear staining (pANCA) have been most commonly described in IBD and have been linked with UC. Other antibodies that have recently been associated with CD include anti-OmpC, anti-cBir1, Anti-I2, ACCA, ALCA, and AMCA. Increased amounts and levels of an antibody's response have been suggested to predict a more complicated course of disease. Large prospective studies are needed, to validate these findings.

Recent data suggest that the presence of serological biomarkers might represent a genetic susceptibility, because patients who have positive antibodies may carry mutations in the NOD2/CARD15 gene or in toll-like receptor genes. However, future studies of larger cohorts with well-defined clinical characteristics and patient populations are needed, to determine the validity of this relationship.

The PROMETHEUS IBD sgi Diagnostic aims to help identify IBD and differentiates between UC and CD. It may also assess a patient's risk for more aggressive disease. The test includes the proprietary and patented serologic markers anti-CBir1, Anti-OmpC and DNAse-sensitive pANCA process as well as, the markers ASCA IgA (ACCA) and IgG (ALCA and AMCA). The sgi Diagnostic test also includes the ATG16L, ECM1, mkX2-3, and STAT3 genetics and inflammation markers such as VEGF, ICAM-1, VACAM-1, CRP, and SAA. The Smart Diagnostic Algorithm technology produces an IBD score; results are reported as consistent with IBD (consistent with ulcerative colitis, consistent with CD, or inconclusive for ulcerative colitis vs. CD) or not consistent with IBD. The test is intended for use in patients with clinical suspicion of IBD.

SUPPORTIVE LITERATURE

A published study compared the predictive values of the Prometheus Inflammatory Bowel Disease (IBD) Serology 7 (IBD7) panel (Prometheus Laboratories, San Diego, CA) with the predictive values of routine blood tests in a population of children referred for initial evaluation of suspected IBD (Benor 2010). Medical records of pediatric patients referred for evaluation of IBD for whom IBD7 testing was performed at Prometheus Laboratories between January 2006 and November 2008 were reviewed. Patients underwent diagnosis by pediatric gastroenterologists on the basis of clinical, radiologic, endoscopic, and pathologic evaluations. A total of 394 records were identified and 90 records were excluded on the basis of age of > 21 years, previous diagnosis of IBD, or unclear diagnosis. The prevalence of IBD in this cohort was 38%. The sensitivity, specificity, positive predictive value, negative predictive value, and kappa value for the serological panel were 67%, 76%, 63%, 79%, and 42%, respectively, compared with values for a combination of three (3) abnormal routine laboratory test results of 72%, 94%, 85%, 79%, and 47%. The antiflagellin antibody assay, the newest assay added to the panel, had sensitivity of 50% and specificity of 53%. Repeat serological testing failed to produce consistent results for four (4) of 10 patients. The authors

concluded this study showed, the IBD7 panel has lower predictive values than routine laboratory tests in pediatric screening for IBD.

The use of serological markers for patients with IBD has not been shown to improve health outcomes by reducing the need for other tests nor has it been proven to increase the accuracy of diagnosis for these patients. Large-scale prospective studies are required, to ascertain the predictive value and cost-effectiveness of the use of these serology markers in the screening and monitoring of IBD patients.

PROFESSIONAL GUIDELINE(S)

The American College of Gastroenterology (ACG) published clinical guidelines for the management of Crohn's disease in adults (Lichtenstein 2025). They do not support serologic testing and state the following:

- "Routine use of serologic markers of IBD to establish the diagnosis of Crohn's disease is not indicated."
- "Because of the heterogeneous nature of IBD there has been extensive research directed toward finding immunologic markers that would assist in disease diagnosis. These studies have focused on antibodies to microbial antigens and autoantibodies. Antiglycan antibodies are more prevalent in CD than in UC but have a low sensitivity, making their use in diagnosis less helpful. Tests have been developed that use a combination of serologic, genetic, and inflammatory markers to try to improve diagnostic efficacy; however, this combination of markers has not improved serology measurements usefulness as a screening tool."

ACG published clinical guidelines for the management of ulcerative colitis in adults (Rubin 2025). They do not support serologic testing and state the following:

- "We recommend against serologic antibody testing to establish or rule out a diagnosis of UC (strong recommendation, very low quality of evidence)"
- "We recommend against serologic antibody testing to determine the prognosis of UC (strong recommendation, very low quality of evidence)."
- "Serologic markers such as perinuclear anti-neutrophil cytoplasmic antibodies (pANCA) may be found in up to 70% of patients with UC, and combination of negative anti-Saccharomyces cerevisiae (ASCA) antibodies with elevated pANCA levels have been proposed to facilitate establishing a diagnosis of UC. However, the pooled sensitivity of antibody testing for diagnosis of UC is low, and such markers are not used for establishing or ruling out a diagnosis of UC. While pANCA positivity has also been associated with treatment refractory UC, the evidence supporting this is limited and there is currently no role for such testing to determine the likelihood of disease evolution and prognosis."

REGULATORY STATUS

Clinical laboratories may develop and validate tests in-house and market them as a laboratory service. Laboratory-developed tests must meet the general regulatory standards of the Clinical Laboratory Improvement Amendments (CLIA).

Laboratories that offer laboratory-developed tests must be licensed by CLIA for high-complexity testing. More information is available at: Clinical Laboratory Improvement Amendments (CLIA) | FDA [accessed 2025 Sep 23]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
There are no specific CPT codes.	Codes 81479, 82397, 83516 83520, 86140, 88346 or 88350 may be used for billing PROMETHEUS IBD sgi Diagnostic; however, these codes are not specific to PROMETHEUS IBD.

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
K50.00-K50.919	Crohn's disease [regional enteritis] (code range)
K51.00-K51.919	Ulcerative colitis (code range)

REFERENCES

Annes V, et al. Familial expression of anti-Saccheromyces cerevisiae mannan antibodies in Crohn's disease and ulcerative colitis: a GISC study. Am J Gastroenterol. 2001;96(8):2407-12.

Benor S, et al. Shortcomings of the inflammatory bowel disease Serology 7 panel. Pediatrics. 2010 Jun;125(6):1230-6.

Bernstein CN, et al. Development of an assay for antibodies to Saccharomyces cerevisiae: easy, cheap, and specific for Crohn's disease. Can J Gastroenterol. 2001 Aug;15(8):499-504.

Bonneau J, et al. Systematic review: new serological markers (anti-glycan, anti-GP2, anti-GM-CSF-Ab) in the prediction of IBD patient outcomes. Autoimmun Rev. 2015 Mar;14(3):231-45.

Desir B, et al. Utility of serum antibodies in determining clinical course in pediatric Crohn's disease. Clin Gastroenterol Hepatol. 2004 Feb;2(2):139-146.

Dotan I. New serologic markers for inflammatory bowel disease diagnosis. Dig Dis. 2010;28(3):418-23.

Fengming Y, et al. Biomarkers of inflammatory bowel disease. Dis Markers. 2014:710915.

Forcione DG, et al. Anti-saccharomyces cerevisiae antibody (ASCA) positivity is associated with increased risk for early surgery in Crohn's disease. Gut. 2004 Aug;53(8):1117-22.

Iskandar HN, et al. Biomarkers in inflammatory bowel disease: current practices and recent advances. Transl Res. 2012 Apr;153(4):313-25.

Kaul A, et al. Serum anti-glycan antibody biomarkers for inflammatory bowel disease diagnosis and progression: a systematic review and meta-analysis. Inflamm Bowel Dis. 2012 Oct;28(10):1872-84.

Kevans D, et al. Serological markers associated with disease behavior and response to anti-tumor necrosis factor therapy in ulcerative colitis. J Gastroenterol Hepatol. 2015 Jan;30(1):64-70.

Kim BG, et al. Diagnostic role of anti-Saccharomyces mannan antibodies combined with antineutrophil cytoplasmic antibodies in patients with inflammatory bowel disease. Dis Colon Rectum. 2002 Aug;45(8):1062-9.

Lichtenstein GR, et al. Combination of genetic and quantitative serological immune markers are associated with complicated Crohn's disease behavior. Inflamm Bowel Dis. 2011 Dec;17(12):2488-96.

Lichtenstein GR, et al. ACG Clinical Guideline: management of Crohn's disease in adults. Am J Gastroenterol. 2025 Jun 3;120(6):1225-1264.

Mitsuyama K, et al. Antibody markers in the diagnosis of inflammatory bowel disease. World J Gastroenterol. 2016 Jan 21;22(3):1304-10.

Papp M, et al. Serological studies in inflammatory bowel disease: how important are they? Curr Opin Gastroenterol. 2014 Jul;30(4):359-64.

Peng C., et al. Serum biomarkers for inflammatory bowel disease. Front Med. 2020 Apr; 7:123.

Rubin DT, et al. ACG Clinical Guideline Update: ulcerative colitis in adults. Am J Gastroenterol. 2025 Jun 3;120(6):1187-1224.

Ryan JD, et al. Predicting complicated Crohn's disease and surgery: phenotypes, genetics, serology, and psychological characteristics of a population-based cohort. Aliment Pharmacol Ther. 2013 Aug;38(3):274-83.

Schoepfer AM, et al. Discriminating IBD from IBS: comparison of the test performance of fecal markers, blood leukocytes, CRP, and IBD antibodies. Inflamm Bowel Dis. 2008; 14(1):32-9.

Sipeki N, et al. Prevalence, significance, and predictive value of antiphopholipid antibodies in Crohn's disease. World J Gastroenterol. 2015 Jun 14;21(22):6952-64.

Smids C, et al. The value of serum antibodies in differentiating inflammatory bowel disease, predicting disease activity and disease course in the newly diagnosed patient. Scand J Gastroenterol. 2017 Oct;52(10):1104-1112.

Torres J, et al. Predicting outcomes to optimize disease management in inflammatory bowel diseases. J Crohns Colitis. 2016 Dec;10(12):1385-1394.

Vermeire S, et al. Classification of inflammatory bowel disease: the old and the new. Curr Opin Gastroenterol. 2012 Jul;29(4):321-6.

Vermeire S, et al. (Auto)Antibodies in Inflammatory Bowel Diseases. Gastroenterol Clin N Am. 2008; 37:429-38.

Vermeire S, et al. Comparative study of ASCA (Anti-saccharomyces cerevisiae antibody) assays in inflammatory bowel disease. Gastroenterol. 2001 Mar;120 (4):827-33.

Zholudev A, et al. Serologic testing with ANCA, ASCA and anti-OmpC in children and young adults with Crohn's disease and ulcerative colitis: diagnostic value and correlation with disease phenotype. Am J Gastroenterol. 2004 Nov;99(11):2235-41.

SEARCH TERMS

Anti-neutrophil cytoplasmic antibodies, ANCA, Anti-Saccharomyces cerevisiae, ASCA, Crohn's disease, Inflammatory bowel disease, Prometheus Labs, Serological markers, Ulcerative colitis.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based on our review, Serological Diagnosis of Inflammatory Bowel Disease or Prometheus IBD is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

MEDICAL POLICY

Medical Policy Title	**Shoulder Joint Procedures for Managed Medicaid (MMC), Health and Recovery Plan (HARP), Child Health Plus (CHP), and Essential Plan (EP) Members**
Policy Number	**7.01.125**
Current Effective Date	**January 1, 2027**
Next Review Date	**September 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

SECTION LINKS

Shoulder Arthroplasty

Shoulder Arthroscopy

Shoulder Stabilization Procedures

Shoulder Synovial and Intra-Articular Procedures

Biceps Procedures

Acromial and Clavicular Procedures

Shoulder Reconstruction and Corrective Procedures

POLICY STATEMENT(S)

Total Shoulder Arthroplasty

I. Shoulder arthroplasty is **not medically necessary** for **ANY** of the following contraindications:
   A. Material allergy incompatible with implantation;
   B. Clinical instability or inadequately managed comorbid conditions;
   C. Poor dentition requiring major dental intervention prior to arthroplasty;
   D. Diabetes with HbA1c greater than 8%;
   E. Nicotine or tobacco use, including cigars, cigarette, e-cigarette, nicotine pouch, smokeless tobacco, or vape pen, within 6 weeks of surgery;
   F. Intra-articular corticosteroid injection within 12 weeks of surgery;
   G. Untreated or unmanaged substance use disorder;
   H. Uncontrolled hypertension;
   I. Active local or systemic infection, including infection that is undergoing treatment or remains unresolved;

J. Neurologic conditions resulting in **one (1) or more** of the following:
   1. Charcot arthropathy;
   2. Complex regional pain syndrome (CRPS) or related CRPS variant; **or**
   3. Loss of deltoid or rotator cuff function;

K. Shoulder arthroscopy of the affected shoulder within the preceding 12 weeks.

Total Shoulder Arthroplasty (TSA) or Resurfacing

II. Total shoulder arthroplasty or resurfacing is **medically necessary** when **ALL** of the following are met:
   A. Shoulder pain and dysfunction result in limitations of activities of daily living (ADLs);
   B. Documentation supports **one (1)** of the following:
      1. Advanced glenohumeral joint disease confirmed by imaging studies (e.g., radiographs, CT, and/or MRI) demonstrating severe joint degeneration and joint space loss associated with **one (1)** of the following:
         a. Degenerative arthritis or post-traumatic arthritis, including findings such as asymmetric joint space loss, glenoid wear, glenoid flattening, subchondral sclerosis, or cuff tear arthropathy; **or**
         b. Inflammatory arthropathy, including rheumatoid arthritis, characterized by uniform joint space narrowing, erosive changes, synovitis, pannus formation, or cartilage loss;
      2. Prior osteotomy associated with persistent loss of shoulder function and range of motion;
      3. **All** the following conditions are present:
         a. Adequate bone stock to support fixation of the prosthesis;
         b. Intact deltoid function; **and**
         c. A reparable rotator cuff;
      4. Conservative management meets **either** of the following:
         a. Conservative management is not required when **any** of the following is documented:
            i. Acute proximal humerus fracture not amenable to internal fixation, including displaced three- or four-part fractures, head-splitting fractures, or complex fracture-dislocations;
            ii. Osteonecrosis (avascular necrosis) of the humeral head with collapse;
            iii. End-stage glenohumeral arthritis with bone-on-bone articulation identified on

radiographs; **or**

iv. Primary or metastatic malignancy involving the shoulder joint or adjacent soft tissues;

OR

b. For all other indications, conservative management must include **both** of the following:

i. Physical therapy (PT) meets **all** the following:

a) Supervised by a licensed PT, chiropractor, or through tele-rehab PT;

b) Participation for a minimum of 6 weeks during the previous 6 months;

c) Failure to improve symptoms or functional impairments; **and**

ii. Pain management includes **either** of the following:

a) Intra-articular, subacromial or bicipital groove corticosteroid injection; **or**

b) Medication management (e.g., non-steroidal anti-inflammatory drugs [NSAIDs] or oral analgesics);

Reverse Total Shoulder Arthroplasty (RTSA)

III. Reverse total shoulder arthroplasty is **medically necessary** when **ALL** the following are met:

A. Shoulder dysfunction results in limitations of activities of daily living (ADLs);

B. Documentation supports **one (1)** of the following:

1. Advanced glenohumeral joint degeneration demonstrated by imaging studies (e.g., radiographs, CT, and/or MRI) with severe joint space loss associated with:

a. Degenerative or post-traumatic arthritis; **or**

b. Inflammatory arthropathy, including rheumatoid arthritis;

2. Massive irreparable rotator cuff pathology, including substantial partial-thickness or full-thickness tearing associated with significant loss of shoulder function;

3. Persistent severe pain following prior rotator cuff repair failure;

4. Failure of a prior total shoulder arthroplasty in the setting of an irreparable rotator cuff deficiency;

5. Conservative management meets **either** of the following:

a. Conservative management is not required when **any** of the following is documented:

i. Acute proximal humerus fracture, including two-part, three-part, or four-part fracture patterns, with or without associated tuberosity involvement;

ii. Symptomatic malunion of a proximal humerus fracture associated with rotator cuff dysfunction;

iii. Primary or metastatic malignancy involving the glenohumeral joint or adjacent soft tissues;

iv. Bone-on-bone glenohumeral degeneration identified on radiographs, CT, or MRI; **or**

v. End-stage glenohumeral arthritis (Kellgren-Lawrence Grade IV); **or**

b. For all other indications, conservative management must include **both** of the following:

i. Physical therapy (PT) meets **all** the following:

a) Supervised by a licensed PT, chiropractor, or through tele-rehab PT;

b) Participation for a minimum of 6 weeks during the previous 6 months;

c) Failure to improve symptoms or functional impairments; **and**

ii. Pain management includes **either** of the following:

a) Intra-articular, subacromial or bicipital groove corticosteroid injection; **or**

b) Medication management (e.g., NSAIDS or analgesics);

C. Glenoid bone loss, bone deficiency, or structural compromise that limits the ability to support a conventional glenoid component;

D. Preserved deltoid muscle function;

E. Painful loss of shoulder motion resulting in pseudoparalysis, demonstrated by inability to actively elevate the arm to 90 degrees without assistance;

F. Imaging demonstrates advanced structural shoulder disease, including **one (1) or more** of the following:

1. Bone-on-bone glenohumeral articulation;
2. Complete or near-complete joint space loss; **or**
3. Significant osseous deformity involving the glenohumeral joint.

IV. Revision of a prior shoulder arthroplasty is **medically necessary** when **ALL** the following are met:

A. Functional impairment of the affected shoulder that interferes with ADLs and/or IADLs;

B. No active or inadequately treated joint infection; **and**

C. **One (1) or more** of the following prosthesis-related complications:

1. Recurrent instability, dislocation, or subluxation;

2. Periprosthetic infection requiring revision;
3. Periprosthetic fracture;
4. Aseptic component loosening;
5. Osteolysis;
6. Implant failure, component dysfunction, instability, or device recall; **or**
7. Symptomatic synovitis or adverse local tissue reaction, including metallosis;

Hemiarthroplasty

V. Shoulder hemiarthroplasty is **medically necessary** when **ALL** the following are met:
   A. Shoulder dysfunction results in limitations of activities of daily living (ADLs);
   B. Documentation supports **one (1)** of the following:
      1. Advanced glenohumeral joint disease demonstrated by imaging studies (e.g., radiographs, CT, and/or MRI) with severe joint space loss associated with:
         a. Degenerative arthritis;
         b. Post-traumatic arthritis;
         c. Inflammatory arthropathy, including rheumatoid arthritis
         d. Massive irreparable partial-thickness rotator cuff pathology;
         e. Full-thickness rotator cuff tear associated with significant functional deficit, including weakness and/or impingement symptoms; **or**
         f. Structural joint destruction demonstrated by bone-on-bone articulation or osseous deformity;
      2. When **all** the following criteria are met:
         a. Humeral bone quality or bone stock is inadequate to support stable internal fixation;
         b. Preserved deltoid;
         c. Rotator cuff function sufficient to support the planned procedure; **and**
      3. Conservative management meets **either** of the following:
         a. Conservative management is not required when **any** of the following is documented:
            i. Osteonecrosis (avascular necrosis) of the humeral head with collapse;
            ii. Acute proximal humerus fracture that is not amenable to internal fixation, including displaced three-part or four-part fractures, head-splitting fractures, or complex fracture-dislocations; **or**
            iii. Primary or metastatic malignancy involving the glenohumeral joint or adjacent

soft tissues; **or**

b. For all other indications, conservative management must include **both** of the following:

i. Physical therapy (PT) meets **all** the following:

a) Supervised by a licensed PT, chiropractor, or through tele-rehab PT;

b) Participation for a minimum of 6 weeks during the previous 6 months;

c) Failure to improve symptoms or functional impairments; **and**

ii. Pain management includes **either** of the following:

a) Intra-articular, subacromial or bicipital groove corticosteroid injection; **or**

b) Medication management (e.g., NSAIDS or analgesics).

Shoulder Arthroscopy

Diagnostic Shoulder Arthroscopy

VI. Diagnostic shoulder arthroscopy is **medically necessary** when **ALL** the following criteria are met:

A. Alternative conditions that could reasonably account for the individual's symptoms have been excluded, including:

1. Glenohumeral arthritis;
2. Brachial plexus pathology;
3. Fracture;
4. Referred cervical pain; **or**
5. Thoracic outlet syndrome;

B. Persistent functional impairment as evidenced by **both** the following:

1. Shoulder pain and functional limitations have been present for at least 6 months; **and**
2. Symptoms interfere with activities of daily living (ADLs) or instrumental activities of daily living (IADLs);

C. Clinical examination demonstrates abnormalities when compared with the unaffected shoulder, including **one (1) or more** of the following:

1. Findings consistent with impingement syndrome;
2. Restricted active or passive range of motion; **or**
3. Measurable loss of strength;

D. Conservative management must include **both** of the following:

1. Physical therapy (PT) meets **all** the following:
    a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
    b. Participation for a minimum of 3 months during the previous 6 months;
    c. Failure to improve symptoms or functional impairments; **and**
2. Pain management includes **either** of the following:
    a. Intra-articular, subacromial or bicipital groove corticosteroid injection; **or**
    b. Medication management (e.g., NSAIDS or analgesics);

E. Both radiographs and MRI have been performed and have not established a definitive diagnosis or explanation for the individual's symptoms.

VII. Rotator cuff repair is **not medically necessary** when **ANY** of the following contraindications are present:

A. Advanced glenohumeral degenerative joint disease, including severe joint-space loss, bone-on-bone articulation, large osteophytes, subchondral sclerosis, or subchondral cyst formation (Kellgren-Lawrence grade II or greater);
B. Full-thickness rotator cuff tear without associated symptoms;
C. Medical or behavioral health conditions that are not adequately controlled or optimized for surgery;
D. Corticosteroid injection into the operative shoulder within the preceding twelve (12) weeks;
E. Deltoid paralysis or rotator cuff paralysis;
F. Poorly controlled diabetes mellitus (HbA1c greater than 8%);
G. Uncontrolled hypertension;
H. Active local or systemic infection; **or**
I. Nicotine or tobacco use within 6 weeks of the planned procedure, including cigarettes, cigars, smokeless tobacco, nicotine pouches, electronic cigarettes, or vaping devices.

VIII. Arthroscopic rotator cuff repair is **medically necessary** when **ALL** the following are met:

A. Shoulder symptoms result in functional impairment affecting activities of daily living (ADLs) and/or instrumental activities of daily living (IADLs);
B. Imaging confirms a rotator cuff tear, including partial-thickness tear; or full-thickness tear;
C. Clinical findings are consistent with rotator cuff pathology, including **both** the following:
    1. Reproducible pain patterns characteristic of rotator cuff disease; **and**
    2. Examination findings demonstrating rotator cuff dysfunction;
D. Symptoms are consistent with shoulder impingement, including pain reproduced with

overhead activity and improvement with lowering of the arm;

E. Conservative management meets **either** of the following:
   1. Conservative management is <u>not</u> required when **either** of the following is documented:
      a. Progressive enlargement of a full-thickness rotator cuff tear by 50% or more on serial imaging obtained at least 3 months apart; **or**
      b. Symptomatic traumatic rotator cuff tear with imaging demonstrating absence of glenohumeral arthritis; **or**
   2. For all other indications, conservative management must include **both** of the following:
      a. Physical therapy (PT) meets **all** the following:
         i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
         ii. Participation for a minimum of 6 weeks during the previous 6 months;
         iii. Failure to improve symptoms or functional impairments; **and**
      b. Pain management includes **either** of the following:
         i. Intra-articular, subacromial or bicipital groove corticosteroid injection; **or**
         ii. Medication management (e.g., NSAIDS or oral analgesics).

<u>Revision Rotator Cuff Repair</u>

IX. Revision rotator cuff repair is **medically necessary** when **ALL** the following are met:
   A. For revision procedures performed more than 1 year after the index repair, the request must satisfy the current rotator cuff repair medical necessity criteria;
   B. MRI or CT arthrography demonstrates **one (1)** of the following:
      1. Failure of tendon healing following prior repair (e.g., Sugaya Type IV or Type V); **or**
      2. Recurrent rotator cuff tear occurring more than 3 months after the original surgical procedure.

<u>Anterior-Inferior Labral Tear Repair (Bankart Repair)</u>

X. Anterior-inferior labral tear repair is **medically necessary** when **ALL** the following are met:
   A. No evidence of moderate-to-severe glenohumeral arthritis (Kellgren-Lawrence grade II or greater);
   B. No nicotine or tobacco use, including cigar, cigarette, e-cigarette, nicotine pouch, smokeless tobacco or vape pen use within 6 weeks of surgery;
   C. Comorbid conditions are appropriately managed and there is no active infection;
   D. For individuals with diabetes mellitus, HbA1c is 8% or less;
   E. Presence of **one (1) or more** of the following:

1. Combined labral pathology;
2. Recurrent glenohumeral instability, including **two (2) or more** subluxation or dislocation episodes; **or**
3. Acute shoulder pain associated with activity or exertion;

F. MRI or CT arthrogram confirms an anterior-inferior labral tear or bony Bankart lesion;

G. Conservative management must include **both** of the following:

1. Physical therapy (PT) meets **all** the following:
   a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
   b. Participation for a minimum of 6 weeks during the previous 6 months; **and**
   c. Failure to improve symptoms or functional impairments; **and**
2. Pain management includes **either** of the following:
   a. Intra-articular, subacromial or bicipital groove corticosteroid injection; **or**
   b. Medication management (e.g., NSAIDS or analgesics);

H. Physical examination reveals **all** the following:

1. Absence of significant shoulder stiffness;
2. Clinical evidence of instability;
3. Restricted or abnormal range of motion; **and**
   a. At least **one(1)** of the following:
      i. Positive apprehension test;
      ii. Positive relocation test;
      iii. Positive labral grind test; **or**
      iv. Objective painful laxity on examination.

<u>Shoulder Capsulorrhaphy</u>

XI. Shoulder capsulorrhaphy is **medically necessary** when **ALL** the following are met:

A. No evidence of moderate-to-severe glenohumeral arthritis (Kellgren-Lawrence grade II or greater);

B. No nicotine or tobacco, including cigar, cigarette, e-cigarette, nicotine pouch, smokeless tobacco or vape pen use within 6 weeks of surgery;

C. Comorbid conditions are appropriately managed and there is no active local or systemic infection;

D. For individuals with diabetes mellitus, HbA1c is 8% or less;

E. Chronic shoulder stiffness resulting from **one (1)** of the following:
   1. Adhesive capsulitis; **or**
   2. Arthrofibrosis related to disease, injury, or prior surgery;
   3. Conservative management must include **both** of the following:
      a. Physical therapy (PT) meets **all** the following:
         i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
         ii. Participation for a minimum of 3 months during the previous 6 months;
         iii. Failure to improve symptoms or functional impairments; **and**
      b. Pain management includes **either** of the following:
         i. Intra-articular, subacromial or bicipital groove corticosteroid injection; **or**
         ii. Medication management (e.g., NSAIDS or analgesics);

F. Physical examination demonstrates excessive glenohumeral joint translation, including **all** the following:
   1. Sulcus sign greater than 1 cm;
   2. Hyperabduction (Gagey) testing demonstrating greater than 105 degrees of abduction; **and**
   3. Beighton hypermobility score greater than 4;

G. Shoulder dysfunction has been present for at least 3 months;

H. Symptoms interfere with ADLs;

I. Documentation supports **one (1)** of the following:
   1. History of shoulder trauma; **or**
   2. Postoperative shoulder contracture.

<u>Shoulder Loose Body or Foreign Body Removal</u>

XII. Removal of an intra-articular loose body or foreign body from the shoulder is **medically necessary** when **ALL** the following are met:

A. No evidence of moderate-to-severe glenohumeral arthritis (Kellgren-Lawrence grade II or greater);

B. No nicotine or tobacco, including cigar, cigarette, e-cigarette, nicotine pouch, smokeless tobacco or vape pen use within 6 weeks of surgery;

C. Comorbid conditions are appropriately managed and there is no active infection;

D. For individuals with diabetes mellitus, HbA1c is 8% or less;

E. Documentation does not support another condition that adequately explains the individual's symptoms, including **any** of the following:
   1. Glenohumeral arthritis;
   2. Brachial plexus pathology;
   3. Fracture;
   4. Referred cervical pain; **or**
   5. Thoracic outlet syndrome;

F. CT or MRI demonstrates an intra-articular loose body or foreign body;

G. Documentation demonstrates **both** of the following:
   1. Shoulder pain or mechanical symptoms, including clicking, catching, or popping; and
   2. Functional limitation affecting ADLs;

H. A minimum of 3 months of conservative management failed, or was not tolerated, or the loose or foreign body results in **any** of the following:
   1. Acute mechanical restriction of shoulder motion;
   2. Locking; **or**
   3. Other severe mechanical symptoms requiring surgical intervention.

<u>Shoulder Lysis of Adhesions, Capsulotomy, and Capsular Release</u>

XIII. Shoulder lysis of adhesions, capsulotomy, or capsular release is **medically necessary** when **ALL** the following are met:

A. No evidence of moderate-to-severe glenohumeral arthritis (Kellgren-Lawrence grade II or greater);

B. Imaging studies do not demonstrate fracture or other significant soft tissue injury as the primary cause of the individual's symptoms;

C. No nicotine or tobacco use, including cigar, cigarette, e-cigarette, nicotine pouch, smokeless tobacco or vape pen use within 6 weeks of surgery;

D. Medical comorbidities are appropriately managed and there is no active infection;

E. For individuals with diabetes mellitus, HbA1c is 8% or less;

F. A minimum of 3 months of conservative management during the previous 6 months failed, or was not tolerated, and includes non-pharmacologic management with **either**:
   a. Chiropractic care; **or**
   b. Supervised physical therapy (PT);

G. Shoulder pain and loss of function interfere with ADLs;

H. Physical examination demonstrates loss of shoulder motion of at least 50% in **two (2)** planes when compared with the contralateral shoulder.

Shoulder Manipulation Under Anesthesia (MUA)

Requests for manipulation under anesthesia of the shoulder will be reviewed on an individual case basis using the clinical information submitted for review.

Shoulder Osteotomy

XIV. Shoulder osteotomy is **medically necessary** when documentation supports **one (1)** of the following indications:

A. Achondroplasia;

B. Degenerative or inflammatory shoulder arthritis;

C. Symptomatic osseous impingement or bone spur formation;

D. Hill-Sachs deformity;

E. Limb-length discrepancy resulting from trauma, infection, hypoplasia, or skeletal dysplasia;

F. Malunited fracture resulting in functional impairment;

G. Symptomatic shoulder instability; **or**

H. Residual shoulder deformity or dysfunction associated with obstetric brachial plexus palsy.

Partial Claviculectomy, Acromioplasty, or Distal Clavicle Excision (DCE)

XV. Partial claviculectomy, acromioplasty, and/or distal clavicle excision is **medically necessary** when **ALL** the following are met:

A. Conservative management must include **BOTH** of the following:

1. Physical therapy (PT) meets **all** the following:
    a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
    b. Participation for a minimum of 6 weeks during the previous 6 months;
    c. Failure to improve symptoms or functional impairments; **and**
2. Pain management includes **either** of the following:
    a. Intra-articular, subacromial or bicipital groove corticosteroid injection; **or**
    b. Medication management (e.g., NSAIDS or analgesics);

B. Localized acromioclavicular joint tenderness;

C. Positive cross-body adduction testing;

D. Shoulder pain and dysfunction have been present for at least 3 months;

E. Symptoms interfere with ADLs;

F. Radiographs or MRI demonstrate pathology involving the acromioclavicular joint, including **one (1) or more** of the following:
   1. Joint-space narrowing;
   2. Moderate-to-severe acromioclavicular degenerative disease;
   3. Distal clavicular edema; **or**
   4. Distal clavicular osteolysis.

Posterior Labral Repair

XVI. Posterior labral repair is **medically necessary** when **ALL** the following are met:

A. Imaging does not demonstrate **any** of the following advanced degenerative diseases:
   1. Posterior glenoid cartilage loss;
   2. Subchondral cyst formation;
   3. Significant joint-space narrowing; **or**
   4. Posterior humeral head subluxation associated with arthropathy;

B. No nicotine or tobacco use, including cigar, cigarette, e-cigarette, nicotine pouch, smokeless tobacco or vape pen use within 6 weeks of surgery;

C. Medical comorbidities are appropriately managed and there is no active infection;

D. For individuals with diabetes mellitus, HbA1c is 8% or less;

E. Conservative management must include **both** of the following:
   1. Physical therapy (PT) meets **all** the following:
      a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
      b. Participation for a minimum of 6 weeks during the previous 6 months;
      c. Failure to improve symptoms or functional impairments; **and**
   2. Pain management includes **either** of the following:
      a. Intra-articular, subacromial or bicipital groove corticosteroid injection; or
      b. Medication management (e.g., NSAIDS or analgesics);

F. MRI confirms a posterior labral tear;

G. Physical examination demonstrates **any** of the following findings:
   1. Positive load-and-shift test;
   2. Positive drawer test;
   3. Positive jerk test; **or**

4. Positive Kim test;

H. Documentation demonstrates **one (1) or more** of the following:
   1. Instability;
   2. Painful mechanical symptoms, including catching or popping; or
   3. Shoulder pain is attributable to the labral pathology.

Superior Labral Anterior-Posterior (SLAP) Repair

Debridement, biceps tenotomy, and biceps tenodesis are distinct procedures and are not considered SLAP repair.

XVII. Superior labral anterior-posterior (SLAP) repair is **medically necessary** when **ALL** the following are met:
   A. No evidence of moderate-to-severe glenohumeral arthritis (Kellgren-Lawrence grade II or greater);
   B. No nicotine or tobacco use, including cigar, cigarette, e-cigarette, nicotine pouch, smokeless tobacco or vape pen use within 6 weeks of surgery;
   C. Medical comorbidities are appropriately managed and there is no active infection;
   D. For individuals with diabetes mellitus, HbA1c is 8% or less;
   E. Documentation supports a shoulder injury associated with development of a SLAP tear, including:
      1. Overhead athletic activity;
      2. Fall;
      3. Traction injury;
      4. Lifting injury; **or**
      5. Motor vehicle accident;
   F. Conservative management must include **both** of the following:
      1. Physical therapy (PT) meets **all** the following:
         a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
         b. Participation for a minimum of 6 weeks during the previous 6 months;
         c. Failure to improve symptoms or functional impairments; **and**
      2. Pain management includes **either** of the following:
         a. Intra-articular, subacromial or bicipital groove corticosteroid injection; **or**
         b. Medication management (e.g., NSAIDS or analgesics);

G. MRI confirms a superior labral tear;

H. The lesion is classified as a Type II or Type IV SLAP tear;

I. At least **one (1)** of the following provocative tests is positive:

1. Anterior slide test;
2. Biceps load test I or II;
3. Forced shoulder abduction and elbow flexion test;
4. Jobe relocation test;
5. O'Brien (active compression) test;
6. Pain provocation test; **or**
7. Resisted supination external rotation test;

J. Shoulder symptoms have persisted for at least three 3 months; and

K. Pain and loss of function interfere with ADLs.

Shoulder Synovectomy

XVIII. Partial or complete shoulder synovectomy is **medically necessary** when **ALL** the following are met:

A. No evidence of moderate-to-severe glenohumeral arthritis (Kellgren-Lawrence grade II or greater);

B. No nicotine or tobacco use, including cigar, cigarette, e-cigarette, nicotine pouch, smokeless tobacco or vape pen use within 6 weeks of surgery;

C. Medical comorbidities are appropriately managed and there is no active infection;

D. For individuals with diabetes mellitus, HbA1c is 8% or less;

E. No uncontrolled hypertension;

F. Documentation demonstrates **one (1)** of the following:

1. Hemochromatosis;
2. Hemophilia;
3. Inflammatory arthropathy, including rheumatoid arthritis, gout, pseudogout, or psoriatic arthritis;
4. Lyme-related or nonspecific synovitis;
5. Pigmented villonodular synovitis (PVNS);
6. Recurrent hemarthrosis; **or**
7. Synovial chondromatosis;

G. Conservative management must include **both** of the following:
   1. Physical therapy (PT) meets **all** the following:
      a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
      b. Participation for a minimum of 6 weeks during the previous 6 months;
      c. Failure to improve symptoms or functional impairments; **and**
   2. Pain management includes **either** of the following:
      a. Intra-articular, subacromial or bicipital groove corticosteroid injection; **or**
      b. Medication management (e.g., NSAIDS or analgesics);

H. MRI or CT findings consistent with primary synovial disease or joint effusion, or prior arthroscopic findings demonstrating secondary hypertrophic synovitis;

I. Shoulder symptoms result in impairment of ADLs.

Long Head of Biceps (LHB) Tenotomy or Tenodesis

Tenodesis may be more appropriate in highly active individuals with greater functional demands, while tenotomy may be preferred when tendon healing capacity is a concern.

XIX. Long head biceps tenotomy or tenodesis is **medically necessary** when **ALL** the following are met:

A. No evidence of moderate-to-severe glenohumeral arthritis (Kellgren-Lawrence grade II or greater);

B. No nicotine or tobacco use, including cigar, cigarette, e-cigarette, nicotine pouch, smokeless tobacco or vape pen use within 6 weeks of surgery;

C. Medical comorbidities are appropriately managed and there is no active infection;

D. For individuals with diabetes mellitus, HbA1c is 8% or less;

E. No uncontrolled hypertension;

F. Documentation demonstrates **one (1) or more** of the following:
   1. Long head biceps hypertrophy, subluxation, or tear confirmed by MRI or CT;
   2. Superior labral anterior-posterior (SLAP) tear demonstrated on MRI;
   3. Full-thickness rotator cuff tear that independently meets medical necessity criteria for repair;
   4. Failure of a prior SLAP repair; **or**
   5. Chronic biceps tenosynovitis associated with localized pain in the bicipital groove;

G. Conservative management must include **both** of the following:
   1. Physical therapy (PT) meets **all** the following:

a. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
b. Participation for a minimum of 6 weeks during the previous 6 months;
c. Failure to improve symptoms or functional impairments; **and**

2. Pain management includes **either** of the following:
a. Intra-articular, subacromial or bicipital groove corticosteroid injection; **or**
b. Medication management (e.g., NSAIDS or analgesics);

H. Physical examination demonstrates at least **two (2)** of the following:
1. Anterior shoulder pain;
2. Positive Yergason test;
3. Positive Speed test;
4. Bicipital groove tenderness; **or**
5. Weakness attributable to long head biceps pathology;

I. Shoulder pain and dysfunction have been present for at least 3 months; **and**

J. Symptoms interfere with ADLs.

<u>Subacromial Decompression (SAD)</u>

XX. Subacromial decompression is **medically necessary** when **ALL** the following are met:

A. Radiographs obtained within the previous 12 months do not demonstrate moderate-to-severe glenohumeral degenerative joint disease, including advanced joint-space loss, large osteophyte formation, or bone-on-bone articulation;

B. No nicotine or tobacco use, including cigar, cigarette, e-cigarette, nicotine pouch, smokeless tobacco or vape pen use within 6 weeks of surgery;

C. Medical comorbidities are appropriately managed and there is no active infection;

D. For individuals with diabetes mellitus, HbA1c is 8% or less;

E. No uncontrolled hypertension;

F. Subacromial decompression is being performed in conjunction with at least **one (1)** of the following medically necessary procedures:
1. Capsulorrhaphy;
2. Debridement;
3. Distal clavicle excision;
4. Labral repair;
5. Removal of an intra-articular loose body or foreign body;

6. Lysis of adhesions or capsular release;
7. Rotator cuff repair;
8. Synovectomy; **or**
9. Long head biceps tenotomy or tenodesis.

RELATED POLICIES

Not Applicable

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Total shoulder arthroplasty (replacement) is a surgical technique that involves replacing the humeral head and the glenoid. A total shoulder arthroplasty is typically the best option if the glenoid is damaged, but sufficient bone and rotator cuff remain to ensure that the glenoid component will last. The primary goal of shoulder replacement surgery is pain relief, with the secondary benefits of restoring motion, strength, and function, and helping individuals return to an activity level as near to normal as possible.

Partial shoulder replacement, also known as hemiarthroplasty, is a surgical technique that involves replacing the humeral head and not replacing the glenoid (socket), which is typically the best option if the glenoid does not have any arthritis or if there is some concern that the glenoid component might fail if it is replaced. Hemiarthroplasty is a highly technical procedure. There are two types of hemiarthroplasties: stemmed hemiarthroplasty and resurfacing hemiarthroplasty. The surgeon determines the type of procedure to perform, based on the nature of the injury and the condition of the shoulder.

Reverse shoulder arthroplasty (replacement) involves replacing both the humeral head and the glenoid, but the ball and socket are reversed to improve muscle function. This allows the deltoid muscle, which has a longer movement arm, to generate greater force, allowing it to act in place of an inadequately functioning or torn rotator cuff.

Revision of shoulder arthroplasty (replacement) is a surgical technique that involves surgical reconstruction or replacement due to failure or complication of previous shoulder arthroplasty.

Shoulder pseudoparesis is a shoulder dysfunction, particularly in the setting of a massive unrepairable or irreparable rotator cuff tear, in which there is the presence of less than 90 degrees of active elevation.

Shoulder pseudoparalysis is a shoulder dysfunction, particularly in the setting of a massive unrepairable or irreparable rotator cuff tear, with all of the following: the presence of true anterosuperior escape; no true active shoulder elevation; and the individual is only able to demonstrate a shrug.

Shoulder resurfacing is a surgical technique that involves replacing the diseased part of the shoulder joint without replacing the humeral head. Resurfacing of the humeral head involves a prosthetic metal covering or cap to provide complete or partial coverage. It can be performed alone (hemi-re surfacing) or in combination with glenoid resurfacing (total or partial shoulder resurfacing.

The Walch classification of glenoid morphology is used to stratify the outcomes of shoulder arthroplasty for varying pathologic glenoid types. It also is used in preoperative planning to recognize morphologies that may pose intraoperative problems.

Type A: Centered humeral head, concentric wear, no subluxation of the humeral head

- A1: minor central erosion
- A2: major central erosion, humeral head protruding into the glenoid cavity

Type B: Humeral head subluxated posteriorly, biconcave glenoid with asymmetric wear

- B1: narrowing of the posterior joint space, subchondral sclerosis, osteophytes
- B2: biconcave aspect of the glenoid with posterior rim erosion and retroverted glenoid
- B3: monoconcave and posterior wear with >15° retroversion or >70% posterior humeral head subluxation, or both

Type C:

- C1: dysplastic glenoid with >25° retroversion regardless of the erosion
- C2: biconcave, posterior bone loss, posterior translation of the humeral head

Type D: Glenoid anteversion or anterior humeral head subluxation <40°

SUPPORTIVE LITERATURE

In a systematic review and meta-analysis, Carter and colleagues (2012) characterized the change in generic and shoulder-specific health-related quality-of-life (QOL) measures resulting from TSA. These investigators identified published studies reporting pre-operative and post-operative health related QOL outcomes for patients receiving TSA. Health-related QOL measures were identified, and meta-analysis was used to calculate standardized mean differences (SMD)s1 reflective of the effect size, and 95% confidence interval (CI) for each scale. A total of 20 studies (1,576 TSAs) met the inclusion criteria. Outcome measures were analyzed after an average post-operative follow-up duration of 3.7 +/- 2.2 years. The Short Form-36 demonstrated significant improvement in physical component summary scores (SMD = 0.7, $p < 0.001$), but not in mental component summary scores (SMD = 0.2, $p = 0.37$). Significant improvements were observed in the visual analog scale score for pain (SMD = -2.5, $p < 0.001$) and scores on three shoulder-specific measures: the Constant score (SMD = 2.7, $p < 0.001$), the American Shoulder and Elbow Surgeons score (SMD = 2.9, $p < 0.001$), and the Simple Shoulder Test (SMD = 2.3, $p < 0.001$). The authors concluded that TSA leads to significant improvement in scores for function and pain. Shoulder-specific measures of function consistently showed the greatest degree of improvement, with large effect sizes. They noted that TSA also leads to significant improvements in overall physical well-being, with a moderate-to-large effect size.

In a multi-centered retrospective study, Favard and colleagues (2012) evaluated the rate of complications and the functional improvement with different types of shoulder arthroplasties after a minimum follow-up of eight years. A total of 198 shoulders, including 85 with primary osteoarthritis (OA) of the shoulder, 76 with rotator cuff tears, 19 with avascular necrosis, and 18 with rheumatoid arthritis (RA), were included in this study. Arthroplasties included 104 anatomic TSAs, 77 reverse arthroplasties, and 17 hemiarthroplasties. Ten patients had their arthroplasty revised, and 134 patients with TSA were able to be present at the final follow-up or provide information on their case. Function was evaluated by the Constant-Murley score, and loosening was evaluated by standard radiographs. In the group with primary OA of the shoulder, there were eight complications (11 %), including six (8.3 %) requiring implant revision. In the group of rotator cuff arthropathies, there were nine (14.7 %) with complications, including four (6.5 %) requiring implant revision. In the group with RA, there was one complication, but no surgical revision was necessary. There were no complications in the group with avascular necrosis. Glenoid migration occurred in 28.5 % of anatomic TSAs, and 3.4 % of reverse arthroplasties. This difference was significant ($p < 0.001$). The Constant-Murley score was significantly improved in all etiologies. The authors concluded that glenohumeral arthropathies can be successfully treated by arthroplasty. Anatomic TSA was shown to be associated with a high risk of glenoid loosening at radiographic follow-up, which made them hesitate to use the cemented polyethylene implant, especially in young patients.

In a Cochrane review, Singh et al (2011) determined the benefits and potential harm associated with surgery for shoulder OA. These investigators performed a systematic review of clinical trials of adults with shoulder OA, comparing surgical techniques (TSA, hemiarthroplasty, implant type and fixation) to placebo, sham surgery, non-surgical modalities, and no treatment. They also reviewed trials that compared various surgical techniques, identifying patient-reported outcomes (pain, function, quality of life, etc.) or revision rates. They calculated the risk ratio for categorical outcomes and mean differences for continuous outcomes with 95% CI. There were no controlled trials of surgery versus placebo or non-surgical interventions. A total of seven studies with 238 patients were included. Two studies compared TSA to hemiarthroplasty (n = 88). Researchers noted significantly worse scores on the 0 to 100 American Shoulder and Elbow Surgeons scale (mean difference, -10.05 at 24 to 34 months; 95 % CI: -18.97 to -1.13; $p = 0.03$) and a non-significant trend toward higher revision rate in hemiarthroplasty compared to TSA (relative risk 6.18; 95 % CI: 0.77 to 49.52; $p = 0.09$). With one study providing data (n = 41), no differences were noted between groups for pain scores (mean difference 7.8; 95 % CI: -5.33 to 20.93), quality of life on Medical Outcomes Study Short-Form 36 physical component summary (mean difference 0.80; 95 % CI: -6.63 to -8.23), or adverse events (relative risk 1.2; 95 % CI: 0.4 to 3.8). The authors concluded that TSA was associated with better shoulder function, with no other demonstrable clinical benefits compared to hemiarthroplasty. They stated that more studies are needed, to compare clinical outcomes between them and comparing shoulder surgery to sham, placebo, and other non-surgical treatment options.

Vancolen et al (2020) conducted a systematic review to evaluate the outcome of six studies totaling 245 participants aged less than 65 years who underwent reverse total shoulder arthroplasty (RTSA), with the most common indications being failed rotator cuff repair and rotator cuff tear arthropathy. The overall concern regarding RTSA is implant longevity and risk of failure necessitating need for

revision surgery which may be a dissatisfier in younger individuals due to their higher postoperative expectations of function and pain relief. A significant level of postoperative functional improvement outcome was reported at a mean follow-up of 49 months (range, 19-140 months) (P < .05) as measured by the American Shoulder and Elbow Surgeons (ASES) and Subjective Shoulder Value (SSV), as well as pain scores as measured by Visual Analogue Scale (VAS) postoperatively. The pooled complication rate was considered high at 18% (n=44/245) with the most common complication reported as postoperative dislocation followed by glenoid loosening. The reoperation (revision) rate was 6% (n=15, range, 2-5) at a mean follow-up of 34 months (range, 19-140 months). The authors concluded that this small group study identified favorable short- to midterm functional outcomes of RTSA in the younger individual (<65 years) for indications including rotator cuff arthropathy and osteoarthritis. Due to the complication and revision rates identified in this systematic review, the authors stated that additional long-term studies are needed to report definitive clinical results regarding prosthesis longevity, complications, and need for revision surgery in this patient population.

Mowers and colleagues (2025) performed a systematic review and meta-analysis which included six (6) studies totaling 4525 individuals (males, n=2288 and females, n=2237) to compare patient-reported outcomes, range of motion, and rates of revision surgery between male and female individuals who had undergone a primary anatomic total shoulder arthroplasty (aTSA). The systematic review identified that males experienced significantly greater improvement in postoperative ASES shoulder pain and functional scores (mean difference 2.18, P<.001) and VAS pain scores (mean difference 0.40, P<.001) compared to females. The study also found that female individuals compared to male individuals had a significantly higher risk of revision surgery (10.1% versus 7.3%, risk ratio 1.43, P<.001) and revision surgeries (6.2% versus 3.7%, risk ratio 1.87, P= .03). It has been well established that female individuals are associated with a higher risk of periprosthetic fracture due to a higher prevalence of osteoporosis in females. The authors concluded that there is a need for further investigation to determine the clinical significance of the identified aTSA comparative outcomes and to identify modifiable biological and social risk factors to improve results in female patients.

Bi and colleagues (2024) conducted a systematic review and meta-analysis which included 23 studies totaling 1178 individuals to analyze comparative studies of surgical treatment options for massive irreparable rotator cuff tears (MIRCTs) in individuals less than 70 years of age for several patient-reported outcomes, range of motion (ROM), and acromiohumeral distance (AHD). The mean age of study participants was 62.8 years of age, male (n=48.2%) to female (n=51.8%) participant numbers with a mean follow-up timeframe of 28.9 months. For the Constant-Murley score, debridement (MD, 21.03; 95% CI, 8.98 to 33.08; P<.001) and arthroscopic bridging graft (aBG) (mean difference [MD], 6.97; 95% CI, 1.88 to 12.05; P= .007) resulted in the highest P-scores. For the ASES score, InSpace balloon arthroplasty (MD, 12.34; 95% CI, 2.18 to 22.50; P= .017), aBG (MD, 7.07; 95% CI, 0.28 to 13.85; P = .041), and long head of biceps augmented superior capsular reconstruction (BSCR) (MD, 5.16; 95% CI, 1.10 to 9.22; P = .013) resulted in the highest P-scores. For AHD, BSCR resulted in the highest P-score (MD, 1.46; 95% CI, 0.45 to 2.48; P= .005). For forward flexion range of motion (ROM), debridement (MD, 45.77; 95% CI, 25.41 to 66.13; P<.001) resulted in the highest P-score,

while reverse shoulder arthroplasty (RSA) resulted in the lowest P-score (MD, -16.70; 95% CI, -31.20 to -2.20; P = .024). The authors concluded that graft interposition repair techniques, superior capsular reconstruction using the long head of the bicep tendon, arthroscopic debridement, and balloon arthroplasty provided superiority in various study outcomes for individuals less than 70 years of age with MIRCTs without significant arthritis or pseudoparalysis and RSA provides the least benefit in forward flexion.

There is a lack of long-term, randomized controlled studies for shoulder resurfacing using metal, polyethylene and biological materials for the treatment of glenohumeral arthritis, humeral head fractures, and osteochondral lesions. Biological glenoid resurfacing with or without prosthetic humeral head replacement has been suggested as a means to avoid the potential complications of polyethylene use in younger patients with glenohumeral arthritis. A variety of biologic surfaces, including anterior capsule, autogenous fascia lata, and Achilles tendon allograft have been used; however, there is minimal evidence in the peer-reviewed literature that these biological grafts can provide a durable bearing surface over time and there is documentation of post-operative infections. Further studies to assess the long-term outcomes and to evaluate alternative surface bearing materials (especially on the glenoid side) are required.

PROFESSIONAL GUIDELINE(S)

According to the 2020 Management of Glenohumeral Joint Osteoarthritis Evidence-based Clinical Practice Guidelines of the American Academy of Orthopaedic Surgeons (AAOS), there is strong evidence that anatomic TSA produces more favorable function and pain relief in the short-to mid-term follow-up, when comparted to hemiarthroplasty, for the treatment of glenohumeral osteoarthritis. These guidelines also recommend, in the absence of reliable evidence, that clinicians use either anatomic TSA or reverse TSA for the treatment of glenohumeral joint osteoarthritis in selected patients with excessive glenoid bone loss and/or rotator cuff dysfunction.

Within the 2020 guidelines, AAOS also advised of limited evidence to support that clinicians may utilize stemmed, stemless or resurfacing prosthesis for patients with glenohumeral joint osteoarthritis undergoing total or hemi-arthroplasty. However, the low-quality studies provided early information that any of these implants are reasonable and safe options but should be used with caution as there are no long-term outcome studies.

According to the 2010 Management of Rotator Cuff Injuries of the AAOS which were updated in 2019, there is strong evidence supporting both physical therapy and surgical management resulted in a notable improvement in PROs for patients with symptomatic small to medium full-thickness rotator cuff tears. AAOS also recommended that there is also strong evidence that supports that PROs improve with physical therapy in symptomatic patients with full-thickness rotator cuff tears. However, the rotator cuff tear size, muscle atrophy, and fatty infiltration may progress over five (5) to 10 years with nonsurgical management.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates a variety of shoulder arthroplasty systems,

including reverse total shoulder arthroplasty (rTSA) and stemless implants as medical devices. All shoulder implants including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Sept 09]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls and Early Alerts | FDA [accessed 2026 Sept 09]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
23334	Removal of prosthesis, includes debridement and synovectomy when performed; humeral or glenoid component
23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (e.g., total shoulder)
23450	Capsulorrhaphy, anterior; Putti-Platt procedure or Magnuson type operation
23455	Capsulorrhaphy, anterior; with labral repair (e.g., Bankart procedure)
23460	Capsulorrhaphy, anterior, any type; with bone block
23462	Capsulorrhaphy, anterior, any type; with coracoid process transfer
23465	Capsulorrhaphy, glenohumeral joint, posterior, with or without bone block
23466	Capsulorrhaphy, glenohumeral joint, any type multi-directional instability
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (e.g., total shoulder).
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component
23480	Osteotomy, clavicle, with or without internal fixation;
23485	Osteotomy, clavicle, with or without internal fixation; with bone graft for nonunion or malunion (includes obtaining graft and/or necessary fixation)
23700	Manipulation under anesthesia, shoulder joint, including application of fixation apparatus

Code	Description
	(dislocation excluded)
29805	Arthroscopy, shoulder, diagnostic, with or without synovial biopsy (separate procedure)
29806	Arthroscopy, shoulder, surgical; capsulorrhaphy
29807	Arthroscopy, shoulder, surgical; repair of SLAP lesion
29819	Arthroscopy, shoulder, surgical; with removal of loose body or foreign body
29820	Arthroscopy, shoulder, surgical; synovectomy, partial
29821	Arthroscopy, shoulder, surgical; synovectomy, complete
29822	Arthroscopy, shoulder, surgical; debridement, limited, 1 or 2 discrete structures (e.g., humeral bone, humeral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies]
29823	Arthroscopy, shoulder, surgical; debridement, extensive, 3 or more discrete structures (e.g., humeral bone, hum-eral articular cartilage, glenoid bone, glenoid articular cartilage, biceps tendon, biceps anchor complex, labrum, articular capsule, articular side of the rotator cuff, bursal side of the rotator cuff, subacromial bursa, foreign body[ies]
29824	Arthroscopy, shoulder, surgical; distal claviculectomy including distal articular surface (Mumford procedure)
29825	Arthroscopy, shoulder, surgical; with lysis and resection of adhesions, with or without manipulation
29826	Arthroscopy, shoulder, surgical; decompression of subacromial space with partial acromioplasty, with coracoacromial ligament (i.e., arch) release, when performed (List separately in addition to code for primary procedure)
29827	Arthroscopy, shoulder, surgical; with rotator cuff repair
29828	Arthroscopy, shoulder, surgical; biceps tenodesis

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
M05.00 - M05.9	Rheumatoid arthritis (code range Felty's syndrome)
M12.511 - M12.519	Traumatic arthropathy, shoulder (code range)

Code	Description
M19.011 - M19.019	Osteoarthrosis, localized, primary, shoulder region (code range)
M19.111 - M19.119	Post-traumatic osteoarthritis, shoulder (code range)
M19.211 - M19.219	Osteoarthrosis, localized, secondary, shoulder region (code range)
M24.811 - M24.819	Other specific joint derangement of shoulder, not elsewhere classified [crepitus] (code range)
M87.021 - M87.029	Idiopathic aseptic necrosis of humerus [head] (code range)
S42.001K - S42.199P	Malunion or nonunion of fracture of shoulder (code range)
S42.201A - S42.496S	Fracture of humerus (code range)
T84.018A - T84.019A	Broken internal joint prosthesis [shoulder] (code range)
T84.028A- T84.029A	Dislocation of other and unspecified internal joint prosthesis (code range)
T84.038A - T84.039A	Mechanical loosening of other or unspecified prosthetic joint [shoulder] (code range)
T84.59XA	Infection and inflammatory reaction due to other internal joint prosthesis [shoulder]

REFERENCES

Ahsan ZS, et al. The Snyder classification of superior labrum anterior and posterior (SLAP) lesions. Clin Ortho Relat Res. 2016;474:2075-2078.

Alkhatib N, et al. Short and long-term outcomes in Bankart repair vs. conservative treatment for first-time anterior shoulder dislocation: a systematic review and meta-analysis of randomized controlled trials. J Shoulder Elbow Surg. 2022;31:1751-1762.

Alquraynis AM. The outcomes of arthroscopic surgery for patients with shoulder impingement syndrome: a systematic review. Orthopedic Reviews. 2025 May 25;17:134100.

American Academy of Orthopaedic Surgeons (AAOS) [Internet]. Management of glenohumeral joint

osteoarthritis. Evidence-based clinical practice guidelines. Original 2020 Mar 23 [accessed 2026 Oct 19] Available from: https://www.aaos.org/gjocpg

American Academy of Orthopaedic Surgeons (AAOS) [Internet]. Management of rotator cuff injuries. Evidence-based clinical practice guidelines. Original 2010 Mar [updated 2019 Mar 11;accessed 2026 Apr 29] Available from: https://www.aaos.org/globalassets/quality-and-practice-resources/rotator-cuff/rotator-cuff-cpg-final-12-20-19.pdf

American Academy of Orthopedic Surgeons (AAOS) [Internet]. OrthoInfo: bone tumor. 2026 [accessed 2026 Oct 19]. Available from: https://orthoinfo.aaos.org/en/diseases--conditions/bone-tumor/

American Academy of Orthopedic Surgeons (AAOS) [Internet]. OrthoInfo: malunion in the lower limb. 2026 [accessed 2026 Oct 19]. Available from: https://www.orthoinfo.org/diseases--conditions/malunion-in-the-lower-limb/

American Academy of Orthopedic Surgeons (AAOS) [Internet]. OrthoInfo: osteoarthritis. 2026 [accessed 2026 Oct 19]. Available from: https://www.orthoinfo.org/diseases--conditions/osteoarthritis/

American Academy of Orthopedic Surgeons (AAOS) [Internet] Rotator cuff injuries. 2025 Aug 18 [accessed 2026 Oct 19]. Available from: https://www.aaos.org/quality/quality-programs/rotator-cuff/

American Academy of Orthopaedic Surgeons (AAOS) [Internet]. OrthoInfo: achondroplasia. 2026 [accessed 2026 Oct 19]. Available from: https://www.orthoinfo.org/diseases--conditions/achondroplasia/

American Academy of Orthopaedic Surgeons (AAOS) [Internet]. Orthoinfo: infections. 2026 [accessed 2026 Oct 19]. Available from: https://www.orthoinfo.org/diseases--conditions/infections/

Baig M, et al. Does acromioplasty enhance arthroscopic rotator cuff repair? A systematic review and meta-analysis of randomized trials. Clin Shoulder Elbow. 2025;28(4):457-463.

Belk JW, et al. Biceps tenodesis versus tenotomy: a systematic review and meta-analysis of level I randomized controlled trials. J Shoulder Elbow Surg. 2021;30:951-960.

Bhatia S, et al. Arthroscopic management of recalcitrant stiffness following rotator cuff repair: a retrospective analysis. Indian Journal of Orthopeadics. 2013 Mar;47(2):143-149.

Bi AS, et al. Comparison of multiple surgical treatments for massive irreparable rotator cuff tears in patients younger than 70 years of age: a systematic review and network meta-analysis. Am J Sports Med. 2024 Sep;52(11):2919-2930.

Brockmeier SF, et al. Outcomes after arthroscopic repair of type-II SLAP lesions. J Bone Joint Surg Am. 2009;91:1595-1603.

Carter MJ, et al. Impact of total shoulder arthroplasty on generic and shoulder-specific health-related quality-of-life measures: a systematic literature review and meta-analysis. J Bone Joint Surg Am. 2012 Sep 5;94(17):e127.

Craig RS, et al. Shoulder replacement surgery for osteoarthritis and rotator cuff tear arthropathy. Cochrane Database Syst Rev. 2020 Apr 21;4(4):CD012879.

Cusano A, et al. Arthroscopic repair for posterior shoulder instability is associated with favorable outcomes and high return to sport or work: a systematic review and meta-analysis. Arth Sports Med Rehab. 2025;7(2):101032.

Dhaliwal K, et al. The role of reverse shoulder arthroplasty in elderly trauma: a systematic review. Cureus. 2020 May 18;12(5):e8180.

Ernstbrunner L, et al. Salvage Reverse total shoulder arthroplasty for failed operative treatment of proximal humeral fractures in patients younger than 60 years: long-term results. J Shoulder Elbow Surg. 2020 Mar;29(3):561-570.

Favard L, et al. Total shoulder arthroplasty - arthroplasty for glenohumeral arthropathies: results and complications after a minimum follow-up of 8 years according to the type of arthroplasty and etiology. Orthop Traumatol Surg Res. 2012 Jun;98(4 Suppl):S41-7.

Gauci MO, et al. Revision of failed shoulder arthroplasty: epidemiology, etiology, and surgical options. J Shoulder Elbow Surg. 2020 Mar;29(3):541-549.

Hartland AW, et al. Clinical effectiveness of tenotomy versus tenodesis for long head biceps pathology: a systematic review and meta-analysis. BMJ Open. 2022;12:e061954.

Li Y, et al. Clinical outcomes of patients with pigmented villonodular synovitis of the shoulder after arthroscopic synovectomy. BMC Musculoskeletal Disorders. 2022;23:1-9.

XXI. Kanto K, et al. Arthroscopic subacromial decompression versus placebo surgery for subacromial pain syndrome: 10-year follow-up of the FIMPACT randomized, placebo surgery controlled trial. BMJ. 2025;391:e086201.

Kennedy JS, et al. The American Society of Shoulder and Elbow Therapist's consensus statement on rehabilitation for anatomic total shoulder arthroplasty. J Shoulder Elbow Surg. 2020;29:2149-2162

Khazzam M, et al. Management of Glenohumeral Joint Osteoarthritis. Journal of the American Academy of Orthopedic Surgeons. 2020 Oct 1;28(19):781-789.

Klein A, et al. Early outcomes and complications of obese patients undergoing shoulder arthroplasty: A meta-analysis. J Clin Orthop Trauma. 2020 Mar;11(Suppl 2):S260-S264.

Knowles NK, et al. Revision shoulder arthroplasty: a systematic review and comparison of North American vs. European outcomes and complications. J Shoulder Elbow Surg. 2020 May;29(5):1071-1082.

Lapner P, et al. A multicenter randomized controlled trial comparing single-row with double-row fixation in arthroscopic rotator cuff repair, long-term follow-up. American J Sport Med. 2021;49(11):3021-3029.

Mancini MR, et al. Arthroscopic rotator cuff repair: a review of surgical techniques and outcomes. Clin Sports Med. 2023;42(2023):81-94.

McKean, J. Orthobullets: avascular necrosis of the shoulder. 2024 Oct 29. [accessed 2026 Oct 19] Available from: https://www.orthobullets.com/shoulder-and-elbow/3060/avascular-necrosis-of-the-shoulder

Migliorini F, et al. Anatomic total shoulder arthroplasty versus hemiarthroplasty for glenohumeral osteoarthritis: A systematic review and meta-analysis. Appl Sci. 2021;11.

Monir JG, et al. Reverse shoulder arthroplasty in patients younger than 65 years, minimum 5-year follow-up. J Shoulder Elbow Surg. 2020 Jun;29(6):e215-e221.

Mowers CC, et al. Females experience inferior outcomes and higher rates of revisions and complications compared to males following anatomic total shoulder arthroplasty: a systematic review and meta-analysis. J Shoulder Elbow Surg. 2025. Online Ahead of Print.

Orman S, et al. Comparison of surgical and non-surgical treatments for 3- and 4-part proximal humerus fractures: a network meta-analysis. Shoulder Elbow. 2020 Apr;12(2):99-108.

Papalia R, et al. Return to sport after anatomic and reverse total shoulder arthroplasty in elderly patients: a systematic review and meta-analysis. J Clin Med. 2020 May 22;9(5):1576.

Polisetty TS, et al. Anatomic and reverse shoulder arthroplasty for management of type B2 and B3 glenoid; a matched-cohort analysis. J Shoulder Elbow Surg. 2023:32(8):1629-1637.

Rangan A, et al. Management of adults with primary frozen shoulder in secondary care (UK FROST): a multicentre, pragmatic, three-arm, superiority randomized clinical trial. Lancet. 2020:396:977-989.

Rava et al. Preoperative partial-thickness rotator cuff tears do not compromise anatomic total shoulder replacement outcomes: medium-term follow-up. J Shoulder Elbow Surg. 2021 Apr;30(4):871-876.

Ricchetti ET, et al. Reliability of the modified walch classification for advanced glenohumeral osteoarthritis using 3-dimensional computed tomography analysis: a study of the ASES B2 glenoid multicenter research group. J Shoulder Elbow Surg. 2021 Apr;30(4) 736-746.

Singh JA, et al. Surgery for shoulder osteoarthritis: a Cochrane systematic review. J Rheumatol. 2011 Apr;38(4):598-605.

Tokish JM, Brinkman JC. Pseudoparalysis and pseudoparesis of the shoulder: definitions, management, and outcomes. J Am Acad Orthop Surg. 2024;32(21):965-974.

Vancolen SY, et al. Reverse total shoulder arthroplasty in the younger patient (≤65 years): a systematic review. J Shoulder Elbow Surg. 2020 Jan;29(1):202-209.

Wright MA, et al. Comparison of clinical outcomes after anatomic total shoulder arthroplasty and reverse shoulder arthroplasty in patients 70 years and older with glenohumeral osteoarthritis and an intact rotator cuff. J Am Acad Orthop Surg. 2020 Mar;28(5):e222-e229.

Zhang C, et al. Biceps tenodesis better improves the shoulder function compared with tenotomy for long head biceps tendon lesions: a meta-analysis of randomized controlled trials. J Clin Med. 2023 Feb 22;12(1754):1-12.

Zhou P, et al. Biceps tenotomy versus tenodesis for lesions of the long head of the biceps tendon- a systematic review and meta-analysis of randomized controlled trials. Medicine. 2021;100(3):e23993.

Zmistowski B, et al. Acromial stress fracture following reverse total shoulder arthroplasty: incidence and predictors. J Shoulder Elbow Surg. 2020 Apr;29(4):799-806.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Shoulder Arthroplasty is not addressed in specific National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original Effective Date

Policy/Procedure Name: Sickle Cell Disease Drug Treatment **Control Number: 1350/20.000377**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care for enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Sickle cell disease (SCD) results from a single amino acid substitution in the β-globin gene causing the sixth amino acid to be changed from glutamic acid to valine. The mutant hemoglobin S (HbS) has abnormal physiochemical properties that make it susceptible to continuous polymerization with other hemoglobin molecules in a hypoxic environment. As the HbS polymerizes, the red blood cell becomes deformed, assuming a characteristic sickle shape, impairing erythrocyte rheology, increasing adhesion-mediated vaso-occlusion, and ruining blood cell survival. Hence, the ordinarily free-flowing cytosol of red blood cells becomes very viscous and too rigid to transverse tight capillary beds. The resulting effects include cycles of microvascular vaso-occlusive events and intravascular hemolysis. These molecular, cellular, and biophysical processes synergize to promote acute and chronic pain, culminating in end-organ injury and failure. Several subtypes of SCD exist, depending on the exact mutation in each hemoglobin gene. However, available treatments so far are independent of these subtypes.

Hydroxyurea increases red blood cell (RBC) hemoglobin F levels and RBC water content, and reduces deformability of sickled cells, thereby altering adhesion of RBCs to endothelium. Hydroxyurea is usually first-line therapy in individuals with SCD who have frequent painful episodes, including infants. There is a strong recommendation to offer chronic hydroxyurea therapy to patients with ≥ 3 sickle-cell-associated moderate-to-severe crises in a 12-month period; sickle cell pain or severe symptomatic chronic anemia that interferes with daily activities and quality of life; and a history of severe and/or recurrent acute chest syndrome (ACS). In a landmark clinical trial in adult patients, hydroxyurea decreased median vascular occlusive crises requiring hospitalizations per year (2.5 vs 4.5, $p < 0.01$) and lengthened median time to first crisis (3.0 vs 1.5 months, p=0.01). Hydroxyurea is available as generic tablets, Droxia capsules, Siklos dissolvable and scored tablets, and Xromi oral solution.

Endari (L-glutamine) is an amino acid indicated to reduce the acute complications of SCD in adult and pediatric patients five years of age and older. In sickle cell disease, nicotinamide adenine dinucleotide (NAD) and its reduced form, NADH, have a role in regulating and preventing red blood cell oxidative damage, but the ratio of NADH to total NAD is lower, resulting in a decreased NAD redox potential. Glutamine may improve NAD redox potential in sickle red blood cells through increased availability of reduced glutathione. The FDA approval was supported by efficacy data from a 48-week Phase 3 clinical trial comparing L-glutamine to placebo (NCT01179217). Patients receiving Endari had a modest reduction in median sickle cell acute crises compared to placebo (3 vs. 4, p=0.05) and in hospitalizations for sickle cell pain (2 vs. 3, p=0.09). Approximately two-thirds of patients in both arms had been receiving a stable dose of hydroxyurea for at least three months and continued during the trial.

Adakveo (crizanlizumab) is a humanized IgG_2 kappa monoclonal antibody that binds to P-selectin and blocks its interaction with P-selectin glycoprotein ligand-1 on neutrophils and monocytes. As a result, Adakveo inhibits interactions between endothelial cells, platelets, red blood cells, and leukocytes, which may result in decreased platelet aggregation, maintenance of blood flow, and minimized sickle-cell-related pain crises. It is indicated to reduce the frequency of vaso-occlusive crises in adults and pediatric patients 16 years of age and older with SCD. Adakveo is administered intravenously based on weight and used mostly in the outpatient setting. Adakveo was studied in a randomized, double-blind, placebo-controlled trial. This phase II SUSTAIN trial demonstrated that patients receiving Adakveo (n=67) had a lower median annual rate of VOCs compared to patients receiving placebo (n=65) (1.63 vs. 2.98, p=0.01), indicating a 45.3% lower rate with Adakveo.

In September 2024, Oxbryta (voxelotor) was withdrawn from the market following recent data showing that there was a higher rate of vaso-occlusive crises in patients receiving Oxbryta compared to placebo, as well as more deaths in the Oxbryta group.

Summary

Effective date of policy:	2/12/2026
Indications	See specific agents listed below
Availability	Siklos (Hydroxyurea) is available as a 100-mg and 1,000-mg oral, scored tablets. Xromi (Hydroxyurea) is available as 100 mg/mL oral solution (148 mL bottle) Endari (L-glutamine) is available as a 5-g oral packet. Adakveo (crizanlizumab) [HCPCS Code: J0791] is available as a 100-mg/10-mL intravenous infusion.

Duration	Siklos - Initial: 12 months; continuation: 12 months Xromi - Initial: 12 months; continuation: 12 months Endari - Initial:12 months; continuation: 12 months Adakveo - Initial: Six months; continuation: 12 months

Required Criteria for Initial Approval

All of the following conditions for the requested drug and indication must be met in order to approve therapy.

Indication	Inclusion	Recommended Dosing
Siklos (hydroxyurea tablets) **Indication** (FDA approval) Reduce the frequency of painful crises and to reduce the need for blood transfusions in adult and pediatric patients, two years of age and older, with sickle cell anemia with recurrent moderate to severe painful crises. **AND** **Xromi (hydroxyurea oral solution)** **Indication** (FDA approval) Reduce the frequency of painful crises and reduce the need for blood transfusions in pediatric patients aged 6 months of age to less than 2 years with sickle cell anemia with recurrent moderate to severe painful crises **Rx Benefit**	1. Must have a diagnosis of Sickle cell disease (SCD) **AND** 2. Must meet the following age requirement based on product being requested: a. For Siklos, must be 2 years of age or older b. For Xromi, must be 6 months of age or older **AND** 3. Must meet one of the following (a, b, or c): a. Must have a valid medical reason why hydroxyurea capsules or Droxia cannot be used (i.e., unable to swallow whole capsules) **OR** b. If the requested dose is exactly divisible by available strengths of hydroxyurea capsules or Droxia, the patient will be required to use those unless there is a valid medical reason, they are unable. i. Hydroxyurea: 500 mg capsules ii. Droxia: 200 mg, 300 mg, 400 mg capsules [NOTE: Droxia does not require prior authorization but may not be on all formularies] iii. Siklos: 1000mg (can split into quarters for doses of 250, 500, 750, or 1000 mg; also available as 100 mg (can split in half for doses of 50 mg) iv. Xromi: 100 mg/mL (148 mL bottle) **OR** c. If the requested dose is not exactly divisible by available strengths of hydroxyurea capsules or Droxia, must meet both of the following (i and ii): i. Must have experienced a hematologic toxicity reaction with the next highest dose that can be made by using Droxia or generic hydroxyurea capsules **AND** a. Hematologic toxicity with hydroxyurea is defined by neutrophil, platelet, hemoglobin and/or reticulocyte count abnormalities concurrent with hydroxyurea use suggestive of hematologic toxicity. After the first hematologic toxicity, hydroxyurea therapy should be stopped and can be restarted with a dose reduction upon hematologic recovery. **AND** ii. Must have had drug failure (e.x., continued frequent and/or severe VOCs or ongoing, frequent transfusion requirements) with the next lowest dose that can be made by using Droxia or generic hydroxyurea capsules Quantity Limit for Xromi: 1 bottle (148 mL) per 30 days. Upon each review and dose escalation request the allowed quantity will be reviewed in accordance with FDA-approved weight-based dosing and as such will be limited to the number of full bottles necessary to obtain the appropriate daily dose. Example 1: Prescriber requests Xromi 700 mg per day (7 mL per day) or Siklos 700mg per day (1000 mg x1/2 + 100 mg x2), the patient would be required to use Droxia (300 mg x1 + 400 mg x1). Example 2: If a prescriber requests Xromi 750 mg per day (7.5 mL per day) or Siklos 750 mg per day (3/4 tab), the patient would be required to have a hematologic toxicity reaction with two Droxia 400 mg capsules taken together to make 800 mg per day **AND** drug failure with two Droxia 300 mg capsules taken together to make 600 mg per day.	Please see product specific prescribing information for FDA approved dosing

Endari (L-glutamine) **Indication** (FDA approval) Reduce the acute complications of sickle cell disease in adults and pediatric patients five years of age and older. **Rx Benefit**	1. Must have a diagnosis of Sickle Cell Disease type HbSS or HbS/β0 thalassemia as determined by hemoglobin electrophoresis **AND** 2. Member must be at least 5 years old **AND** 3. Must be experiencing symptomatic pain that is a result of Sickle Cell Disease **AND** 4. Must have had (See **Table 1** for additional hydroxyurea info) **(either a, b, or c)**: a. A therapeutic failure (ex. continued frequent and/or severe VOCs or ongoing, frequent transfusion requirements) to a ≥ 6 consecutive month trial of hydroxyurea at maximum tolerated dosing. Adherence will be based on: i. Pharmacy refill history. If the patient does not have pharmacy benefits through this health plan, a recent pharmacy profile will be requested. Progress notes documenting usage of sample medication may also be requested **OR** b. A contraindication to hydroxyurea defined as a hypersensitivity to hydroxyurea or any component of the formulation **OR** c. Must have experienced **two** hematologic toxicity reactions with hydroxyurea that resulted in discontinuation of therapy i. Hematologic toxicity with hydroxyurea is defined by neutrophil, platelet, hemoglobin and/or reticulocyte count abnormalities concurrent with hydroxyurea use suggestive of hematologic toxicity. After the first hematologic toxicity, hydroxyurea therapy should be stopped and can be restarted with a dose reduction upon hematologic recovery. If a second hematologic toxicity is experienced, treatment should be discontinued. 5. Endari and generic L-glutamine will not be approved in combination with Adakveo as there are currently no clinical studies evaluating the combinations Quantity limit exceptions will require a recent (within the past 6 months) weight and will be approved in accordance with the FDA-approved weight-based dosing as follows: a. < 30kg = 60 packets/30 days b. 30-65 kg = 120 packets/30 days c. > 65 kg = 180 packets/30 days	• < 30 kg: 5 g orally twice daily. • 30 to 65 kg: 10 g orally twice daily. • > 65 kg: 15 g orally twice daily.
Adakveo (crizanlizumab) **Indication** (FDA approval) Reduce the frequency of vaso-occlusive crises in adults and pediatric patients, age 16 years and older, with sickle cell disease. **Medical Benefit** **HCPCS:** J0791	1. The enrollee is at least 16 years of age 2. Must have a diagnosis of sickle cell disease (SCD) 3. Medication is prescribed by or in consultation with a hematologist or provider who specializes in management of SC 4. Enrollee had at least four or more vaso-occlusive crises (VOCs) within the previous 12 months that required a medical facility visit (ER, clinic, hospital, local physician visit). a. Examples of VOC events include but are not limited to: acute episode of pain caused by VOC, acute chest syndrome, hepatic sequestration, splenic sequestration, or priapism 5. Must have had (See Table 1 for additional hydroxyurea info) (either a, b, or c): a. A therapeutic failure (ex. continued frequent and/or severe VOCs or ongoing, frequent transfusion requirements) to a ≥ 6 consecutive month trial of hydroxyurea at maximum tolerated dosing. Adherence will be based on: i. Pharmacy refill history. If the patient does not have pharmacy benefits through this health plan, a recent pharmacy profile will be requested. Progress notes documenting usage of sample medication may also be requested OR	• 5 mg/kg IV infused over 30 minutes at week 0, week two, and every four weeks thereafter.

	b. A contraindication to hydroxyurea defined as a hypersensitivity to hydroxyurea or any component of the formulation OR c. Must have experienced two hematologic toxicity reactions with hydroxyurea that resulted in discontinuation of therapy. i. Hematologic toxicity with hydroxyurea is defined by neutrophil, platelet, hemoglobin and/or reticulocyte count abnormalities concurrent with hydroxyurea use suggestive of hematologic toxicity. After the first hematologic toxicity, hydroxyurea therapy should be stopped and can be restarted with a dose reduction upon hematologic recovery. If a second hematologic toxicity is experienced, treatment should be discontinued. 6. Adakveo will not be approved in combination with Endari/generic L-glutamine as there are currently no clinical studies evaluating the combinations 7. Initial approval will be for 6 months	

Exclusion Criteria

Coverage will not be administered for Siklos, Xromi, Adakveo, or Endari following gene therapy treatment for Sickle Cell Disease.

Continuation Criteria

- For Siklos, Endari, Xromi – documentation of positive clinical response to therapy (e.g., reduction in vaso-occlusive crises).
- For Adakveo - Recertifications will be for 1 year and require documentation of a decrease in the number and/or severity (ex. fewer/shorter hospitalizations) of VOCs compared to baseline.

Considerations

- Enrollee must have prescription drug coverage administered by CDPHP for hydroxyurea, Siklos, Xromi, or Endari.
- Adakveo will be covered under the medical benefit.
- Prior authorization is obtained through the CDPHP pharmacy department.

Table 1: NIH Consensus Treatment Protocol and Technical Remarks for the Implementation of Hydroxyurea Therapy

Initiation

- Starting dosage for adults (500 mg capsules): 15 mg/kg/day (round up to the nearest 500 mg); 5–10 mg/kg/day if patient has chronic kidney disease
- Starting dosage for infants and children: 20 mg/kg/day

Monitor

- Monitor CBC with WBC differential and reticulocyte count at least every 4 weeks when adjusting dosage.
- Aim for target ANC = 2,000/uL; however, younger patients with lower baseline counts may safely tolerate absolute neutrophil counts down to 1,250/uL.
- Maintain platelet count = 80,000/uL

Management of toxicities

- If neutropenia or thrombocytopenia occurs:
  - Hold hydroxyurea dosing
  - Monitor CBC with WBC differential weekly
  - When blood counts have recovered, reinstitute hydroxyurea at a dose 5 mg/kg/day lower than the dose given before onset of cytopenias

Response considerations

- A clinical response to treatment with hydroxyurea may take *3–6 months.* Therefore, a *6-month* trial on the maximum tolerated dose is required prior to considering discontinuation due to treatment failure, whether due to lack of adherence or failure to respond to therapy.
- A lack of increase in MCV and/or HbF is ***not*** an indication to discontinue therapy.

References

		Updated	Accessed
1.	Droxia prescribing information, Bristol-Myers Squibb Company. Princeton, NJ08543	6/23	11/24
2.	Siklos prescribing information, Medunik USA. Rosemont, PA 19010	11/23	11/24
3.	Endari prescribing information, Emmaus Medical Inc. Torrance, CA 90503	10/20	11/24
4.	Adakveo prescribing information, Novartis Pharmaceuticals Corporation. East Hanover, NJ 07936	6/24	11/24
5.	Xromi oral solution prescribing information. Rare Diseases Therapeutics Inc., Franklin, TN	12/24	3/25
6.	Niihara Y, Miller ST, et al. Investigators of the Phase 3 Trial of l-Glutamine in Sickle Cell Disease. A Phase 3 Trial of l-Glutamine in Sickle Cell Disease. N Engl J Med. 2018 Jul 19;379(3):226-235. doi: 10.1056/NEJMoa1715971. PubMed PMID:30021096	7/18	11/22
7.	Vichinsky E, Hoppe CC, Ataga KI, et al; HOPE Trial Investigators. A Phase 3 Randomized Trial of Voxelotor in Sickle Cell Disease. N Engl J Med. 2019 Aug 8;381(6):509-519. doi: 10.1056/NEJMoa1903212. Epub 2019 Jun 14. PubMed PMID: 31199090.	8/19	11/22
8.	Ataga KI, Kutlar A, et al. Crizanlizumab for the Prevention of Pain Crises in Sickle Cell Disease. N Engl J Med. 2017 Feb 2;376(5):429-439. doi:10.1056/NEJMoa1611770. Epub 2016 Dec 3. PubMed PMID: 27959701; PubMed Central PMCID: PMC5481200	2/17	11/22
9.	Sundd P, Gladwin MT, Novelli EM. Pathophysiology of Sickle Cell Disease. Annual Rev Pathol. 2019 Jan 24;14:263-292. doi: 10.1146/annurev pathmechdis-012418-012838. Epub 2018 Oct 17. PubMed PMID:30332562.	1/19	11/22
10.	Hematology: Sickle Cell in IPD Analytics. Retrieved 11/2/22 from https://www.ipdanalytics.com/. Subscription required to view		11/22
11.	Evidence-Based Management of Sickle Cell Disease: Expert Panel Report. National Heart, Lung, and Blood Institute. 2014. Available at https://www.nhlbi.nih.gov/health-topics/evidence-based-management-sickle-cell-disease	9/14	3/25
12.	M. R. DeBaun, L. C. Jordan, A. A. King, J. Schatz, E. Vichinsky, C. K. Fox, R. C. McKinstry, P. Telfer, M. A. Kraut, L. Daraz, F. J. Kirkham, M. H. Murad; American Society of Hematology 2020 guidelines for sickle cell disease: prevention, diagnosis, and treatment of cerebrovascular disease in children and adults. Blood Adv 2020; 4 (8): 1554–1588. doi: https://doi.org/10.1182/bloodadvances.2019001142	4/20	11/23
13.	Robert I. Liem, Sophie Lanzkron, Thomas D. Coates, Laura DeCastro, Ankit A. Desai, Kenneth I. Ataga, Robyn T. Cohen, Johnson Haynes, Ifeyinwa Osunkwo, Jeffrey D. Lebensburger, James P. Lash, Theodore Wun, Madeleine Verhovsek, Elodie Ontala, Rae Blaylark, Fares Alahdab, Abdulrahman Katabi, Reem A. Mustafa; American Society of Hematology 2019 guidelines for sickle cell disease: cardiopulmonary and kidney disease. Blood Adv 2019; 3 (23): 3867–3897. doi: https://doi.org/10.1182/bloodadvances.2019000916	12/19	11/23
14.	Julie Kanter, Robert I. Liem, Françoise Bernaudin, Javier Bolaños-Meade, Courtney D. Fitzhugh, Jane S. Hankins, M. Hassan Murad, Julie A. Panepinto, Damiano Rondelli, Shalini Shenoy, John Wagner, Mark C. Walters, Teonna Woolford, Joerg J. Meerpohl, John Tisdale; American Society of Hematology 2021 guidelines for sickle cell disease: stem cell transplantation. Blood Adv 2021; 5 (18): 3668–3689. doi: https://doi.org/10.1182/bloodadvances.2021004394	9/21	11/22
15.	Kanter J, Walters MC, Krishnamurti L, Mapara MY, Kwiatkowski JL, Rifkin-Zenenberg S, Aygun B, Kasow KA, Pierciey FJ Jr, Bonner M, Miller A, Zhang X, Lynch J, Kim D, Ribeil JA, Asmal M, Goyal S, Thompson AA, Tisdale JF. Biologic and Clinical Efficacy of LentiGlobin for Sickle Cell Disease. N Engl J Med. 2022 Feb 17;386(7):617-628. doi: 10.1056/NEJMoa2117175. Epub 2021 Dec 12. PMID: 34898139.		11/23
16.	https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerting-patients-and-health-care-professionals-about-voluntary-withdrawal-oxbryta-market-due	9/24	11/24
17.	The National Institutes of Health – National Heart, Lung, and Blood Institute Evidence-Based Management of Sickle Cell Disease, Expert Panel Report 2014. Available at: http://www.nhlbi.nih.gov/guidelines Accessed on December 8th, 2019		12/19

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE CHOICES: Medical Benefit – Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Medical Benefit – Subject to all terms and conditions noted in above application.

Pharmacy Benefit - Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program.

CDPHP Pharmacy Services 2/12/2026

New: 2/2020

Revised	Reviewed
2/21, 2/22, 2/23, 2/24, 2/25, 6/25, 9/25, 2/26	

Revision Date	Changes Made
2/2022	Reduced Oxbryta age requirement from 12 years of age to four years of age; adjusted dosing to reflect pediatric reference. Added quantity limits based on available package sizes of 300mg tablets.
2/2023	Updated age range for Siklos from ages two to 18, to ages two and up to match updated indication Updated dosing for Siklos for adults.
2/2024	Added exclusion criteria that coverage will not be administered for Siklos, Adakveo, Oxbryta, or Endari following gene therapy treatment for Sickle Cell Disease.
2/2025	Oxbryta removed from policy following withdrawal from market.
6/2025	Added Xromi to the policy, modified inclusion criteria for Siklos to remove clinical requirements and shift to requiring dose optimization of formulary alternatives (generic hydroxyurea and Droxia), updated inclusion criteria for Endari to require therapeutic failure of 6 months of hydroxyurea instead of 12 months **or** contraindication to hydroxyurea **or** Hematologic toxicity to hydroxurea for Endari coverage, added NIH table regarding hydroxyurea treatment protocol and implementation into considerations, added quantity limits for Siklos, Xromi, Endari.
9/2025	Dosing update for Endari for individuals under 30kg
2/2026	Adakveo: Updated enrollee has had at least two or more vaso-occlusive crises (VOCs) within the previous 12 months to four or more and added examples of VOCs Updated hydroxyurea trial language for Adakveo

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MEDICAL POLICY

Medical Policy Title	**Sinus Excision/Destruction, Implants, and Repair**
Policy Number	**7.01.99**
Current Effective Date	**January 1, 2027**
Next Review Date	**December 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Drug- Eluting Implants (Mometasone Furoate)

A. The SINUVA implant is considered **medically necessary** when **ALL** of the following criteria are met:

1. 18 years of age or older;
2. Diagnosis of recurrent nasal polyps secondary to chronic rhinosinusitis;
3. History of ethmoid sinus surgery and would be candidates for revision sinus surgery;
4. Have nasal obstruction/congestion syndromes despite use of intranasal steroid irrigations or sprays;
5. Previous treatment, contraindication, intolerance to conventional nasal polyp therapy such as leukotriene receptor antagonist, steroid taper, or intranasal steroids.

B. The use of the PROPEL drug-eluting sinus stent is considered **investigational**.

C. Repeat use of drug-eluting sinus stents has not been medically proven to be effective and, therefore, is considered **investigational**.

II. Repair of Nasal Valve Collapse (NVC)/Nasal Obstruction

A. The use of an absorbable nasal implant (e.g., Latera) is **investigational** for the treatment of NVC in patients with nasal obstruction.

B. Radiofrequency ablation/neurolysis of the nasal valve (e.g., VivAer stylus) is considered **investigational** for **ALL** indications, including treatment of nasal airway obstruction.

III. Excision/Destruction of the Posterior Nasal Nerve (PNN)

A. Excision/Destruction of the PNN utilizing ANY of the following approaches is **investigational** for **ALL** indications, including the treatment of chronic rhinitis (allergic or nonallergic):

1. Cryoablation (e.g., ClariFix device);
2. RF ablation (e.g., RhinAer stylus, NEUROMARK);
3. Laser ablation.

RELATED POLICIES

Corporate Medical Policy

7.01.41 Surgical Management of Sleep Disorders

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Rhinosinusitis is defined as inflammation of the sinuses and nasal cavity. Rhinosinusitis may be classified based on duration. Acute sinusitis is defined as having symptoms lasting for fewer than 12 weeks. Recurrent acute rhinosinusitis consists of three or more episodes of acute bacterial rhinosinusitis in a year, while chronic rhinosinusitis is characterized by symptoms lasting 12 weeks or more. Chronic rhinosinusitis (CRS) is characterized by four cardinal symptoms: nasal obstruction (congestion), mucopurulent drainage (anterior and/or posterior), facial pain/pressure/fullness, or decreased/loss of sense of smell. Non-specific symptoms can include fatigue, cough, ear pain/pressure, dental pain, or sleep disturbance) CRS may occur with or without nasal polyps. Symptoms persist for weeks to months. In some cases of CRS, surgical drainage may be necessary.

Rhinitis is defined as symptomatic inflammation of the paranasal sinuses and nasal cavity. Chronic rhinitis is defined as rhinorrhea with or without nasal congestion symptoms despite medical therapy lasting longer than three months. Allergic rhinitis is defined as an immunoglobulin E (IgE)–mediated inflammatory response of the nasal mucous membranes after exposure to inhaled allergens. Symptoms include rhinorrhea (anterior or postnasal drip), nasal congestion, nasal itching, and sneezing. Allergic rhinitis can be seasonal or perennial, with symptoms being intermittent or persistent.

Nasal obstruction is a symptom of difficulty moving air through the nose and can be cause by a variety of factors including anatomic narrowing (e.g., deviated nasal septum, neoplasm, scarring, nasal fracture), dynamic collapse (e.g., internal nasal valve collapse), inflammation (e.g., swelling, polyposis), turbulent airflow (e.g., septal perforation), and excessive secretions or crusting in the nasal cavity. Commonly, patients will feel that they have nasal congestion or stuffiness. Unilateral symptoms are more suggestive of structural causes of nasal obstruction. A history of trauma or previous nasal surgery, especially septoplasty or rhinoplasty, is also important.

Nasal valve collapse (NVC) is a readily identifiable cause of nasal obstruction. Specifically, the internal nasal valve represents the narrowest portion of the nasal airway with the upper lateral nasal cartilages present as supporting structures. The external nasal valve is an area of potential dynamic collapse that is supported by the lower lateral cartilages. Damaged or weakened cartilage will further decrease airway capacity and increase airflow resistance and may be associated with symptoms of obstruction (e.g., congestion, difficulty breathing with exertion or lying down, and mouth breathing). Patients with NVC may be treated with nonsurgical interventions to increase the airway capacity, but surgery may be necessary for severe symptoms and anatomic distortion.

Nasal and sinus conditions are a commonly diagnosed disease in the U.S. Symptoms are associated with significant negative impacts on quality of life, missed days from work and school, and high healthcare costs due to medical visits, prescriptions and over-the-counter medications, sinus surgeries. Treatments are based on the underlying etiology and experienced symptoms. Medical management (e.g., over-the-counter nasal strips, intranasal corticosteroids, short-term oral corticosteroid, saline nasal irrigation, nasal valve dilator) is the standard first-line treatment option; however, minimally invasive surgical interventions (e.g., post-operative stents, implants, ablation) may be necessary for patient who fail medical therapy.

Drug-Eluting Sinus Stents

Endoscopic sinus surgery (ESS), a fiberoptic nasal endoscope is used to visualize the sinus ostia, and any obstruction found is corrected. The procedure restores patency and allows air and mucous transport through the natural ostium. ESS for CRS may be compromised by post-operative inflammation, polyposis, and adhesions, often requiring subsequent medical and surgical intervention. Post-operative interventions employed to reduce these complications are often time-consuming and uncomfortable for the patient. Current medical therapies (e.g., oral corticosteroids, topical steroid spray, and nasal packing) all have limitations; therefore, sinus stents have been investigated as an option to maintain patency of the sinus openings in the post-operative period, and/or serve as a local drug delivery vehicle. Reducing post-operative inflammation and maintaining patency of the sinus may be important in achieving optimal sinus drainage and may impact recovery from surgery.

The PROPEL sinus implant manufacturer claims that the PROPEL stent "separates mucosal tissues, provides stabilization of the middle turbinate, prevents obstruction by adhesions, and reduces edema." The implant is manufactured from a synthetic bioabsorbable copolymer, poly (L-lactideco-glycolide), and contains 370µg mometasone furoate, a synthetic corticosteroid. The implant is designed to accommodate the size and variability of the post-surgical ethmoid sinus anatomy. The device is dissolvable over a period of several weeks, and, therefore, does not require removal.

The SINUVA sinus implant contains 1350 mcg of mometasone furoate and implantation can be performed in the physician's office. It is left in place for up to 90 days, or earlier, at the physician's discretion, to gradually release the corticosteroid, and then requires removal.

Treatment of Nasal Valve Collapse (NVC) with Obstruction

The placement of an absorbable implant to support the lateral nasal cartilage has been proposed as an alternative to more invasive grafting procedures in patients with severe nasal obstruction and can be implanted in the office-setting under local anesthesia. The concept is that the implant may provide support to the lateral nasal wall prior to its resorption and then stiffens the wall with scarring as it is resorbed. The Latera absorbable nasal implant consists of a PLLA-PDLA copolymer that is predominantly cylindrical in shape with an approximate diameter of one mm and length of 24mm as well as a disposable delivery device and is intended to support cartilage in the nasal lateral wall. Latera is designed to be absorbed by the body over the period of 18-24 months post-implant.

Temperature-controlled RF ablation has been proposed as a minimally invasive option to reduce nasal-valve obstruction by submucosal remodeling to improve nasal airflow (Jacobowitz et al 2022). The VivAer Stylus delivers bipolar temperature-controlled RF energy to targeted nasal tissue. Researchers theorize that as the tissue heals, the scarring and remodeling may increase the nasal valve opening, shrink submucosal tissue, and increases resistance to valve collapse.

Treatment of Chronic Rhinitis (Allergic or Nonallergic)

Excision/ destruction (cryoablation, RF, and laser) is a proposed alternative to medical management for patients with chronic rhinitis symptoms (allergic or nonallergic). Excision/destruction of the distal branches of the nasal parasympathetic system, the posterior nasal nerve (PNN), is a proposed treatment to improve symptoms of chronic rhinitis by reducing parasympathetic innervation to the nasal cavity. The procedure is thought to correct the imbalance of autonomic input to the nasal mucosa, reducing nasal antigen responses and vascular hyperreactivity.

Cryoablation freezes nerve fibers of the PNN to reduce the overactivity that causes excess mucus. The ClariFix device is a cryosurgical tool that uses nitrous oxide to freeze the PNN to correct the imbalance of autonomic input to the nasal mucosa to reduce nasal antigen responses and vascular hyperreactivity.

RF ablation uses low-temperature energy to disrupt the PNN to correct the imbalance of autonomic input to the nasal mucosa to reduce symptoms of chronic rhinitis. The RhinAer Stylus delivers temperature-controlled RF energy to target and calm overactive nerves in the PNN region to reduce symptoms of moderate to severe chronic rhinitis.

Laser surgery is a common minimally invasive treatment for a wide range of otolaryngological conditions including but not limited to hereditary hemorrhagic telangiectasia, turbinate hypertrophy, septoplasty, and choanal atresia. Its use has also been proposed for the treatment of rhinitis via destruction of the PNN. Lasers utilized for rhinology include argon, potassium titanyl phosphate, diode, neodymium-doped yttrium aluminum garnet, and carbon dioxide. Each laser type has different properties for whether it cuts, coagulates, or evaporates tissues, and many have differing delivery systems.

SUPPORTIVE LITERATURE

Drug-Eluting Stents

A 2025 systematic review and meta-analysis (Zamaili et al) aimed to assess the impact of steroid-eluting middle meatal implant after ESS for patients with CRS. The primary outcome was the rate of

adhesion following surgery, and secondary outcomes were mucosal inflammation, polyp reformation, the need for oral steroids and additional surgery, post-operative bleeding, sinus pain and discomfort, postoperative sinus infection and change in intraocular pressure. Randomized controlled trials were included and eligible if they involved adult patients receiving ESS for CRS with or without nasal polyps utilizing a steroid-eluting middle meatal implant within the four weeks postoperative period. A total of seven studies were included in the review, representative of 1122 participants (568 in implant and 554 in control groups). The implants utilized in the studies included PROPEL, PROPEL Mini or Contour, BISORB, and SinuBand FP. Results indicated that although beneficial effects were noted including fewer postoperative treatments, decreased rates of adhesions, inflammation and recurrent polyp development, these effects are based on measurements conducted 30 days post-surgery. Authors noted that only a few studies examined outcomes after this time frame. Additionally, the study design is open to potential bias impacting the overall conclusion of the analysis, therefore, trials looking into longer-term effects of the implants on the outcome of ESS are warranted.

There are four randomized controlled trials evaluating PROPEL implants. Murr et al (2011) and Marple et al (2012) compared unilateral PROPEL stent use in the ethmoid sinus with a non-drug eluting stent on the contralateral side. These studies, although they demonstrated some success in the reduction of inflammation rated by the treating physician, were also limited by a lack of knowledge on whether the comparator received optimal treatment (e.g., packing, intranasal steroids, and irrigation). Smith et al (2016) and Luong et al (2017) aimed to compare the use of PROPEL mini or PROPEL Contour sinus implant in the frontal sinus versus surgery alone on the contralateral side. These trials demonstrated a 22% reduction in the need for additional surgical intervention but also consisted of a high percentage of patients that were not included in the evaluation due to poor video quality. Further studies are needed with appropriately treated comparison subjects to provide high-quality evidence that steroid-eluting stents reduce adhesion, mucosal inflammation, polyp recurrence, the need for oral steroids post-surgery or additional surgical procedures.

Han et al (2014) reported on results from the RESOLVE trial, which was a sham-controlled, randomized trial evaluating the use of office-based placement of the RESOLVE mometasone-eluting nasal stent for patients with recurrent nasal polyposis after ESS. Eligible patients had CRS, had undergone prior bilateral total ethmoidectomy more than three months earlier, had endoscopically confirmed recurrent bilateral ethmoid sinus obstruction due to polyposis that was refractory to medical therapy, and were considered candidates for repeat surgery based on the judgment of the surgeon and patient. Patients and those who administered symptom questionnaires at follow-up visits were blinded to treatment group. The trial was powered to detect a between-group difference of at least a 0.6-point change in polyp grade from baseline, and at least a 1.0- point change in nasal obstruction/congestion score. One hundred subjects were randomized to treatment (n=53) or control (n=47). For endoscopically measured outcomes, at 90 days of follow-up, the treatment group had a greater reduction in polyp grade than the control group (-1.0 vs -0.1; p=0.016) and a greater reduction in percent ethmoid obstruction on a 100-mm VAS (-21.5 mm vs 1.3 mm; p=0.001), both, respectively. For patient-reported outcomes, there were no significant differences in change in nasal obstruction/congestion scores between groups. Compared with controls, fewer treatment-group patients required oral steroids for ethmoid obstruction (11% vs 26%), and fewer treatment group

patients were indicated for sinus surgery at three months based on established criteria (47% vs 77%), although statistical comparisons were not reported.

For individuals with recurrent or persistent nasal polyposis after ESS, the use of steroid-eluting nasal implants was investigated to determine improvements in polyp grade and ethmoid obstruction in two randomized controlled trials (RCTs) (RESOLVE I and RESOLVE II, Forwith et al (2016) and Kern et al (2018)). A total of 400 patients were represented between these two studies, and did demonstrate improvements utilizing a sham-controlled design, however both studies were at high risk for bias as the outcome assessment was unblinded to the treatment group.

In 2019, Ernst and colleagues aimed to evaluate the economic impact of insertion of a steroid-eluting sinus implant (SINUVA) after a previous endoscopic surgery compared to a repeat sinus surgery in adults with chronic sinusitis and nasal polyps. A budget impact analysis over a one-year period was conducted to determine annual total and per-member per-month (PMPM) direct health care costs for a commercial health plan with one-million members. Multiple data sources were utilized to inform the input model values, including a database of 86,052 patients with an ESS performed between 2012-2015. Results from the RESOLVE trial were used to calculate the rate of recurrent sinusitis and the proportion of patients still indicated for revision surgery at study completion. Several other assumptions were made including no preprocedural work up required for the drug implant procedure as well as likelihood of two implants obtained per encounter (bilateral nature of sinonasal polyps). Results of the analysis estimated that 1000 hypothetical members of a commercial health plan would be candidates to receive an implant or revision surgery. Estimated treatment costs for patients with chronic sinusitis with nasal polyps using only revision surgery was $11.03 million, or $0.92 PMPM. Authors used the assumption that the implant would replace surgery in 50% of cases, and if 63% of those individuals received a second treatment with implant during the year, the cost savings would be $2.56 million or $0.21 PMPM. An additional scenario analysis revealed that the cost savings would decrease to $1,278,336 ($0.11 PMPM) if uptake of the implant were 25% versus 50% or would conversely increase to $3,835,007 ($0.32 PMPM) if uptake of the implant was 75%. Authors concluded that use of the implant over revision surgery could result in considerable savings given much lower procedure-related costs and that more research is warranted to include real-world market adoption data for the implants.

Per the drug labeling, the repeat implantation of SINUVA has not been studied.

Absorbable Nasal Implant for Nasal Obstruction

Research evaluating the use of absorbable nasal implants (i.e., Latera) in individuals with symptomatic nasal obstruction due to internal NVC has included one small, short-term RCT and four non-randomized prospective cohort studies with follow-up of up to 24 months. Overall, improvements in nasal obstruction symptom scores have been demonstrated. Additionally, adverse effects have been mild and self-limiting. There have been no prospective studies evaluating device efficacy against a comparable procedure (e.g., inferior turbinate reduction and/or septoplasty), and the evidence is insufficient to determine patient selection criteria as well as net health outcomes.

A 2020 meta-analysis by Kim et al evaluated the effectiveness of Latera in the treatment of nasal obstruction caused by lateral wall insufficiency (LWI). Five studies, including 396 patients, which

scored endoscopic lateral wall movement and nasal obstruction related to quality of life (QOL) before and after bioabsorbable nasal implants were included in the analysis. One study included a comparison of the treatment to a sham group. Researchers found that bioabsorbable nasal implants significantly reduced endoscopic lateral wall motion as well as improved QOL up to 12 months postoperatively. Adverse effects were reported in five percent of implant patients, were mild and resolved without sequalae. Researchers acknowledged that, while bioabsorbable nasal implants may reduce nasal wall movement and subjective symptoms compared to preoperative status, more RCTs must be conducted to verify their effectiveness.

Stolovitzy et al (2019) conducted a prospective, multicenter, randomized sham-controlled single blinded trial evaluating the safety and efficacy of a bioabsorable implant treatment for NVC. A total of 137 patients with NAO due to dynamic bilateral wall insufficiency confirmed by a positive modified Cottle maneuver with Nasal Obstruction Symptom Evaluation (NOSE) scores of at least 55 (classified as severe) and failed medical management were randomized into the treatment (n=71) and sham control (n=66) groups. Following initial evaluation, patients underwent cannula-introduced bioabsorbable nasal implant (treatment group) or sham procedure involving the cannula without implant insertion. Patients were followed for three months. The primary endpoint was the responder rate at three months after the index procedure. Responders were defined as patients who had at least one NOSE class improvement or a NOSE score reduction of at least 20% from baseline. Secondary endpoints included the frequency of procedure-related adverse events at index procedure and all follow-up visits, and the change in NOSE and VAS scores from baseline to all follow-up visits. At three months after treatment, the treatment arm had a significantly greater reduction in NOSE and VAS scores compared to the sham group (-42.4 ± 23.4 vs -22.7 ± 27.9, $p < 0.0001$ and -39.0 ± 29.7 vs -13.3 ± 30.0, $p < 0.0001$, respectively). A total of 19 procedure-related or implant-related adverse events were reported in 17 patients, including six implant retrievals. This study's conclusions are limited by the short-term follow-up and the single blind design introduced risk of bias.

Bikhazi et al (2021) performed a follow-up to the Stolovityzy et al (2019) three-month trial in which sham participants still meeting inclusion criteria (i.e., NOSE score of 55 or greater) were invited to crossover to the treatment arm and were followed up to 24 months post-placement. A total of 111 participants (71 treatment as well as 40 out of 66 sham participants) enrolled in this follow-up, however 70 participants completed the 24-month follow-up visit. Participants underwent follow-up visits at three, six, 12-, 18-, and 24-months post implant. Visits included collection of patient-reported outcome measures of the NOSE, a nasal obstruction visual analog scale (VAS), and the Epworth Sleepiness Scale (ESS). Adverse event reporting was also evaluated at each visit. A NOSE responder was defined as a participant with at least one NOSE class improvement or a NOSE score reduction of at least 20% compared with baseline. Researchers found NOSE responder rates are greater than 80% at all follow-ups through 24 months. Mean reduction from baseline in NOSE scores is equal to or greater than 30 points and statistically significant ($p<0.001$) at all timepoints through 24 months. The mean VAS score reduction was at least 29.7 points and statistically significant ($p <0.001$) at all time points. A subgroup of participants with baseline ESS values greater than 10 experienced statistically significant ($p <0.001$) and clinically meaningful reductions at all postimplant periods, suggesting that the reduction in nasal symptoms may reduce daytime sleepiness for patients who have problems with sleep quality. No serious device-/procedure-related adverse events were reported. Implant

migration/retrieval rate was 4.5%. This study is limited by design as well as small and homogenous population, demonstrating the need for more robust, comparable, long-term clinical trials.

Cryoablation of the Posterior Nasal Nerve (PNN) (e.g., ClariFix device)

Chang et al (2020) conducted an industry-sponsored, prospective, multi-center, single-arm study of 98 adults diagnosed with chronic, medically intractable rhinitis (moderate to severe allergic or non-allergic) and treated with PNN cryoablation. Participants were over the age of 21 and had a minimum total score of four out of 12 on the Reflective Total Nasal Symptom Score (rTNSS). Excluded from the study, were participants with anatomy-limiting visualization and access to the posterior nasal cavity, ocular symptoms, sinus infection, recent history of epistaxis, bleeding disorder, anticoagulation medication, Raynaud's disease, or pregnancy. All 98 participants underwent PNN cryoablation in-office under local anesthesia. Patients discontinued use of intranasal ipratropium three days prior to treatment and throughout the study period. There were no comparators. Following treatment, the total rTNSS scores were significantly improved over baseline at all post-procedure evaluations: baseline (6.1 ± 1.9), at one month (2.9 ± 1.9, $p<0.001$), three months (3.0 ± 2.3, $p<0.001$), six months (3.0 ± 2.1, $p<0.001$), and nine months (3.0 ± 2.4, $p<0.001$). The authors defined the minimal clinically important difference (MCID) as a 30% reduction in baseline score. Following the procedure, 29 adverse events (AEs) related to the procedure or device were reported. AEs included two instances of epistaxis requiring office cautery or suction cautery in the operating room; two cases of new ostia (one uncinate process perforation and one maxillary sinus accessory os); and one case of nasal synechia. Other reported AEs were headache, eye dryness and sinus infections. The study was limited by a lack of control group, unblinded provider and patient, short term follow-up period, participant loss to follow up and exclusion only for use of intranasal corticosteroids (but not other medications that would affect rhinorrhea). The authors concluded cryoablation of the PNN for chronic rhinitis was safe, could decrease nasal symptoms of rhinitis, and could improve disease-specific quality of life. They acknowledged future RCTs, perhaps incorporating a sham treatment arm, would be helpful to further validate the efficacy of PNN cryoablation.

Ow et al (2021) published additional post-procedure results (12-24 months) of the prospective single arm study above (Chang 2020). Individuals were evaluated by office visit or phone for changes rTNSS scores from baseline at 12 and 24 months. Ninety-one participants completed the study through the initial 12-month study period. Fifty-seven participants completed the 24-month follow-up. Significant improvements in the total rTNSS were reflected in a median change from baseline of −3.0 or −4.0 at all-time points ($P < .001$). Greater than 80.0% of participants achieved the minimum clinically important difference (MCID) of improvement by greater than or equal to one (1) point on the rTNSS at all follow-ups. Total RQLQ scores indicated significant improvement ($P < .0001$) in quality of life. Over 77% of participants achieved the MCID (≥ 0.5 points) for the total RQLQ score. One participant experienced two treatment-related serious AEs (epistaxis and retained pledget). A total of 29 nonserious treatment related AEs were reported in 23 participants; most events were transient and resolved with little to no intervention. This follow-up study is limited by single arm design without a concurrent control arm and loss of 30% of the participants after the 12-months. The authors concluded cryotherapy significantly and clinically improves rhinitis symptoms and quality of life with outcomes that are durable through 24 months after treatment. Randomized trials with a

control or sham treatment arm evaluating outcomes are needed to evaluate the relative net health benefit of this treatment compared to standard treatment.

Yen et al (2020) evaluated cryoablation of the PNN at the inferior and middle meatus in 30 individuals with moderate to severe rhinorrhea and mild to severe nasal congestion for at least three months. Most previous studies were limited to applying cryoablation to the PNN at the middle meatus. While the participants reported significant symptom improvement at three months, the study was limited by the limited number of participants and follow-up and no control arm. This is representative of the body of evidence for this technology; larger studies with long-term follow-up are needed to better assess the safety and efficacy of this therapy.

Hwang et al (2017) reported on a series of 27 adults who were treated with the ClariFix cryoablation device for allergic and non-allergic rhinitis with or without nasal congestion symptoms despite medical therapy greater than or equal to three months. Individuals were evaluated using the TNSS and those with a minimum rhinorrhea and/or congestion subscore of two (moderate symptoms) were included. Treatment was completed in office under topical or injected local anesthesia. TNSS mean scores decreased significantly at seven days post procedure compared to baseline (6.2 ± 0.5 versus 4.3 ± 0.4; $p<0.005$). At 90 days, the 27 individuals continued to report a decline in the TNSS mean score at 2.7 ± 0.4; $p<0.001$. While the TNSS scores continued to decline at 180 days (2.3 ± 0.5) and 365 days (1.9 ± 0.3), six individuals (22%) were lost to follow-up at 180 days and 12 individuals (44%) were lost to follow-up at 365 days. Subjects reported mild pain/discomfort, severe ear blockage and severe nasal dryness, all of which had improved or resolved at the 30-day follow-up. A moderate nosebleed reported approximately one-month post-procedure, was managed by electrocautery. The findings of this study were limited by its small size and the high rate of subject attrition during follow-up. In addition, as medication use was not tracked during the study, other factors for improvement in symptoms may have confounded the results. The authors concluded cryotherapy of the PNN region is safe and well tolerated.

Radiofrequency (RF) Ablation of the Posterior Nasal Nerve (PNN) (e.g., RhinAer Stylus)

Stolovitzky et al (2021) evaluated the safety and efficacy of RF ablation (also known as neurolysis) of the PNN in the treatment of moderate to severe chronic rhinitis. Individuals were randomized to receive active treatment of the PNN area with a RF device (n=77) or with a sham device (n=39). The primary endpoint was the responder rate (at least a 30 improvement in rTNSS score from baseline) at 3 months. A significantly higher responder rate was reported in the active treatment arm compared to the sham arm: 67.5% (95% CI, 55.9%-77.8%) versus 41.0% (95% CI, 25.6%-57.9%) at 3 months. No serious AEs were reported. The study did not limit the use of prescribed medications but did track medication use. At three-month follow-up seven individuals (9.1%) in the active treatment arm and 5 individuals (12.8%) in the sham treatment group increased their use of medications during the follow-up. Individuals who increased their medication use were assigned to non-responder status, regardless of rTNSS scores.

Takashima et al (2023) reported the 12-month safety and efficacy of the Stolovitzky et al (2021) study. At 12 months, the responder rate was 80.6% (n = 67) and the mean change in rTNSS was −4.8 ($p < 0.001$), a 57.8% improvement. The improvement in rTNSS of the index active treatment arm, significantly greater than of the index sham-control arm at three months was also sustained

through 12 months. The mean baseline rTNSS for the index active treatment arm was 8.3, with an adjusted mean change in rTNSS of −3.6, −4.4, and −4.8 at 3-, 6-, and 12-months ($p < 0.001$), when comparing each follow up timepoint vs baseline. This represents improvement of 43.3%, 53.0%, and 57.8% over baseline at three, six and 12-months, respectively. Although nasal itching and sneezing did not exhibit a difference between the index active treatment and index sham-control arms at three months, the researchers reported a sustained reduction in the severity of these symptoms over baseline through 12 months. Postnasal drip and cough, which are common and troublesome symptoms of chronic rhinitis, showed a similar improvement compared with baseline over time, although there was no significant difference between the index active treatment and index sham-control arms at three months.

Ehmer et al (2022) reported on the results of a prospective, single-arm multicenter study of 50 individuals with chronic rhinitis who underwent RF treatment to the PNN area. Participants were evaluated at two, four, 12-, 26- and 52-weeks post-procedure, with 47 participants completing the study. The primary efficacy point was the change in rTNSS score from baseline through 12 weeks. The mean rTNSS score improved from 8.5 at baseline to 3.4 at 12 weeks. At 12 months, the mean rTNSS score was reported to be 3.6. There were no serious AEs reported. This early study was limited by the lack of blinding and lack of a control group.

Kim et al (2024) conducted a systematic review and meta-analysis to compare posterior nerve ablation with cryoablation versus RF neurolysis. The review included 10 studies representing 738 patients with 12 months of follow-up, by assessing the clinical response rates after both treatments using the TNSS score as well as quality of life scoring. Of the studies included, there were none that directly compared the two treatments, therefore, the results must be carefully interpreted. Score differences at the 12-month mark were less than those at 6 months, with quality-of-life scores not differing between the two treatments. Additionally, there were several limitations to the review, including a majority of the studies being of a single-arm design and small number of participants. The authors also state that medications, both pre- and post-surgery, were not carefully controlled and therefore, conclude that long term double blinded RCTs are needed.

Hwang and colleagues (2025) aimed to determine if the combination of RF ablation of the inferior turbinates and intraturbinate segments of the PNN with laser PNN would improve short-term response rates and enhance symptom control in chronic rhinitis patients. The retrospective study enrolled 54 patients aged 18-65 years with chronic rhinitis refractory to medical treatment for greater than six months with sinonasal symptoms. All patients were treated with both RF ablation and laser ablation. A total of 50 patients completed a 6-month follow-up. Outcomes measured were Reflective Total Nasal Symptom Score (rtNSSS) and Nasal Obstruction Symptom Evaluation (NOSE). Results demonstrated a significant post-surgical reduction in both rTNSS and NOSE (From baseline scores of 8.7 [95% CI, 8.2–9.2] and 61.6 [95% CI, 56.8–66.3], respectively, rTNSS decreased to 1.46 [95%CI, 1.9–1.1] and NOSE to 2.9 [95% CI, 4.4–1.4] at 6 months [both $p < 0.001$]). The study's retrospective design, lack of a comparator group, and short six-month follow-up period limit the interpretation of the findings. Authors conclude that future prospective studies with longer follow up and comparative analyses are needed.

Radiofrequency (RF) Ablation of Nasal Valves to Treat Nasal Airway Obstruction (NAO) (VivAer ARC Stylus)

Han et al (2022) and Yao et al (2023) reported the long-term (12-month and 2-year respectively) follow-up outcomes from the industry-sponsored trial conducted by Silvers et al in 2019, summarized below. Following the three-month primary end point, the trial was unblinded and all patient eligible to cross-over to the treatment arm (n=31) elected to undergo treatment. After two patients were excluded, 108 patients underwent treatment in the trial (77 as index active treatment, 31 after crossover). The crossover arm had a mean baseline NOSE Scale score comparable to the index arm.

The researchers acknowledge the study's limitations of lacking a control arm and the predominantly while study population. They indicated that although further studies that incorporate more liberal application of temperature-controlled radiofrequency (TCRF) to address multiple nasal airway obstruction (NAO) contributors are needed; the researchers concluded that this multi-institutional cohort study contributes substantial real-world evidence that minimally invasive TCRF device treatment of the internal nasal valve for NAO is well tolerated and effective in significantly and sustainably reducing NAO symptom severity through two years. Furthermore, TCRF treatment is effective in patients with either static or dynamic NVC, septal deviation, turbinate enlargement, and prior nasal surgery, all of which are common characteristics of patients who present at clinics seeking relief from their symptomatic NAO.

Silvers et al (2021) conducted an industry-sponsored prospective, multicenter, single-blinded, randomized controlled trial comparing a temperature-controlled RF device for treatment of the NVC in subjects with obstruction. Participants were randomized to either active treatment arm (n=77; RF device/VivAer Stylus) or a sham procedure arm (n=40; control group/where a stylus was applied in the same manner but without RF energy delivery). Patients were assessed with a physical and endoscopic exam, NOSE scale score, a 100-mm ease-of-breathing visual analog scale (VAS), and a 100-mm VAS for nasal pain. At baseline, patients had a mean NOSE-scale score of 76.7 (95% confidence interval [CI], 73.8 to 79.5) and 78.8 (95% CI, 74.2 to 83.3) ($p = 0.424$) in the active treatment and sham-control arms, respectively. At three months, the responder rate was significantly higher in the active treatment arm (88.3% [95% CI, 79.2%-93.7%] vs 42.5% [95% CI, 28.5%-57.8%]; $p < 0.001$). The active treatment arm had a significantly greater decrease in NOSE scale score (mean, -42.3 [95% CI, -47.6 to -37.1] vs -16.8 [95% CI, -26.3 to -7.2]; $p < 0.001$). Three AEs likely related to the device and/or procedure were reported, and all resolved. This study is limited by non-blinded physicians, medication use was not dictated by the protocol, and short-term follow-up.

Jacobowitz et al (2019) six-month results of an industry-sponsored study of minimally invasive office treatment for nasal airway obstruction. This nonrandomized, prospective, multicenter case series assessed the safety and effectiveness of in-office bipolar temperature-controlled RF treatment of nasal valve obstruction. The study included 50 patients with severe or extreme obstruction (NOSE score at baseline ≥ 60 who had a positive response to nasal mechanical dilators or lateralization maneuvers. Bilateral RF treatment was applied intranasally, using the Vivaer Stylus, under local anesthesia in one session. Efficacy was determined by using the NOSE score and patient-reported satisfaction survey at 26 weeks. The mean baseline NOSE score was 79.9 (SD 10.8, range 60-100), and all had severe or extreme obstruction. At 26 weeks, mean NOSE score was 69% lower at 24.7

(P<.0001) with 95% two-sided confidence intervals 48.5 to 61.1 for decrease. The decrease in NOSE score did not differ significantly between patients who did or did not have prior nasal surgery. Patient satisfaction mean by survey was 8.2 of 10. No device or procedure-related serious AEs occurred. The study is limited by the small sample size, lack of randomization, single-arm study with short-term follow-up.

Ephrat et al (2021) conducted an extended 24-month follow-up of subjects who participated in the above study conducted by Jacobowitz et al (2019). This study aimed to determine whether the results achieved at six (6) months would be sustained through 24-months and included 39 patients from the original cohort of 49 patients. Study participants completed self-administered evaluations of the NOSE and QoL measures at 12-, 18-, and 24-months post procedure. The researchers reported clinically significant improvement from baseline in NOSE Scale score change demonstrated at six months (mean, 55.9; standard deviation [SD], 23.6; $p < 0.0001$) was maintained through 24 months (mean, 53.5; SD, 24.6; $p < 0.0001$). Responders (≥ 15-point improvement) consisted of 92.3% of participants at six months and 97.2% at 24 months. Responses to the QOL questions also showed improvement in patients' QOL. Other than the short duration, this trial shares the limitations of the Jacobowitz study cited above. In addition, it is limited by loss of 22% of the original cohort, raising the possibility of retention bias. Ephrat and colleagues acknowledged that in order to distinguish the relative true treatment effect from placebo effects, "it will be necessary to confirm the results of this study in additional patients as part of a planned randomized, controlled trial."

Jacobowitz et al (2022) reported extended 48-month follow-up outcomes following the initial 26-week study by Jacobowitz et al (2019). Of the 49 patients in the initial study, 39 completed follow-ups through 24 months and 29 completed follow-ups through 48 months. Compared with baseline, mean total NOSE scores improved after treatment and were maintained throughout the 48 months. Mean NOSE scores decreased from 81.0 at baseline to 21.6 after 6 months (73.3% change), 25.6 after 12 months (68.3% change), 29.3 after 18 months (63.8% change), 22.5 (±20.9) after 24 months (72.2% change), 32.3 after 36 months (60.1% change), and 25.7 after 48 months (68.3% change) ($p < 0.001$ for all comparisons). Mean NOSE domain scores showed sustained improvement through 48 months, including patients with NOSE scores in the "extreme" (score of 80-100) or "severe" (score of 55-75) categories at baseline.

Brehmer et al (2019) conducted a nonrandomized prospective study to evaluate the safety and efficacy of low-dose RF energy, using the Vivaer system, for the treatment of narrowed nasal valves. The study included 31 participants presenting with symptoms of nasal obstruction and snoring. Researchers used the VivAer low energy RF system to remodel the nasal sidewall to improve airflow. Thirty days after the treatment patients completed two questionnaires measuring nasal obstruction and snoring (NOSE, Snore Outcomes Survey [SOS]). Patient satisfaction was then assessed 90-days after the intervention by means of a 10-point Likert scale (1 = completely dissatisfied; 10 = very satisfied). An improvement in nasal breathing was observed in all patients by NOSE score, sleep quality by SOS questionnaire and quality of life as measured by EQ-5D and SNOT-22. The study is limited by the small number of participants, the lack of randomization, control group and comparator, and by the short follow-up period.

PROFESSIONAL GUIDELINE(S)

The following information is included for reference purposes only. Its inclusion does not imply endorsement or alignment with the outcomes of the review of the evidence.

Drug-Eluting Sinus Stents

In 2023, the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) issued a position statement on the use of drug-eluting sinus implants for the management of mucosal inflammation of the paranasal sinuses. This statement was not based on a systematic review of the evidence.

"The AAO-HNS considers drug-eluting implants in the paranasal sinuses as a proven and effective therapeutic option for mucosal inflammation." The recommendation additionally states, "Multiple studies have demonstrated the efficacy and safety of drug-eluting implants in controlling sinonasal inflammation. Clinical evidence regarding the use of drug-eluting implants after sinus surgery has particularly shown enhanced wound healing through the reduction of both scar formation and anatomic obstruction."

In 2025, AAO-HNS updated a 2015 position statement on the use of biomaterials in sinonasal procedures, supporting the use of FDA-approved implants, stents, and packing material in sinonasal procedures to improve patient outcomes and reduce complications, stating that, "Updated studies continue to support the statistically significant efficacy of drug eluting implants in maintaining sinus outlet patency following surgery compared to other standard nasal dressings in nearly all clinical situations. It remains clear that the decision to place stents, either at surgery or in the office environment needs to be made expeditiously, based upon endoscopic findings and surgical judgement, before scarring or polyposis obstructs the region. This is not an intervention that should be delayed by requirements to try stepwise less invasive or less expensive therapies, as findings can be evident at 2 to 4 weeks in patients."

In 2021, the International Consensus Statement on Allergy and Rhinology (ICAR) (Orlandi et al) was updated and included the following recommendation regarding the management of CRS with nasal polyps, using non-surgical steroid-eluting implants: Sinuva was investigated in 2 RCTs and a pooled analysis. Outcomes reported were positive but there has been no long term follow up past 6 months, and given this, it is not known whether some patients may need the implant more or less frequently. Additionally, both RCTs had implants removed at 60 days despite their ability to release drug up to 90 days. They state, "Clinical experience with this device is still relatively limited and the evidence, though at a high level, is restricted to short-term outcomes." Regarding absorbable steroid-eluting stents (i.e., PROPEL), ICAR states, "While the authors recognize the high cost of these implants, given the level of evidence, absorbable steroid-eluting implants are recommended in carefully selected patients that are similar to those included in the underlying clinical trials."

ICAR additionally commented on the use of office-based versus operating room procedures stating, "While the data suggest that office-based sinus procedures can be performed safely, there remain significant gaps in evidence. Robust long-term outcomes data is necessary, especially for emerging in-office technologies."

The American Rhinologic Society (2023) position statement on criteria for drug eluting implants, endorses the use of drug-eluting implants into the sinus cavities to optimize sinonasal inflammation resulting in a decreased use of systemic steroid prescriptions and potentially delays the need for revision surgery. The society states that "drug-eluting implants should in no way be considered investigational and should be available to patients, when selected by the physician, in order to maximize outcomes." Further, the ARS states that they endorse the AAO-HNS position statement on drug eluting sinus Implants.

Excision/Destruction of the PNN

Published in 2023, ICAR's recommendations for the treatment of allergic rhinitis (Wise et al) addressed cryotherapy/ RF ablation of the PNN, stating it may be considered in allergic rhinitis patients that have failed medical management, particularly for rhinorrhea, adding that the aggregate grade of evidence is a C (observational studies). Further, "because the current evidence is primarily based on industry-sponsored studies with limited long-term data, these office-based interventions remain an option for properly selected patients".

In 2023, AAO-HNS published a position statement on PNN ablation for the treatment of chronic rhinitis, stating the following:

"Posterior nasal nerve neurolysis techniques such as RF ablation and cryotherapy thermal application methods have been used to disrupt the PNN in the posterior aspect of the middle meatus in the region of the sphenopalatine foramen. Multicenter, patient-blinded, sham-controlled RCTs have been performed for RF ablation and cryoablation and have demonstrated clinical benefit for nasal symptoms. For both methods, validated quality of life surveys have demonstrated statistically significant improvement with treatment, with therapeutic effect. Based on these safety and efficacy data, the AAO endorses the use of PNN ablation for the treatment of medically-refractory chronic rhinitis. We do not consider these treatments to be experimental."

The AAO-HNS does not reference the use of laser for destruction of the PNN.

Repair of Nasal Valve Collapse (NVC)

In 2023, AAO-HNS issued a position statement on nasal valve repair stating that treatment options of nasal valve dysfunction may include implants aimed at stabilizing the nasal valve. With regards to surgical repair of the nasal valve, the AAO-HNS states:

"The treatment of nasal valve dysfunction may involve techniques that include cartilage grafting and open surgical repair, suture suspension techniques, and implants or RF treatment aimed at stabilizing the nasal valve. Surgical repair of the nasal valve can be performed as a standalone surgical procedure or in conjunction with other procedures to improve nasal obstruction. These may include septoplasty, turbinate reduction, ESS, among others. These procedures, such as septoplasty, may be complementary to nasal valve repair, but are not effective substitutes as they do not address nasal valve dysfunction. When feasible, surgical treatment to address all contributing anatomic sites should be performed concomitantly, based on patient and physician shared decision making. Requiring septoplasty and/or turbinate surgery prior to nasal valve surgery is not recommended, as this may lead to unnecessary increases in surgical encounters. The nasal valve may be stabilized using office-based treatments, such as implants or RF treatment. For patients who require anatomic widening and

definitive stabilization of the nasal valve, surgical treatment of NVC, along with treatment of other possible causes of nasal airway obstruction, is required to optimize patient outcomes. Failure to perform nasal valve repair, when indicated, is a common cause of incomplete symptom resolution for patients with nasal obstruction and nasal valve dysfunction."

The ARS published a statement in 2022 endorsing the use of bioabsorbable nasal implants for the treatment of NVC as an option compared with cartilage grafts, stating that initial studies in humans support their use with studies demonstrating safety and tolerance through 18-months post procedure, with prospective studies demonstrating improvements in the NOSE survey scores through the six-month mark.

In the International Consensus Statement on Allergy and Rhinology: Allergic Rhinitis (Wise et al 2023), authors assess inferior turbinate surgery as a level of evidence grade B, that its benefits include an improvement in rhinitis symptoms including nasal breathing, congestion, sneezing, and itching, and is recommended in patients with medically refractory nasal obstruction. Authors conclude that inferior turbinate surgery is a safe and effective treatment to reduce symptoms and improve nasal function, however, more studies are warranted to directly compare surgery methods, including RF ablation, laser-assisted, and microdebrider assisted) for the most efficacious and long-lasting outcome.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates implants and devices for excision/destruction of the sinuses as medical devices. All devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Oct 8]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 Oct 8]

In 2011, the PROPEL system (Intersect ENT, Menlo Park, CA) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process (P100044). In 2012, a smaller version of the PROPEL device, the PROPEL Mini Sinus Implant, was approved for use in patients older than age 18 years following ethmoid sinus surgery to maintain patency. In 2017, the PROPEL Contour was approved through a premarket approval supplement. The PROPEL Contour sinus implant is an adaptable implant that is designed to maximize drug delivery to the frontal and maxillary sinus.

In 1987, the SINUVA Sinus Implant (Intersect ENT, Inc., Menlo Park, CA) received its initial FDA approval. In 2017, the SINUVA Sinus Implant was approved with a new dose (1350 µg mometasone furoate) under a New Drug Application (NDA 209310). The SINUVA Sinus Implant is indicated for the treatment of nasal polyps in adult patients who have had ethmoid sinus surgery.

In May 2016, the Latera (Entellus Medical/Stryker ENT) was cleared for marketing by the FDA through the 510(k) process for the indication of supporting nasal upper and lower lateral cartilage.

In December 2017, the VivAer device (Aerin Medical) received its first 510(k) premarket notification FDA clearance (K172529). In April 2020, a second clearance (K200300) was issued for the VivAer Stylus, as substantially equivalent in function, design, and intended use as the predicate device for the intended use of coagulation of soft tissue in the nasal airway, to treat nasal airway obstruction by shrinking submucosal tissue, including cartilage in the internal nasal valve area.

In February 2019, the ClariFix device (Stryker) was cleared for use in adults with chronic rhinitis by the FDA through the 510(k) process (K190356). Clearance was based on substantial equivalence to the predicate device, ClariFix (K162608). The only modification to the subject device was an update to the indications for use to include adults with chronic rhinitis.

In December 2019, the RhinAer stylus (Aerin Medical) was cleared for use by the FDA through the 510(k) process as a tool to treat chronic rhinitis (K192471). Clearance was based on equivalence in design and intended use of a predicate device, the InSeca ARC Stylus (K162810). The RhinAer stylus includes modification of the InSeca ARC stylus shaft components and flexibility.

The NEUROMARK System (Neurent Medical) originally received 510(k) approval in October of 2021, indicated for use in otorhinolaryngology surgery for creation of RF lesions to disrupt PNNs in patients with chronic rhinitis.

There are currently no laser ablation devices with FDA clearance for treatment of chronic rhinitis.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
30117 *E/I	Excision or destruction (e.g., laser), intranasal lesion; internal approach (*E/I when treating the posterior nasal nerve [e.g., RhinAer, NEUROMARK or ClariFix procedures])
30468 E/I	Repair of nasal valve collapse with subcutaneous/submucosal lateral wall implant(s) (e.g., Latera)
30469 *E/I	Repair of nasal valve collapse with low energy, temperature-controlled (i.e., radiofrequency) subcutaneous/submucosal remodeling (*E/I when treatment is for radiofrequency ablation of the nasal valve [e.g., VivAer procedure])

Code	Description
30801 *E/I	Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method (e.g., electrocautery, radiofrequency ablation, or tissue volume reduction); superficial (*E/I when treatment is to be completed in combination with 30117, 30469, 30999 [ClariFix, RhinAer, NEUROMARK or VivAer procedure])
30802 *E/I	Ablation, soft tissue of inferior turbinates, unilateral or bilateral, any method (e.g., electrocautery, radiofrequency ablation, or tissue volume reduction); intramural (i.e., submucosal) (*E/I when treatment is to be completed in combination with 30117, 30469, 30999 [ClariFix, RhinAer, NEUROMARK or VivAer procedure])
30999 *E/I	Unlisted procedure, nose (*E/I when treatment is to be completed in combination with C1874, S1091, 30117, 30801, 30802, 30468, 30469)
31237	Nasal/sinus endoscopy, surgical; with biopsy, polypectomy, or debridement (separate procedure)
31242 E/I	Nasal/sinus endoscopy, surgical; with destruction by radiofrequency ablation, posterior nasal nerve (e.g., RhinAer, NEUROMARK)
31243 E/I	Nasal/sinus endoscopy, surgical; with destruction by cryoablation, posterior nasal nerve (e.g., ClariFix)
31299 *E/I	Unlisted procedure, accessory sinuses (*E/I when requested/billed with C1874, S1091, 30117, 30801, 30802, 30468, 30469)

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HCPCS Codes

Code	Description
C1874 E/I	Stent, coated/covered, with delivery system
C2625 E/I	Stent, non-coronary, temporary, with delivery system (Effective 01/01/04)
J7402	Mometasone furoate sinus implant, (Sinuva), 10mcg
S1091 E/I	Stent, non-coronary, temporary, with delivery system, (propel)

ICD10 Codes

Code	Description
D14.0	Benign neoplasm of middle ear, nasal cavity and accessory sinuses (effective 10/15/2015)
J30.0 - J30.9	Vasomotor and allergic rhinitis (code range)
J31.0 - J31.2	Chronic rhinitis, nasopharyngitis and pharyngitis (code range)
J32.0 - J32.9	Chronic sinusitis (code range)
J33.0 - J33.9	Nasal polyp (code range)
J34.8200	Internal nasal valve collapse, unspecified
J34.8201	Internal nasal valve collapse, static
J34.8202	Internal nasal valve collapse, dynamic
J34.8210	External nasal valve collapse, unspecified
J34.8211	External nasal valve collapse, static
J34.8212	External nasal valve collapse, dynamic
J34.829	Nasal valve collapse, unspecified
J34.89-J34.9	Other specified/unspecified disorders of nose and nasal sinuses (code range)
R09.81	Nasal Congestion
R09.82	Postnasal drip

REFERENCES

American Academy of Otolaryngology- Head and Neck Surgery (AAO-HNS) [Internet]. Position statement: PNN ablation for the treatment of chronic rhinitis. 2023 Jan 17 [accessed 2025 Oct 08]. Available from: Position Statement: PNN Ablation for the Treatment of Chronic Rhinitis - American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) [Internet]. Position statement: The use of biomaterials in sinonasal procedures. 2025 Jun 10. [accessed 2025 Oct 08]. Available from: Position Statement: The Use of Biomaterials in Sinonasal Procedures - American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)

American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) [Internet]. Position statement: drug-eluting sinus implants. 2023 Jan 17 [accessed 2025 Oct 08]. Available from: Position Statement: Drug-Eluting Sinus Implants - American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)

American Rhinologic Society (ARS) [Internet]. Bioabsorbable nasal implants. 2022 Jan [accessed 2025 Oct 08]. Available from: https://www.american-rhinologic.org/index.php?option=com_content&view=article&id=477:bioabsorbable-nasal-implants&catid=26:position-statements&Itemid=197

American Rhinologic Society (ARS) [Internet]. Position statement: criteria for drug-eluting implants. 2023 Jan 28 [accessed 2025 Oct 08]. Available from: https://www.american-rhinologic.org/index.php?option=com_content&view=article&id=32:drug-eluting-implants&catid=26:position-statements&Itemid=197

American Rhinologic Society (ARS) [Internet]. Posterior nasal nerve ablation ARS position statement. 2022 Jan [accessed 2025 Oct 08]. Available from: https://www.american-rhinologic.org/index.php?option=com_content&view=article&id=478:posterior-nasal-nerve-ablation&catid=26:position-statements&Itemid=197

Bikhazi N, et al. Long-term follow-up from the treatment and crossover arms of a randomized controlled trial of an absorbable nasal implant for dynamic nasal valve collapse. Facial Plastic Surgery. 2022;38(5):495-503.

Chang MT, et al. Cryosurgical ablation for treatment of rhinitis: a prospective multicenter study. Laryngoscope 2020; 130(8):1877-1884.

Del Signore AG, et al. Cryotherapy for treatment of chronic rhinitis: 3-month outcomes of a randomized, sham-controlled trial. Int Forum Allergy Rhinol. 2022 Jan;12(1):51-61.

Desai V, et al. Cryoablation for the treatment of chronic rhinitis: a systematic review. J of Otolayrn – Head & Neck Surgery. 2023;52(37).

Ehmer D, et al. Temperature-controlled radiofrequency neurolysis for the treatment of rhinitis. Am J Rhinol Allergy. 2022; 36(1):149-156.

Ephrat M, et al. Quality-of-life impact after in-office treatment of nasal valve obstruction with a radiofrequency device: 2-year results from a multicenter prospective clinical trial. Int Forum of Allergy & Rhinology. 2021 Apr;11(4):755-765.

Forwith KD, et al. ADVANCE: A multisite trial of bioabsorbable steroid-eluting sinus implants. Laryngoscope. 2011;121:2473-2480.

Forwith KD, et al. RESOLVE: bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis after sinus surgery: 6-month outcomes from a randomized, controlled, blinded study. Int Forum Allergy Rhinol 2016;6(6):573-581.

Gerka Stuyt JA, et al. Evaluation of in-office cryoablation of posterior nasal nerves for the treatment of rhinitis. Allergy Rhinol. 2021;12: 2152656720988565.

Goshtabi K, et al. Efficacy of steroid eluting stents in management of chronic rhinosinusitis following endoscopic sinus surgery: updated meta-analysis. Int Forum Allergy Rhinol. 2019; 9(12):1443-1450.

Han JK, et al. RESOLVE: A randomized, controlled, blinded study of bioabsorbable steroid-eluting sinus implants for in-office treatment of recurrent sinonasal polyposis. Int Forum Allergy Rhinol. 2014;4(11): 861-870.

Han JK, et al. Outcomes 12 months after temperature-controlled radiofrequency device treatment of the nasal valve for patients with nasal airway obstruction. JAMA Otolaryngol Head Neck Surg. 2022;148(10):940-946.

Han JK, et al. Multidisciplinary consensus on a stepwise treatment algorithm for management of chronic rhinosinusitis with nasal polyps. Int Forum Allergy Rhinol. 2021;11:1407–1416.

Han JK and Kern RC. Topical therapies for management of chronic rhinosinusitis: steroid implants. Int Forum Allergy Rhinol. 2019 Mar; 9: S22–S26.

Haung Z, et al. Comparison of bioabsorbable steroid-eluting sinus stents versus nasopore after endoscopic sinus surgery: a multicenter, randomized, controlled, single-blinded clinical trial. Ear Nose Throat J. 2022 May;101(4):260-267.

Huang Z, Hwang P, Sun Y, et al. Steroid-eluting sinus stents for improving symptoms in chronic rhinosinusitis patients undergoing functional endoscopic sinus surgery. Cochrane Database Syst Rev. 2015 Jun 10;6(6):CD010436. PMID 26068957.

Hwang PH, et al. Cryosurgical posterior nasal tissue ablation for the treatment of rhinitis. Int Forum Allergy Rhinol. 2017 Oct;7(10):952-956. PMID 28799727.

Hwang YL, et al. Radiofrequency ablation of inferior turbinates with laser posterior nasal nerve neurolysis for the treatment of chronic rhinitis. Int Forum Allergy Rhinol. 2025 May;15(5):477-572.

Jacobowitz O, et al. Long-term outcomes following repair of nasal valve collapse with temperature-controlled radiofrequency treatment for patients with nasal obstruction. Int Forum Allergy Rhinol. 2022 Nov;12(11):1442-1446.

Jacobowitz O, et al. In-office treatment of nasal valve obstruction using a novel, bipolar radiofrequency device. Laryngoscope Investig Otolaryngol. 2019;4(2):211–217.

Kim DH, et al. Effectiveness of using a bioabsorbable implant (Latera) to treat nasal valve collapse in patients with nasal obstruction: systemic review and meta-analysis. International Forum of Allergy & Rhinology. 2020 June; 10(6): 719-725.

Kim DH, et al. An indirect comparative analysis of two posterior nasal nerve ablation techniques for treating chronic rhinitis: a systemic review and meta-analysis. A J Oto Head Neck Med Surg 2024;45(2):1-8.

Kern RC, et al. A phase 3 trial of mometasone furoate sinus implants for chronic sinusitis with recurrent nasal polyps. Int Forum Allergy Rhinol. 2018 Apr;8(4):471-481.

Krespi YP, et al. Laser ablation of posterior nasal nerves for rhinitis. Am J Otolaryngol. 2020;41(3):102396.

Luong A, et al. Safety and effectiveness of a bioabsorbable steroid-releasing implant for the paranasal sinus ostia: a randomized clinical trial. JAMA Otolaryngol Head Neck Surg. Jan 2018; 144(1): 28-35.

Marple BF, et al. Advance II: a prospective, randomized study assessing safety and efficacy of bioabsorbable steroid-releasing sinus implants. Otolaryngol Head Neck Surg. 2012 Jun;146(6):1004-11.

Narwani, Vishal, et al. Adverse events associated with corticosteroid-eluting sinus stents: a MAUDE database analysis. Otolaryngol Head Neck Surg. 2022 Jan;166(1):179-182.

National Institute for Health and Care Excellence (NICE) [Internet]. Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis: Interventional procedures guidance. IPG551. 2016 Mar 23 [accessed 2025 Oct 8]. Available from: Overview | Corticosteroid-eluting bioabsorbable stent or spacer insertion during endoscopic sinus surgery to treat chronic rhinosinusitis | Guidance | NICE

Orlandi RR, et al. International Consensus Statement on Allergy and Rhinology: Rhinosinusitis 2021. Int Forum Allergy Rhinol. 2021 Mar;11(3):1-527.

Ow RA, et al. Cryosurgical ablation for treatment of rhinitis: Two-year results of a prospective multicenter study. Laryngoscope. 2021;131(9):1952-1957.

Rank MA, et al. The joint task force on practice parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. Journal of Allergy and Clinical Immunology. 2023 Feb;151(2), 386-398.

Silvers SL, et al. Temperature-controlled radiofrequency device treatment of the nasal valve for nasal airway obstruction: A randomized controlled trial. Int Forum Allergy Rhinol. 2021;11(12):1676-1684.

Singh AK, et al. Adverse events associated with ClariFix posterior nasal nerve cryoablation: a MAUDE database analysis. Otolaryngol Head Neck Surg. 2021;165(4):597-601.

Smith TL, et al. Randomized controlled trial of a bioabsorbable steroid-releasing implant in the frontal sinus opening. Laryngoscope. 2016 Dec;126(12):2659-2664.

Stolovitzky P, et al. Assessment of bioabsorbable implant treatment for nasal valve collapse compared to a sham group: A randomized control trial. International Forum of Allergy and Rhinology. 2019 Aug; 9(8): 850-56.

Stolovitzky JP, et al. Effect of radiofrequency neurolysis on the symptoms of chronic rhinitis: A randomized controlled trial. OTO Open. 2021 Sept 10;5(3):2473974X211041124.

Takashima M, et al. Temperature-controlled radiofrequency neurolysis for treatment of chronic rhinitis: 12-month outcomes after treatment in a randomized controlled trial. Int Forum Allergy Rhinol. 2023 Jun;13(2):107-115.

Wise SK, et al. International consensus statement on allergy and rhinology: allergic rhinitis-2023. Int Forum Allergy Rhinol. 2022 Sep 13;13:293-859.

World Allergy Organization [Internet]. Rhinosinusitis: synopsis. 2005 Jun [updated 2021 Jan; accessed 2025 Oct 08]. Available from: Rhinosinusitis - Synopsis - Peters AT, Patel G (Updated 2021)

Yen D, et al. Multiple site cryoablation treatment of the posterior nasal nerve for treatment of chronic rhinitis: an observational feasibility study. Allergy Rhinol. 2020 Aug;11:1-7.

Yao WC, et al. Two-year outcomes of temperature-controlled radiofrequency device treatment of the nasal valve for patients with nasal airway obstruction. Laryngoscope Investig Otolaryngol. 2023 Jun;8(4):808-815.

Zamaili AM, et al. The impact of middle meatal steroid-eluting implants on the postoperative outcomes of chronic rhinosinusitis: a systematic review and meta-analysis. J Anorl. 2025;142:26-37.

SEARCH TERMS

Sinus stent, sinus implant, nasal implant, nasal valve collapse, Propel, Sinuva, Latera, posterior nasal nerve, radiofrequency ablation, cryoablation, rhinitis, rhinorrhea, nasal airway obstruction, ClariFix, RhinAer, VivAer.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for sinus stents for postoperative use following ESS, PNN ablation or intranasal RF ablation to treat NAO.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

Policy/Procedure Name: SIPULEUCEL-T IMMUNOTHERAPY (PROVENGE) **Control Number: 1350/20.0000272**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care for enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Provenge (sipuleucel-T) is an autologous cellular immunotherapy treatment indicated for patients with asymptomatic or minimally symptomatic, metastatic, castration-resistant (hormone-refractory) prostate cancer. The precise mechanism of action is unknown, but Provenge is designed to induce an immune response targeted against prostatic acid phosphatase (PAP), an antigen expressed in most prostate cancers.

The therapy involves a multi-step process through which the patient's white blood cells (WBCs) are removed and exposed to PA2024, which is a molecule created by linking PAP with GM-CSF. GM-CSF is a protein that targets a receptor on the surface of WBCs. PAP serves to externally manipulate the immunological functioning of the patient's WBCs, while GM-CSF serves to stimulate the WBCs into action. Thus, the WBCs are "trained" to target and attack the prostate cancer cells. Clinically, this is expected to result in a decrease in the size and/or number of cancer cells, an increase in the time to cancer progression, and/or an increase in survival of the patient. Consistent with recognized evidence-based and peer-reviewed clinical criteria, the following policy is described.

The National Comprehensive Cancer Network Guidelines for Prostate Cancer recommend sipuleucel-T only for patients who are asymptomatic or minimally symptomatic, whose life expectancy is greater than six months, and who have no liver metastases and an Eastern Cooperative Oncology Group performance level of 0–1. Currently, sipuleucel-T has not been studied in patients with visceral metastases and is not recommended for patients with small cell/neuroendocrine prostate cancer.

Summary

Effective date of policy:	04/06/2022
Indications	Asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer
ICD10 diagnosis codes	Q2043
Availability	*Suspension for injection*
Duration	Six (6) months

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve Provenge therapy:

Indication	Inclusion	Recommended Dosing Regimen
Indication: Asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone-refractory) prostate cancer (FDA approval) ICD10: C61	• The enrollee is an adult male 18 years of age or older. • Presence of metastatic castration-resistant prostate resistance as evidenced by: o The enrollee has a histologically confirmed adenocarcinoma of the prostate with radiologic evidence of metastases to soft tissue, lymph nodes, or bone. o The enrollee has undergone treatment with surgical castration (bilateral orchiectomy) or ≥ 3 months of chemical castration (luteinizing hormone-releasing hormone [LHRH] agonists or antagonists*). ▪ Evidence of sufficient castration by a serum testosterone concentration < 50 ng/dL (current or at initiation of chemical castration). o Evidence of progressive disease after surgical or chemical castration (known as castrate-resistant, hormone-refractory, or androgen-	• Each dose of sipuleucel-T contains a minimum of 50 million autologous CD54+ cells activated with PAP-GM-CSF suspended in 250ml of Lactated Ringer's Injection, USP in a sealed, patient-specific infusion bag. Administer the entire contents of the bag via IV infusion over 60 minutes; give approximately every two weeks for three doses

	independent prostate cancer), showing one or more of the following: ▪ Progressive measurable disease: defined by response evaluation criteria in solid tumors (RECIST) as an increase of at least 20% in the sum of tumor diameters AND an absolute increase of at least 5 mm. One or more new lesions is additionally considered progression. ▪ Worsening disease on bone scan: appearance of two or more new lesions (Progression identified in the first follow-up scan must be confirmed by a second scan, which must show additional new lesions from the first follow-up scan). ▪ PSA progression: After decline from baseline, an increase in PSA 25% above the nadir AND an absolute increase in PSA of at least 2 ng/mL. Confirmed by a second value three or more weeks later. • The enrollee is asymptomatic or minimally symptomatic, without cancer-related bone pain or use of opioid analgesics for cancer pain. • The enrollee has an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1. • The enrollee has a life expectancy of ≥ 6 months. • The ordering physician is an oncologist, or there is documented collaboration with an oncologist in the decision to prescribe Provenge. • The administration of Provenge must be done in an infusion site equipped to handle infusion-related adverse events. *LHRH agonists include leuprolide (Lupron, Viadur, Eligard), goserelin (Zoladex), triptorelin (Trelstar), and histrelin (Vantas). Degarelix (Firmagon) and relugolix (Orgovyx) is an LHRH antagonist that is thought to work like LHRH agonists.	

Exclusion Criteria

CDPHP will <u>not</u> provide coverage for Provenge in the following situations:

- Presence of liver or brain metastases.
- The enrollee has a life expectancy of < 6 months.
- Provenge is not recommended for small cell/NEPC.

Continuation Criteria

- Requests will be reviewed per criteria every six months.

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.
- If prior authorization is approved, coverage for Provenge will be administered as a medical benefit (a prescription drug benefit is not required) when obtained and administered by a participating practitioner.
- Requests for off-label uses of Provenge will be reviewed on a case-by-case basis. Please refer to pharmacy policy, Off-Label Uses of FDA Approved Drugs, control # 1350/20.000048.

- The concomitant use of immunosuppressive drugs, such as systemic corticosteroids, may interfere with the safety and/or efficacy of Provenge. Therefore, an evaluation of whether such therapy can be safely reduced or discontinued must be conducted prior to Provenge use.
- Provenge has a maximum duration of 3 doses for prostate cancer.

References

		Updated	Accessed
1	Tsang C. Provenge (sipuleucel-T) suspension for intravenous infusion. CVS Caremark Pharmacy and Therapeutics Drug Monograph. CVS Caremark; 2013 Jan 18.		
2	National Comprehensive Cancer Network. Prostate Cancer. Version 1.2025. Accessed Jan 2025. Available at: http://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf	12/24	1/25
3	Provenge prescribing information. Seattle, WA: Dendreon Corporation; 2014 Oct.	07/17	1/25
4	National Coverage Determination (NCD) for Autologous Cellular Immunotherapy Treatment (110.22). Centers for Medicare & Medicaid Services. Baltimore, MD; 2012 Jan.		1/25
5	Kantoff PW, et al. Sipuleucel-T Immunotherapy for Castration-Resistant Prostate Cancer. N Engl J Med. 2010 Jul; 363(5):411-22.		01/25
6	Sipuleucel-T. In: Lexi-drugs online [database on the Internet]. Hudson (OH): Lexicomp, Inc.; 2023 [updated 29 Sep 2022; cited 27 Jan 2023]. Available from: http://online.lexi.com.	9/22	1/25

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Refer to the National Coverage Determination (NCD) for Autologous Cellular Immunotherapy Treatment (110.22): https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=344&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&CptHcpcsCode=Q2043&bc=gAAAABAAAAAAAA%3d%3d&

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 5/14/2026

New:
06/13

Revised:	Reviewed:
04/14, 04/15, 04/16, 04/17, 4/22	04/18, 4/19, 4/20, 4/21, 4/21, 4/23, 4/24, 4/25, 5/26

Revision Date	Changes
4/22	• Added small cell/NEPC to exclusion criteria • Added relugolix as one of the two possible LHRH antagonists that are used in chemical castration

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Policy/Procedure Name: Skysona (elivaldogene autotemcel) **Control Number: 1350/20.000458**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Adrenoleukodystrophy (ALD) is a rare genetic condition characterized by progressive loss of white matter in the nervous system and degradation of adrenal glands. It is caused by a mutation in the ABCD1 gene on the X-chromosome. Because it is an X-linked disorder males develop more serious complications than females, while some females will have no symptoms. Diagnosis can be established given clinical findings and elevated very long-chain fatty acids (VLCFA) and confirmed via genetic testing. Prevalence of ALD is approximately 1 in 10,000 to 1 in 17,000 individuals in the general population. New York State does include Adrenoleukodystrophy (ALD) in their newborn screening panel.

ALD is highly heterogeneous with a wide variety of symptomatology. There are four main types described:
Childhood Cerebral type (ccALD)
Adult Cerebral type (acALD)
Adrenomyeloneuropathy (AMN)
Addison's-only type

The most severe form of ALD is cerebral adrenoleukodystrophy (CALD) which affects 35-40% of those with ALD. Male children develop symptoms between three and ten years of age (almost never occurring before 2.5 -3 years of age). Affected males will develop normally and then start to show a regression of previously acquired skills. Before the loss of skills, affected males may exhibit behavioral problems including attention deficit and hyperactivity disorder (ADHD) and learning disabilities. Affected individuals usually develop cognitive deficits which means that they may have impairment of their mental processes and have difficulty acquiring information and knowledge. Children may "space out" in school or at various times, have difficulty understanding speech, difficulty reading or understanding written words, difficulty with spatial references, and show a deterioration in handwriting skills. As the condition progresses additional symptoms include diminished visual acuity, hearing loss, gait difficulty, weakness and stiffness of limbs, convulsions, and seizures. Within two to three years of neurologic symptom onset the disease progresses to a vegetative state and death.

Diagnosis for CALD is centered around identifying the characteristic symptoms as well as diagnostic tests. Initially one would assess the levels of VLCFAs in the blood and, if elevated, would follow up with genetic testing to confirm the diagnosis. The ACTH stimulation test is also available which tests the function of the adrenal glands. Lastly, MRI imaging is utilized to assess how ALD has affected the brain including the loss of the myelin in the cerebral white matter.

Treatment for CALD is extremely limited. For individuals with adrenal insufficiency, corticosteroid replacement therapy is essential. Management of spinal cord disease, urinary complications, polyneuropathy tend to follow standard accepted guidance. Allogeneic hematopoietic stem cell transplantation (HSCT) for the treatment of certain individuals, particularly young boys, or adolescents with evidence of central nervous system involvement who are early in the course of the disease and have no neurological symptoms is currently standard of care and only existing effective therapy to stop progression of neurological symptoms in childhood. While studies have shown that a HSCT stops the progression of neurological disease in ALD, although it does not improve adrenal insufficiency. HSCT is a major medical procedure that carries significant risk. Since Allogeneic HSCT is only effective in early stages of the disease, it is pertinent that newborn screening is expanded to all states and that all boys diagnosed with ALD undergo repeated brain MRI studies and follow up routinely with a neurologist.

Elivaldogene autotemcel (Eli-Cel) uses ex vivo transduction with the Lenti-D lentiviral vector (LVV) to add functional copies of the ABCD1 gene into a patient's own hematopoietic stem cells (HSCs). The addition of the functional ABCD1 gene allows patients to produce the ALD protein (ALDP), which is thought to facilitate the breakdown of very long-chain fatty acids (VLCFAs). This expression of the ALDP and the effect to is stop progression of CALD and preserve as much neurologic function as possible, for as long as possible (expected to be life-long). Eli-Cel is specifically being proposed for treatment of early active cerebral adrenoleukodystrophy (CALD) in patients less than 18 years of age who do not have an available and willing human leukocyte antigen (HLA)-matched sibling hematopoietic stem cell (HSC) donor.

Clinical Trial experience for Eli-Cel includes Phase 2/3 Starbeam study (ALD-102) and the Phase 3 ALD-104 study (ongoing, no results posted). Additionally, bluebird bio is conducting a long-term safety and efficacy follow-up study (LTF-304) for patients who have received Eli-Cel for CALD and completed two years of follow-up in ALD-102 or ALD-104. In ALD-102, 90.6% (29/32) of patients met the primary endpoint of Major Functional Disabilities (MFD)-free survival at 24 months. As previously reported, two patients withdrew from study ALD-102 at investigator discretion, and one additional subject experienced rapid disease progression early after treatment, resulting in MFDs and subsequent death. All patients who completed ALD-102 enrolled in a long-term follow-up study (LTF-304). The median duration of follow-up is approximately four years (49 months; 13.4, 88.1).

Adverse reactions attributed to Eli-Cel observed in clinical trials include myelodysplastic syndrome, viral cystitis, pancytopenia, and nausea and vomiting. There have been no reports of graft-versus-host-disease, graft failure or rejection, transplant-related mortality, or replication competent lentivirus in the 67 patients who received Eli-Cel in clinical studies (ALD-102, ALD-104, LTF-304).

In June 2022, the Food and Drug Administration's (FDA) Cellular, Tissue, and Gene Therapies Advisory Committee (CTGTAC) discussed the use of Eli-Cel for early active CALD and determined the answer to the question, "Do the benefits of Eli-Cel outweigh the risks, for the treatment of any sub-population of children with early active cerebral adrenoleukodystrophy (CALD)?" with a vote of, CTGTAC voted 15 (yes) to 0 (no). Importantly, the FDA highlighted the safety issues that have been reported with Eli-Cel, including myelodysplastic syndrome (MDS), which emerged in 3 of 67 patients (4%) in clinical trials. The committee cautioned that this incidence is likely to increase due to the short duration of follow-up in the trials, however this did not dissuade their unanimous decision in support of therapy, weighing the risks and benefits.

The FDA granted approval under the accelerated approval pathway to Skysona on September 16, 2022, to slow the progression of neurologic dysfunction in boys 4–17 years of age with early, active cerebral adrenoleukodystrophy (CALD). This indication is approved under accelerated approval based on 24-month Major Functional Disability (MFD)-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). The FDA prescribing information provided some additional information from the clinical trials, on limitations of use for Skysona. In patients who have a full deletion of ABCD1, an immune response may lead to a rapid loss of efficacy of Skysona, Skysona was not studied in patients with CALD secondary to head trauma, and patients with isolated pyramidal tract disease do not typically have clinical manifestations of disease until adulthood.

Summary	
Effective Date of Policy:	5/14/26
Indications	Treatment to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD)
ICD10 Diagnosis Codes	E71. 520
HCPCS Code	J3387
Availability	*See FDA Prescribing Information*
Duration	Authorization will be for 6 months to allow sufficient time for administration

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy:

Specific Indication	Inclusion Criteria	Recommended Dosing

Indication
Slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD)
 	
ICD10: E71.520
	• Must be prescribed by an endocrinologist, neurologist, hematologist/oncologist, or prescriber who specializes in the management of cerebral adrenoleukodystrophy (CALD)
	• Must be 4-17 years of age
	• Must be designated male at birth
	• Must have a diagnosis of early, active cerebral adrenoleukodystrophy (CALD) defined as:
	  o Neurologic function score, NFS ≤ 1 AND
	  o Have gadolinium enhancement on brain magnetic resonance imaging (MRI) AND
	  o Loes scores of 0.5-9
	• Confirmed adenosine triphosphate binding cassette, sub family D, member 1 (ABCD1) gene mutation
	• Enrollee must NOT have a full ABCD1-gene deletion
		• One lifetime single-dose intravenous administration of Skysona (elivaldogene autotemcel)
		• The minimum recommended dose of Skysona is 5.0×10^6 CD34+ cells/kg
		• See FDA Prescribing Information for Dosing

	• Must have elevated very-long-chain fatty acid (VLCFA) values for all the following (see Appendix for VLCFA reference values in CALD):
	  o Concentration of C26:0
	  o Ratio of C24:0/C22:0
	  o Ratio of C26:0/C22:0
	• Enrollee must have negative serologic test for HIV infection (as per US FDA prescribing label, apheresis material from individuals with a positive test for HIV will not be accepted for Skysona manufacturing)
	• Enrollee has been screened for hepatitis B (HBV), hepatitis C (HCV), human immunodeficiency virus 1 & 2 (HIV-1/HIV-2) and human T-lymphotropic virus 1 & 2 (HTLV-1/HTLV-2) in accordance with clinical guidelines before collection of cells for manufacturing
	• Prescriber must attest ALL the following:
	  o Enrollee does NOT have a contraindication to the use of granulocyte colony stimulating factor (GCSF), plerixafor, busulfan, cyclophosphamide, fludarabine, or any other medicinal products required during myeloablative and lymphodepleting conditioning including hypersensitivity to the active substances or to any of the excipients AND
	  o Enrollee will avoid concomitant therapy with antiretroviral medications for at least one month prior to initiating medications for stem cell mobilization and for the expected duration for elimination of the medications, and until all cycles of apheresis are completed (Note: if a patient requires antiretroviral for HIV prophylaxis, confirm a negative test for HIV before beginning mobilization) AND
	  o Enrollee will receive periodic lifelong monitoring for hematological malignancies (including myelodysplastic syndrome (MDS)) AND
	  o Enrollee will NOT be administered vaccinations within the 6-weeks prior to the start of therapy and will NOT be administered concurrently while on therapy AND
	  o Enrollee is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy AND
	  o Enrollee does not have a known and available human leukocyte antigen (HLA)-matched family donor AND
	  o Enrollee is clinically stable and eligible for hematopoietic stem cell transplantation
	  o Enrollee does NOT have isolated pyramidal tract disease
	  ▪ 1) NOTE: Patients with isolated pyramidal tract disease will be reviewed on a case-by-case basis
	  o Enrollee does NOT have an active infection, including clinically important localized infections AND
	  o Enrollee does NOT have an immediate family member with a known or suspected Familial Cancer Syndrome (including but not limited to hereditary breast and ovarian cancer syndrome, hereditary non-polyposis colorectal cancer syndrome, and familial adenomatous polyposis).	

Exclusion Criteria

Therapy will not be approved if any of the above Inclusion Criteria are not met OR any of the below noted Exclusion Criteria are met:

- Enrollee has previously received gene therapy
- Enrollee has had prior HSCT
- Enrollee has CALD secondary to head trauma
- Enrollee has available and willing 10/10 HLA-matched sibling donor (excluding female heterozygotes)
- Enrollee has active, uncontrolled HBV or HCV infection
- Enrollee has hematologic compromise including any of the following:
  - Peripheral blood absolute neutrophil count (ANC) < 1500 cells/mm^3, Platelets count < 100,000 cells/mm^3, Hemoglobin < 10 g/dL, an uncorrected bleeding disorder
- Enrollee has hepatic compromise including any of the following:
  - AST > 2.5x ULN, ALT > 2.5x ULN, Total bilirubin > 3 mg/dL (except if diagnosed with Gilbert's syndrome and otherwise stable)
- Enrollee has renal compromise as evidenced by a creatinine clearance (CrCl) < 50 mL/min OR estimated glomerular filtration rate (eGFR) < 70 mL/min/1.73 m2
- Therapy is being requested for treatment of adrenal insufficiency due to adrenoleukodystrophy

Continuation Criteria

- Not applicable, therapy is authorized only for one lifetime administration of Skysona (elivaldogene autotemcel). Authorization will be for 6 months to allow sufficient time for administration.
- Retreatment will be considered not medically necessary when any FDA approved gene therapy, or any other gene therapy under investigation, has been previously administered.

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.
- This indication is approved under accelerated approval based on 24-month Major Functional Disability (MFD)-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- **Physician acknowledges that CDPHP will request documentation, not more frequently than biannually, of follow-up patient assessments including neuroimaging (i.e., MRI) and disability scale assessments (examples may include Major Functional Disability assessment, Neurologic Function Score) and others as required for monitoring of outcomes of therapy.**

VLCFA concentrations[3]

	Normal	Males with ALD	Women with ALD
C26:0 µmol/L	0.67 +/- 0.13	2.94 +/- 0.87	1.54 +/- 0.72
C24:0/C22:0 ratio	0.86 +/- 0.13	1.52 +/- 0.21	1.18 +/- 0.15
C26:0/C22:0 ratio	0.01 +/- 0.003	0.05 +/- 0.02	0.02 +/- 0.01

References

		Updated	Accessed
1	National Organization for Rare Disorders (NORD). Rare Disease Database – X-Linked Adrenoleukodystrophy. Available at: https://rarediseases.org/rare-diseases/adrenoleukodystrophy/	9/2022	7/2024
2	Mallack EJ, et al. Clinical and radiographic course of arrested cerebral adrenoleukodystrophy. Neurology. 2020 June 16; 94(24): e2499-e2507.	6/2020	8/2022
3	Moser HW, et al. Diagnosis of ALD. Website: Adrenoleukodystrophy Info. Available at: https://adrenoleukodystrophy.info/clinical-diagnosis/diagnosis-of-ald	6/2024	7/2024
4	Study ALD-102 Elivaldogene Autotemcel Clinical Trial (NCT01896102). Available at: https://clinicaltrials.gov/ct2/show/NCT01896102	4/2022	7/2024
5	ALD-104	5/2024	7/2024

	Elivaldogene Autotemcel Clinical Trial (NCT03852498). Available at: https://clinicaltrials.gov/ct2/show/NCT03852498		
6	Wanders RJA, et al. X-linked adrenoleukodystrophy and adrenomyeloneuropathy. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com (Accessed 7/2023)	11/2022	7/2023
7	Bluebird Bio, Inc. Press Release. Bluebird bio Receives EC Approval for SKYSONA (elivaldogene autotemcel, Lenti-D) Gene Therapy for Patients Less Than 18 Years of Age with Early Cerebral Adrenoleukodystrophy (CALD) Without Matched Sibling Donor. Published July 21, 2021. Available at: https://investor.bluebirdbio.com/news-releases/news-release-details/bluebird-bio-receives-ec-approval-skysonatm-elivaldogene	7/2021	8/2022
8	IPD Analytics. New Drug Review: Skysona (elivaldogene autotemcel). Published October 2022. Available by subscription only.	10/2022	7/2023
9	Skysona prescribing information, Bluebird Bio, Inc., Somerville, MA 02145.	8/2025	8/2025

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE CHOICES: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 5/14/2026

New: 9/2022

Revised	Reviewed
9/2023, 9/2025, 12/2025, 5/2026	9/2024

Revision Date	Changes Made
9/2023	Updated to reflect FDA indication from prescribing information (PI), updated age and gender in inclusion criteria per FDA label, added exclusions from the limitations section of the PI, added normal levels for VLCFA table to considerations section.
9/2025	Added Loes score and provider attestations to inclusion criteria Added exclusion criteria enrollee has contraindication to conditioning regimen Removed exclusion of ejection fraction Removed inclusion ruling out additional possible causes
12/2025	Updated duration language - Authorization will be for 6 months to allow sufficient time for administration
5/2026	Re-worded and re-formatted policy criteria

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MEDICAL POLICY

Medical Policy Title	**Sleep Studies**
Policy Number	**2.01.28**
Current Effective Date	**January 1, 2027**
Next Review Date	**January 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. A facility-based polysomnography (PSG) is considered **medically appropriate** for the evaluation of sleep disorders when **ANY** of the following are met:

- A. To diagnose sleep-related breathing disorders when home sleep testing is negative, inconclusive, or technologically inadequate;
- B. To assess the quality and quantity of night-time sleep in an individual with suspected narcolepsy or hypersomnia (PSG is performed the night prior to the Multiple Sleep Latency Test (MSLT);
- C. As a pre and post evaluation test for the U.S. Food & Drug Administration (FDA) approved hypoglossal nerve stimulation (e.g., Inspire) device;
- D. To diagnose sleep-related disorders in infants and children under 18 years of age whose medical records document **ONE or more** of the following:
  1. Observations of gross or subtle snoring (snoring may be of a continuous nature, rather than periodic as in adults);
  2. Cessation in breathing, difficulty breathing, and sleep disturbances;
  3. Symptoms associated with cardio-pulmonary;
  4. Growth delays;
  5. Behavior and/or developmental problems that are suspected to be caused by upper airway obstruction;
- E. When performed for individuals after standard evaluation is inconclusive and treatment decisions will be made based on the results of the study;
- F. When symptoms are of a severity which place the individual at risk for serious complications or injuries for **ANY** of the following indications:
  1. Neuromuscular disorders and sleep-related symptoms;
  2. Paroxysmal arousals or other sleep disturbances thought to be seizure-related;
  3. Sleep-related epilepsy that does not respond to conventional therapy;

4. Unexplained hypersomnolence;
5. Complicated/injurious parasomnias;
6. Periodic limb movement disorder;
7. Central nervous system (CNS) hypoventilation;
8. Chronic opioid medication misuse or abuse, including for individuals on a methadone maintenance program or a chronic pain treatment program;
9. Recent stroke or myocardial infarction (MI) within the last six (6) months;
10. Moderate or severe congestive heart failure (CHF) (NYHA Class III or IV);
11. Moderate (FEV1 between 50% and 80% of normal) or severe (FEV1 between 30% and 50% of normal) chronic obstructive pulmonary disease (COPD) with hypercapnia or hypoxemia;
12. Congenital syndromes (e.g., spina bifida) in an adult;
13. Cognitive deficits making understanding of instructions difficult;
14. Limb extremity impediments (missing or non-functioning);
15. BMI greater than or equal to 45 kg/m^2;
16. Drainage tubes in abdomen (e.g., post operative colostomy/urostomy);
17. Significant arrhythmias (not including atrial fibrillation);
18. Burns or wounds affecting significant portion of the abdomen;
19. Language barrier, where attempts to give instructions are unavailable or have failed;
20. Group home resident; elderly or disabled person;
21. Infant or child being considered for removal of a tracheostomy;
22. Infant or child with suspected congenital central alveolar hypoventilation syndrome or sleep-related hypoventilation due to neuromuscular disorders or chest wall deformities;
23. Child being considered for adenotonsillectomy to treat obstructive sleep apnea (OSA) syndrome; **or**
24. Male impotency for **EITHER** of the following indications:
    a. nocturnal penile tumescence test is positive; **or**
    b. brachiopenile impotence is suspected.

II. Follow-up or repeat facility-based PSG is considered **medically appropriate** in the following circumstances:

A. When a prior, medically necessary PSG that was appropriately prepared and performed was inadequate/not diagnostic due to limited sleep time or other variable (not an inconclusive or negative exam);

B. For the re-evaluation of an individual diagnosed with OSA with adequate treatment and persistent symptoms;

C. For individual with a current OSA diagnosis who is seeking to discontinue positive airway pressure, continuous positive airway pressure, automatic positive airway pressure (PAP/CPAP/APAP) therapy (e.g., as a result of expected symptom improvement after treatment);

D. To assess treatment response after surgical intervention for OSA or after initiation of an oral appliance to ensure therapeutic benefit;

E. After a substantial weight loss (10% of body weight) to determine whether CPAP is still needed at the previously titrated pressures;

F. After a substantial weight gain (10% of body weight) in an individual who has been treated successfully with CPAP/APAP and whose symptoms have returned, to assess whether pressure adjustments are needed;

G. To re-evaluate a pediatric individual diagnosed with OSA who:

1. After adequate treatment with tonsillectomy and/or adenoidectomy;
2. Compliance with PAP therapy and has continued signs and symptoms of OSA (including disturbed or restless sleep);
3. Has a high risk of having persistent OSA after tonsillectomy or adenoidectomy.

III. Split-night study is considered **medically appropriate** when criteria for PSG are met (refer to Policy Statement I or IV).

IV. A facility-based CPAP titration study is considered **medically appropriate** when criteria for PSG are met (refer to Policy Statement I) **AND** the individual has been diagnosed with **ANY** of the following indications:

A. Co-morbid conditions (e.g., COPD, asthma, documented neuromuscular disease, CHF with left ventricular ejection fraction (LVEF) less than 45%, cognitive impairment) and positive diagnosis of OSA;

B. Central sleep apnea; (e.g., central hypopnea/apnea greater than 50% of the total apnea hypopnea rate, or central hypopnea/apnea rate/index greater than five events per hour);

C. Mixed sleep apnea;

D. Significant hypoxemia defined as oxygen saturation less than or equal to 88% for a minimum of five continuous minutes during a two-hour diagnostic time period; **or**

E. Oxygen deficiency requiring supplemental oxygen.

V. An initial Multiple Sleep Latency Test (MSLT) is considered **medically appropriate** as a diagnostic tool when **ALL** of the following are met:

A. The individual is suspected of having narcolepsy or idiopathic hypersomnia, as evidenced by **ONE** of the following indications:

1. Excessive sleepiness;
2. Recurrent daytime naps or lapses into sleep daily for at least three months;
3. Cataplexy – the sudden loss of muscle tone occurring in association with intense emotion (e.g., laughing or crying);
4. Sleep paralysis, hypnagogic hallucinations, hypnopompic hallucinations, automatic behaviors, or disrupted major sleep episodes; **or**
5. Idiopathic hypersomnia;

B. The MSLT immediately follows a PSG that was negative for OSA, where total sleep time is greater than six (6) hours (however, it should not follow a split-night study);

C. The individual has not used stimulants, stimulant-like medications, sedatives, or REM-suppressing medications for two (2) weeks prior to the test or negative results on urine drug testing immediately preceding within a day of the study;

D. A comprehensive sleep evaluation, including established sleep disorder tools or questionnaires, has been performed;

AND EITHER of the following:

1. If OSA is suspected, a diagnostic study has been performed;

OR

2. OSA is present, therapy has been initiated and has resolved the individual's symptoms.

VI. Repeat MSLT testing is considered **medically appropriate** when **BOTH** of the following criteria are met:

A. The initial MSLT results are negative, ambiguous, or did not provide polygraphic confirmation after a properly performed test; **and**

B. The clinical history strongly indicates a diagnosis of narcolepsy or idiopathic hypersomnia's or when the response to treatment must be ascertained.

VII. Nocturnal pulse oximetry is considered **medically appropriate** when **ONE** of the following criteria are met:

A. As a follow-up study, when a diagnosis has been established by standard polysomnography, CPAP, BiPAP, or APAP;

B. Oxygen therapy has been initiated;

C. When determining the proper oxygen dose for chronic pulmonary disease;

D. When ordered by a pulmonologist or sleep medicine specialist (The intent is most often to evaluate response to therapy).

VIII. Actigraphy is considered **medically appropriate** when **BOTH** of the following criteria are met:

A. For children aged four (4) to 18 years who have insomnia or circadian rhythm disorder associated with excessive daytime sleepiness; **and**

B. There is a discrepancy between reported sleep history and described symptoms (Only one actigraphy study per year is allowed).

IX. PSG is considered **not medically appropriate** for **ANY** the following indications:

A. Diagnosis of chronic lung disease;

B. Cases of typical uncomplicated and non-injurious parasomnias (e.g., somnambulism, pavor nocturnus, or nocturnal seizures) when the diagnosis is clearly delineated;

C. Epilepsy in individuals who have no specific complaints consistent with a sleep disorder;

D. Diagnosis or treatment of restless leg syndrome, except where uncertainty exists in the diagnosis;

E. Diagnosis of circadian rhythm sleep disorders;

F. Diagnosis of depression;

G. Determining risk of sudden infant death syndrome (SIDS);

H. Diagnosis of bruxism (grinding of teeth);

I. Diagnosis of drug dependency;

J. Insomnia (inability to sleep);

K. Night terrors/dream anxiety;

L. Migraine headaches;

M. Male impotence, other than the allow indications of Policy Statements I.H;

N. Evaluation of for medication-related (titration) sleep stage effects;

O. CPAP titration studies that do not meet criteria for a facility-based PSG (see Policy Statement I.) and CPAP criteria (see Policy Statement IV.);

P. Nocturnal pulse oximetry as a diagnostic tool for any other OSA indication.

X. The following tests are considered **investigational**:

A. EEG topography when used for diagnosis or medical management of OSA syndrome;

B. PAP-Nap;

C. Pharyngometry and Rhinometry Testing for screening, diagnosis, or treatment planning in persons with suspected or known OSA including but not limited to:

1. Acoustic pharyngometry (e.g., Eccovision Acoustic Pharyngometer)
2. Versions of the SNaP Testing System using fewer than three channels;
3. Rhinomanometry;

4. Acoustic rhinometry; **or**
5. Optical rhinometry.

RELATED POLICIES

Corporate Medical Policy

1.01.06 Positive Airway Pressure Devices: CPAP, BPAP, APAP and Noninvasive Positive Pressure Ventilators (NIPPV)

1.01.07 Medical Management Obstructive Sleep Apnea (OSA)

7.01.41 Surgical Management of Sleep Disorders

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Polysomnography after hypoglossal nerve stimulation implant will require follow up polysomnography specifically related to titration of device.

II. Wrist actigraphy requires a minimum of 14 days of recording, with interpretation of report and results generated. Commercial fitness trackers (e.g., Fitbit) are **ineligible for coverage**.

III. The probability of OSA is determined via a comprehensive sleep evaluation by a sleep specialist. Established sleep disorder tools and questionnaires (e.g., Epworth Sleepiness Scale; Berlin questionnaire, Wisconsin questionnaire, STOP, and STOP-BANG questionnaires) may assist the specialist in the evaluation of an individual with a suspected sleep disorder.

IV. The testing facility must be a sleep disorder center. A sleep disorder center is a medical facility providing clinical diagnostic services and treatment to individuals who present with symptoms or features that suggest the presence of a sleep disorder.

V. The American Academy of Sleep Medicine must accredit all sleep disorder centers, for coverage of the services to be considered.

VI. Sleep studies should be interpreted by a physician who meets any of the following criteria:

   A. Certified by the American Board of Sleep Medicine (ABSM);

   B. Holds subspecialty certification in sleep medicine by a member board of the American Board of Medical Specialties (ABMS), such as the American Board of Family Medicine, the American Board of Internal Medicine, the American Board of Otolaryngology, the American Board of Pediatrics, or the American Board of Psychiatry and Neurology;

   C. Has completed a residency in sleep medicine and meets the Health Plan's credentialing criteria for board certification; or

   D. Is an active staff member of a sleep disorder center certified by the American Academy of Sleep Medicine.

VII. An unattended, cardiorespiratory sleep study (Type III device) may be an acceptable alternative to full night PSG for those individuals with a high-pretest probability of OSA who are without significant comorbid conditions. A full PSG may be required for those symptomatic individuals who have a negative cardiorespiratory home sleep study.

VIII. A home/portable sleep study (HST) is an alternative to a facility-based PSG for individuals who do not meet medically necessary criteria in Policy Statement I.

DESCRIPTION

Sleep disorders medicine is a clinical specialty concerned with diagnosis and treatment of individuals with disorders of sleep and daytime alertness. Categories of sleep disorders include:

Insomnia

Insomnia is a persistent difficulty with sleep initiation, duration, consolidation, or quality that occurs despite adequate opportunity and circumstances for sleep, and results in daytime impairment. Among adults with insomnia, sleep complaints most typically include difficulties initiating or maintaining sleep. Concerns about lengthy periods of nocturnal wakefulness, insufficient amounts of nocturnal sleep, or poor sleep quality often accompany these complaints. Insomnia among children is often reported by their caretakers and characterized by bedtime resistance, frequent nighttime awakenings and/or an inability to sleep independently. Regardless of the exact nature of the nocturnal sleep concerns, daytime impairments are reported, presumably caused by the nighttime sleep difficulties or by some common but unidentified mechanism during sleep and wakefulness. Daytime symptoms typically include fatigue, decreased mood or irritability, general malaise, and cognitive impairment.

Sleep Related Breathing Disorders

Sleep related breathing disorders are characterized by abnormalities of respiration during sleep. In some of these disorders, respiration is also abnormal during wakefulness. The disorders are grouped into OSA disorders, central sleep apnea disorders, sleep related hypoventilation disorders, and sleep-related hypoxemia disorder. However, many individuals will meet diagnostic criteria for more than one of these groups. In particular, many individuals have a combination of obstructive and central sleep apnea. Although a diagnosis is often based on which disorder predominates, this may vary from night to night, as well as over time, in individuals. There is also overlap in pathophysiology, as some central apneas are associated with a closed upper airway and many obstructive apneas begin during a time of falling ventilatory drive.

An individual with a high pre-test probability of moderate to severe obstructive sleep apnea may exhibit the following signs and symptoms, which have been persistent for greater than four weeks in duration. The individual has reported excessive sleepiness or non-restorative, disturbed, or restless sleep and apneas, gasping, or choking at night has been witnessed. The individuals has reported excessive sleepiness or non-restorative, disturbed, or restless sleep and has at least two of the following supporting signs, symptoms, or risk factors: neck circumference greater than or equal to 17 inches for males or 16 inches for females; obesity (BMI greater than 30); physiologic abnormalities compromising respiration (e.g., retrognathia, tonsillar hypertrophy); regularly observed disruptive snoring; refractory hypertension; morning headaches; decreased concentration; memory loss;

decreased libido; irritability; nocturia; individual has unexplained documented pulmonary hypertension; individual has unexplained polycythemia with Hg greater than 18.5 g/dL in males or 16.5 g/dL in females.

Pediatric individuals, aged six years or less, may exhibit the following symptoms: neurobehavioral problems including attention deficit hyperactivity disorder; failure to thrive; neuromuscular disorders; paradoxical breathing; nocturnal diaphoresis; secondary enuresis; or persistent symptoms present for greater than four weeks in duration not only associated with respiratory infections.

Central Disorders of Hypersomnolence

Central disorders of hypersomnolence include a group of disorders in which the primary complaint is daytime sleepiness not caused by disturbed nocturnal sleep or misaligned circadian rhythms. Other sleep disorders may be present, but they must be adequately treated before a diagnosis in this category can be established. The term "hypersomnolence" is used to describe the symptom of excessive sleepiness, whereas "hypersomnia" refers to specific disorders, such as idiopathic hypersomnia.

Circadian Rhythm Sleep-Wake Disorders

Circadian rhythm sleep-wake disorders (CRSWDs) are disorders that are caused by alterations of the circadian time-keeping system or its entrainment mechanisms, or a misalignment of the endogenous circadian rhythm and the external environment. Most CRSWDs arise when a substantial misalignment exists between the internal rhythm and the required timing of the individual's school, work, or social activities. The most common presenting symptoms of CRSWDs are difficulty initiating and maintaining sleep and excessive sleepiness, but their impact extends to adverse health outcomes; impairments in social, occupational, and educational performance; and safety concerns.

Parasomnias

Parasomnias are undesirable physical events or experiences that occur during entry into sleep, within sleep, or during arousal from sleep. Parasomnias may occur during non-rapid eye movement sleep (NREM), rapid eye movement sleep (REM), or transitions to and from sleep. Parasomnias encompass abnormal, sleep-related, complex movements, behaviors, emotions, perceptions, dreams, and autonomic nervous system activity. Parasomnias are clinical disorders because of the resulting injuries, sleep disruption, adverse health effects, and untoward psychosocial effects. The clinical consequences of the parasomnias can affect the individual, the bed partner, or both.

Sleep Related Movement Disorders

Sleep-related movement disorders are primarily characterized by simple, usually stereotyped, movements that disturb sleep or its onset. Restless leg syndrome (RLS) is an exception in that individual typically engage in walking or non-stereotypic limb movement to reduce leg discomfort. However, RLS is closely associated with periodic limb movements (PLMs), which are usually simple and stereotyped within a series. Nocturnal sleep disturbance or complaints of daytime sleepiness or fatigue are a prerequisite for a diagnosis of a sleep-related movement disorder. Body movements that disturb sleep also are seen in many other sleep disorder categories (e.g., parasomnias such as sleepwalking, sleep terrors, and REM sleep behavior disorder). However, these parasomnias differ

from the simple stereotyped movements categorized as sleep-related movement disorders in that they involve complex behaviors during the sleep period. Parasomnia-related movements may appear purposeful and goal-directed but are outside the conscious awareness of the individual. Parasomnias are listed in a separate section from the sleep-related movement disorders.

Types of Sleep Assessments

A polysomnography, or PSG, refers to any one of a class of tests that utilizing continuous polygraph recording, usually over the course of a night, of electrophysiological measurements relevant to diagnosing sleep disorders. The four components of a PSG include: (1) electrographic recordings (EKG, EMG, EEG, EOG); (2) ventilatory variables that permit the identification of apneas and their classification as central or obstructive; (3) arterial oxygen saturation by finger oximetry; and (4) heart rate. In addition, a PSG may also include additional monitoring modalities such as esophageal monitoring and blood pressure monitoring. By definition, a PSG always requires sleep staging (EEG, EOG, and EMG).

In contrast, an unattended cardiorespiratory sleep study does not include sleep staging. The components of any sleep test are dictated by the clinical situation. The number and nature of parameters studied depends upon the judgment of the sleep disorders medical specialist. The terms "sleep studies" and "polysomnogram" are often used interchangeably. However, CPT and HCPCS coding makes the distinction between the two in the following way: polysomnography includes EEG monitoring, while unattended cardiorespiratory sleep studies do not.

An at home sleep apnea test (HSAT) is an alternative to an attended PSG for OSA diagnosis. The test is performed in the individual home, unsupervised by a sleep technician and usually consist of a recording device and related accessories. Home sleep apnea test measures fewer parameters than attended sleep study. Depending on the type of home device, it can monitor and track breathing efforts, detect snoring, oxygen level, and body movements. Most HSAT measure airflow, breathing efforts, blood oxygen levels and heart rate and produce an estimate of severity (i.e., respiratory event index (REI) based on monitoring time. The conventional sensors used in HSAT devices are unable to detect hypopneas and may underestimate the severity of OSA.

Sleep studies have been categorized as Type I, Type II, Type III, or Type IV. Unattended studies fall into categories Type II through Type IV. Type II studies use the same monitoring sensors as full PSGs (Type I) but are unattended and can be performed outside of the sleep laboratory. Type III studies are conducted with portable monitors that have at least two respiratory channels in addition to measuring oxygen saturation and heart rate. Some Type III devices may offer extra measurements, such as detection of snoring and movement. Type IV studies utilize devices that measure only 1 or 2 parameters, typically oxygen saturation and heart rate, or in some cases, just air flow.

Split-night sleep studies utilize the final portion of the overnight PSG to titrate CPAP. A split-night sleep study is an alternative to a full night of diagnostic PSG followed by a second night of CPAP titration.

Multiple Sleep Latency Test (MSLT) is performed the day after overnight PSG is completed. MSLT utilizes the same parameters as a basic polysomnogram for sleep staging (e.g., EEG, EKG, EMG,

EOG). It measures mean sleep latency (MSL), calculated by the average time elapsed from the start of daytime nap periods to the onset of sleep. The standardized MSLT is conducted with four or five nap attempts during a single day, which are each separated by two hours. Each nap attempt is ended if the subject fails to fall asleep within 20 minutes. An MSL of eight minutes or less and two or more sleep onset REM periods on the MSLT is indicative of a pathological state called narcolepsy (Iskander et al., 2023).

Pharyngometer and rhinometer testing, the pharyngometer graphically displays the relationship between the cross-sectional area of the airway and the distance down the airway in centimeters. The rhinometer uses acoustic reflection to map out the cross-sectional area measurements into the nasal airway.

EEG Topography is a computer based electroencephalographic mapping of the spatial distributions of pre-defined frequency bands.

Nocturnal pulse oximetry is the measurement of oxygen saturation, usually overnight, in the home. It is utilized for several clinical purposes such as evaluating individuals for obstructive sleep apnea and for determining oxygen dosing in individuals with chronic pulmonary disease.

Actigraphy consists of a small portable device, usually worn on the wrist or ankle, that senses physical motion and stores that information for future displaying, scoring, and interpretation. Recordings can be conducted for days or weeks on individuals in their own homes. Actigraphy has been used by researchers to measure sleep disturbances reflective of a variety of clinical sleep disorders, including insomnias, hypersomnia, circadian rhythm disorders, and PLM disorders.

PAP-Nap (Positive Airway Pressure Nap) is an abbreviated daytime sleep evaluation that has been proposed as a method of assessing, addressing and alleviating physical, mental, and emotional barriers in individuals who may benefit from PAP therapy. PAP-NAPs include mask and pressure desensitization, emotion-focused therapy to overcome aversive emotional reactions, mental imagery to divert individual attention from mask or pressure sensations, and physiological exposure to PAP therapy during a 100-minute nap period. The primary goal of PAP-Nap is to help individuals use PAP therapy for more than one hour, during which they have the potential to fall asleep with the mask in place or at least report that the experience was comfortable. PAP-Nap is not a titration but instead provides the individual with physiologic exposure to PAP therapy as well as to the lab environment. It does not provide definitive sleep or breathing evaluations.

SUPPORTIVE LITERATURE

Overnight PSG is an established diagnostic procedure used in conjunction with clinical examination in determining the presence and extent of OSA. PSG is considered the "gold standard" of OSA diagnosis and follow-up. It provides objective data on the type and severity of sleep-disordered breathing.

Pulse oximetry, when used alone, has not shown to have an adequate negative predictive value to rule out OSA (all individuals with symptoms of OSA would require PSG regardless of whether pulse oximetry was negative or positive). Overnight oximetry has not been demonstrated to be a sufficiently reliable predictor of the presence of OSA, particularly mild OSA.

Actigraphy has been used in many research studies for the evaluation of rest-activity cycles. This technique has not been validated as a method of diagnosing OSA. The major limitation of the methodology is precision, as well as the lack of correlation between physical movement and sleep architecture. The role of actigraphy in clinical management of OSA is not clear, but it can be helpful in determining the length of time in bed and activity levels. Actigraphy studies show that it is not a sufficiently accurate substitute measure for sleep time, to recommend for routine use. The default actigraphy settings may not be optimal for people with COPD and coexisting insomnia. The American Academy of Sleep Medicine (AASM) 2018 guidelines considered the use of actigraphy "conditional" (low degree of certainty of the outcome and appropriateness of the patient-care strategy) for all indications including insomnia (adult and pediatric) and circadian rhythm sleep-wake disorder, and to estimate or monitor total sleep time for patients with sleep-disordered breathing. The AASM indicated that actigraphy should not be used in place of electromyography for the diagnosis of periodic limb movement (PLM) disorder in either adults or pediatric patients.

MSLT is a validated, objective measure of the tendency to fall asleep and the ability to stay awake for a defined time, respectively. Studies of the MSLT procedure demonstrate significant differences in mean sleep latency values between healthy subjects and patients with excessive sleepiness due to narcolepsy or idiopathic hypersomnia.

There is insufficient evidence in the published medical literature to determine whether PAP-Nap studies result in improved adherence to therapy of improved patient outcomes.

The diagnosis of PLM disorder requires quantification of PLMs and PLM-related arousals, assessment of the impact of the movements upon sleep architecture, and identification and exclusion of other sleep disorders. Although PLM disorder can exist independent of restless leg syndrome (RLS), it is estimated that over 80% of individuals with RLS have evidence of PML on PSG, so PSG may be helpful in increasing the confidence in the RLS diagnosis.

Pharyngometer and rhinometer testing for screening, diagnosis, or treatment planning in persons with suspected or known OSA and for all other indications lacks clinical studies demonstrating that these tests improve clinical outcomes, and their effectiveness has not been established. The methods that detect structural and functional abnormalities of the upper airway implicated as risk factors for OSA continue to stimulate interest, because it is hoped that they may allow physicians to distinguish patients more easily with OSA from those without it, and, thereby, reduce the number of unnecessary sleep studies. The evidence of efficacy necessary to support the correlation between test results and OSA diagnosis is lacking.

PROFESSIONAL GUIDELINE(S)

The American Academy of Sleep Medicine issued recommendation in 2017 that were intended as a guide for clinicians diagnosing OSA in adults. A STRONG recommendation was one that clinicians should follow under most circumstances. A WEAK recommendation reflected a lower degree of certainty regarding the outcome and appropriateness of the patient-care strategy for all individuals. The AASM indicated that the ultimate judgment regarding the propriety of any specific care must be made by the clinician in light of the individual circumstances presented by the individuals, available diagnostic tools, accessible treatment options, and resources.

The AASM considered the following to be good practice statements:

- Diagnostic testing for OSA should be performed in conjunction with a comprehensive sleep evaluation and adequate follow-up.
- Polysomnography is the standard diagnostic test for the diagnosis of OSA in adult individuals in whom there is a concern for OSA based on a comprehensive sleep evaluation.

The AASM 2017 recommendations include:

- Clinical tools, questionnaires and prediction algorithms should not be used to diagnose OSA in adults, in the absence of polysomnography or home sleep apnea testing. (STRONG)
- Polysomnography, or home sleep apnea testing with a technically adequate device, should be used for the diagnosis of OSA in uncomplicated adult individuals presenting with signs and symptoms that indicate an increased risk of moderate-to-severe OSA. (STRONG)
- If a single home sleep apnea test is negative, inconclusive, or technically inadequate, polysomnography should be performed for the diagnosis of OSA. (STRONG)
- Polysomnography, rather than home sleep apnea testing, should be used for the diagnosis of OSA in individuals with significant cardiorespiratory disease, potential respiratory muscle weakness due to neuromuscular condition, awake hypoventilation or suspicion of sleep-related hypoventilation, chronic opioid medication use, history of stroke or severe insomnia. (STRONG)
- If clinically appropriate, a split-night diagnostic protocol, rather than a full-night diagnostic protocol for polysomnography should be used for the diagnosis of OSA. (WEAK)
- When the initial polysomnogram is negative and clinical suspicion for OSA remains, a second polysomnogram should be considered for the diagnosis of OSA. (WEAK)
- The AASM Position Statement for the Use of Home Sleep Apnea Test (HSAT) for Diagnosis of OSA in Children states that the use of a home sleep apnea test is not recommended for the diagnosis of OSA in children.

According to the American Association of Sleep Technologists (2020), and the AASM (2017) a technically adequate HSAT device incorporates a minimum of the following sensors: nasal pressure, chest and abdominal respiratory inductance plethysmography, and oximetry; or peripheral arterial tonometry (PAT) with oximetry and actigraphy (2). The technical requirements for these channel types should meet the standards outlined in the current AASM Manual for the Scoring of Sleep and Associated Events (3). A single HSAT recording should be conducted over at least one night. If a HSAT result is negative, inconclusive or technically inadequate, polysomnography should be performed to rule out the diagnosis of OSA.

In 2021, the AASM published a guidance statement that focused on indications for follow-up sleep apnea testing with PSG or home sleep apnea tests in individuals with OSA. The following clinical guidance statements were provided:

- Follow-up PSG or HSAT is not recommended for routine reassessment of asymptomatic individuals with obstructive sleep apnea on PAP therapy, however, follow-up PSG or HSAT can be used to reassess individuals with recurrent or persistent symptoms, despite good PAP adherence;
- Follow-up PSG or HSAT is recommended to assess response to treatment with non-PAP interventions;
- Follow-up PSG or HSAT may be used if clinically significant weight gain or loss has occurred since diagnosis of OSA or initiation of its treatment;
- Follow-up PSG may be used for reassessment of sleep-related hypoxemia and/or sleep-related hypoventilation following initiation of treatment for OSA;
- Follow-up PSG or HSAT may be used in individuals being treated for OSA who develop or have a change in cardiovascular disease;
- Follow-up PSG may be used in individuals with unexplained PAP device-generated data.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates sleep study devices as medical devices. All sleep study devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Dec 15]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 Dec 15]

The United States Food and Drug Administration (FDA) has approved several home sleep devices to diagnosis sleep related breathing disorders. The Somfit system is a non-invasive prescription device intended for home use with individuals suspected to have sleep-related breathing disorders. It collects physiological data and is comprised of a single-use adhesive-gel electrode worn on the individual forehead, an app and a cloud-based data management and reporting system. The device calculates and reports to clinicians EEG/EOG channels, sleep stages, oxygen saturation, peripheral arterial tonometry signal, pulse rate, and snoring level. The Sleep Doctor is another FDA approved home sleep device that utilizes finger, wrist, and chest sensors to monitor seven metrics associated with sleep apnea quality.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
92512 (E/I)	Nasal function studies (e.g., rhinomanometry)
92520 (E/I)	Laryngeal function studies (i.e., aerodynamic testing and acoustic testing)
94762	Noninvasive ear or pulse oximetry for oxygen saturation by continuous overnight monitoring (separate procedure)
95782	Polysomnography; younger than 6 years, sleep staging with four (4) or more additional parameters of sleep, attended by a technologist
95783	Polysomnography; younger than 6 years, sleep staging with four (4) or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bi-level ventilation, attended by a technologist
95803	Actigraphy testing, recording, analysis, interpretation, and report (minimum of 72 hours to 14 consecutive days of recording)
95805	Multiple sleep latency or maintenance of wakefulness testing, recording, analysis and interpretation of physiological measurements of sleep during multiple trials to assess sleepiness
95807	Sleep study, simultaneous recording of ventilation, respiratory effort, ECG or heart rate, and oxygen saturation, attended by a technologist. Please note: 95807 with modifier 52 (reduced service) may be billed for a PAP-NAP and is considered E/I.
95808	Polysomnography; any age, sleep staging with 1-3 additional parameters of sleep, attended by a technologist
95810	Polysomnography; age 6 years or older, sleep staging with four (4) or more additional parameters of sleep, attended by a technologist
95811	Polysomnography; age 6 years or older, sleep staging with four (4) or more additional parameters of sleep, with initiation of continuous positive airway pressure therapy or bilevel ventilation, attended by a technologist

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
F51.8	Other sleep disorders not due to a substance or known physiological condition
G40.001-G40.219	Localization-related (focal) (partial) idiopathic of symptomatic epilepsy and epileptic syndromes (code range)
G40.301-G40.319	Generalized idiopathic epilepsy and epileptic syndromes (code range)
G40.401-G40.419	Other generalized epilepsy and epileptic syndromes (code range)
G40.501-G40.509	Epileptic seizures related to external causes (code range)
G40.801-G40.804	Other epilepsy (code range)
G40.811-G40.814	Lennox-Gastaut syndrome (code range)
G40.821-G40.824	Epileptic spasms (code range)
G40.89	Other seizures
G40.901-G40.919	Epilepsy, unspecified (code range)
G40.A01-G40.A19	Absence epileptic syndrome (code range)
G40.B01-G40.B19	Juvenile myoclonic epilepsy (code range)
G47.00	Insomnia, unspecified
G47.10	Hypersomnia, unspecified
G47.20	Circadian rhythm sleep disorder, unspecified type
G47.30	Sleep apnea, unspecified
G47.411-G47.429	Narcolepsy (code range)
G47.8-G47.9	Other and unspecified sleep disorders (code range)

Code	Description
R56.9	Unspecified convulsions

REFERENCES

Agency for Healthcare Research and Quality Technology Assessment [Internet]. Home diagnosis of obstructive sleep apnea-hypoapnea syndrome. 2007 Aug 8 [accessed 2025 Dec 15.] Available from: http://www.cms.hhs.gov/determinationprocess/downloads/id48TA.pdf

American Academy of Pediatrics [Internet]. Clinical Practice Guideline: Diagnosis and management of childhood obstructive sleep apnea syndrome. Pediatrics 2012 Aug Sep;130(3):576-84.

American Academy of Sleep Medicine [Internet: unable to access as a subscription is required]. International Classification of Sleep Disorders – Third Edition (ICSD-3) Darien, IL. 2014.

American Association of Sleep Technologist [Internet]. Home Sleep Apnea Testing (HSAT) December 2020. [Accessed 2025 Dec 15] Available from: HSAT Technical Guideline 2020_FINAL_New Template-1.pdf

Caples SM, et al. Use of polysomnography and home sleep apnea tests for the longitudinal management of obstructive sleep apnea in adults: an American Academy of Sleep Medicine clinical guidance statement. J Clin Sleep Med. 2021 Jun 1;17(6):1287-1293.

Chinoy ED, et al. Performance of seven consumer sleep-tracking devices compared with polysomnography. Sleep. 2021 May 14;44(5).

Iskander A, et al. Normal multiple sleep latency test values in adults: A systematic review and meta-analysis. Sleep Med. 2023 Sep;109:143-148.

Kapur VK, et al. Clinical Practice Guideline for Diagnostic Testing for Adult Obstructive Sleep Apnea: An American Academy of Sleep Medicine Clinical Practice Guideline. J Clin Sleep Med. 2017 Mar 15;13(3):479-504.

Khan LE, et al. Recommended protocols for the Multiple Sleep Latency Test and Maintenance of Wakefulness Test in adults: guidance from the American Academy of Sleep Medicine. J Clin Sleep Med. 2021 Dec 1;17(12):2489-2498.

Torstensen EW, et al. Diagnostic value of actigraphy in hypersomnolence disorders. Sleep Med. 2021 Sep;85:1-7.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Sleep Testing for Obstructive Sleep Apnea (OSA) (240.4.1) [accessed 2025 Dec 15].

LCD - Polysomnography and Other Sleep Studies (L36839) accessed 2025 Dec 15].

Article - Polysomnography and Sleep Studies – Medical Policy Article (A53019) [accessed 2025 Dec 15].

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

MEDICAL POLICY

Medical Policy Title	**Small Bowel and Multivisceral Transplants in Adults and Children**
Policy Number	**07.02.05**
Current Effective Date	**July 1, 2026**
Next Review Date	**March 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Candidates for Small Bowel (SB) or Multivisceral (MV) transplant must meet **ALL** of the following criteria:

A. Adequate cardiopulmonary status;

B. Absence of active infection;

C. Absence of malignancy (other than non-melanoma skin cancers), unless malignancy has been completely resected, or (upon medical review) it is determined that malignancy has been treated with small likelihood of recurrence and acceptable future risks;

D. Documentation of patient compliance with medical management; **and**

E. Meet **ALL** of the transplant specific criteria:

Small Bowel Transplant

1. Small bowel (SB) transplantation is considered **medically appropriate** in pediatric and adult patients with short bowel syndrome (SBS) for **ANY** of the following indications:

a. Impending or overt liver failure due to total parenteral nutrition (TPN)-induced liver injury;

b. Thrombosis of two (2) or more central veins;

c. Two (2) or more episodes per year of systemic sepsis secondary to line infection that require hospitalization;

d. A single episode of line-related fungemia, septic shock, or acute respiratory distress syndrome; **or**

e. Frequent episodes of severe dehydration, despite intravenous fluid supplementation in addition to TPN;

2. SB transplant is considered **investigational** for **BOTH** of the following:

a. Being considered for adult or pediatric individuals with intestinal failure who can

tolerate TPN; **and**

b. SB transplant using live donor tissue.

Multivisceral Transplant

3. Multivisceral (MV) transplantation is considered **medically appropriate** in pediatric and adult patients with intestinal failure **AND** concurrent liver failure.

RELATED POLICIES

Corporate Medical Policy

7.02.07 Liver Transplantation

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Pre-transplant evaluation documentation should include the following clinical information (if testing is unable to be performed, the rationale for not performing the testing should be included in the documentation):

A. Clinical Evaluation:

1. Confirmation of diagnosis;
2. Identification of comorbidities;
3. Current assessment of co-morbidities;
4. Management of co-morbidities; **and**
5. Consult notes (if applicable);

B. Psycho-Social Evaluation:

1. Identification of stressors (e.g., family support, noncompliance issues, motivational issues, alcohol, or smoking/substance abuse);

C. Performance Status:

1. Karnofsky performance score;
2. Palliative Performance Scale (PPS) score;
3. Eastern Cooperative Oncology Group (ECOG) performance status; **or**
4. Lansky Play-Performance Scale (for age 1 to 16 years);

D. Oral Health Evaluation;

E. Lab Tests:

1. CBC, metabolic profile;

2. Serologies: CMV, Hepatitis B and C; **and**
3. HIV Testing;

F. Cardiac Assessment:
1. 12 Lead EKG;
2. Stress (exercise, nuclear, or dobutamine), **and**
3. Echo or MUGA Scan;

G. Pulmonary Assessment:
1. Chest X-ray;
2. Pulmonary function tests (PFTs); for high-risk for respiratory failure (COPD, emphysema, alpha-1-antritrypsin deficiency, hepatopulmonary syndrome, or significant smoking history); **and**

H. Age-Appropriate Screening Tests: Please refer to the U.S Preventive Services Task Force (USPSTF) website for list of age-appropriate screening guidelines. [accessed 2026 Jan 30]. Available from: https://uspreventiveservicestaskforce.org/uspstf/

II. Small Bowel and Multivisceral Transplants are considered a relative contraindication in human immunodeficiency virus (HIV) positive recipients, unless **ALL** of the following criteria are met:

A. Patient's CD4 count is greater than 200 cells/mm3;

B. HIV-1RNA is undetectable;

C. Patient has been on stable anti-retroviral therapy for greater than three (3) months;

D. Patient has no other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections, Kaposi's sarcoma, or other neoplasm); and

E. Patient meets all other criteria for transplantation.

DESCRIPTION

Small Bowel Transplant

The purpose of a small bowel (SB) transplant is to restore bowel function and allow for adequate nutrition in patients with short bowel syndrome (SBS). It may be an alternative to total parenteral nutrition (TPN) for selected patients who are predicted to have poor survival on TPN. SBS is a condition in which the absorbing surface of the small intestine is inadequate due to extensive disease or surgical removal. The spectrum of clinical disease varies widely, from only single micronutrient malabsorption to complete intestinal failure, defined as the reduction of gut function below the minimum necessary for the absorption of macronutrients and/or water and electrolytes.

In adults, etiologies of short bowel syndrome include ischemia, trauma, volvulus, and tumors. In children, gastroschisis, volvulus, necrotizing enterocolitis, and congenital atresia are predominant

causes. The actual prevalence of short bowel syndrome is not clear primarily due to under-reporting and a lack of reliable patient databases.

Multivisceral Transplant (MV)

MV is the most extensive form of intestinal transplant, and an infrequently performed procedure, but, without it, most candidates, candidates will likely face 100% mortality. MV includes the simultaneous transplant of multiple abdominal organs that are reliant on the celiac axis and superior mesenteric artery, including the stomach, duodenum, pancreas, and small intestine, with or without the liver (modified multivisceral transplant). Some centers may also include the colon or elect to simultaneously remove the spleen. Organs selected in addition to the small intestine are dependent upon the patient's specific disease.

Candidates for MV transplant have SBS and terminal liver failure or other gastrointestinal problems, such as pancreatic failure, thromboses of the celiac axis and the mesenteric artery, or pseudo-obstruction affecting the entire gastrointestinal tract.

Total parenteral nutrition (TPN) is the only established treatment that can produce long-term survival, once the small intestine is dysfunctional, and oral nutrition is ineffective. TPN requires placement of a permanent venous access device. There are some serious, life-threatening complications that can occur as a result of TPN, including hepatobiliary disease, thrombosis due to the venous catheter, or sepsis from the venous access line.

SUPPORTIVE LITERATURE

There are limited long-term data on SB and MV transplants, due to the small numbers of transplantations performed. Intestinal transplants (including multivisceral and bowel/liver) represent a small minority of all solid organ transplants. In 2024, 80 intestinal transplants were performed in the U.S. according to the U.S. Department of Health and Human Services (DHHS) Organ Procurement and Transplantation Network National Data 2024. The number of new patients added to the intestinal transplant waiting list as of January 30, 2026, was 200.

Sudan (2010) published a review of the literature on long-term outcomes after intestinal transplantation. Sudan noted that intestinal transplantation had become standard therapy for patients with life-threatening complications from parenteral nutrition therapy. Data from current single center series have indicated 1-year patient survival rates between 78% and 85% and 5-year or more survival rates between 56% and 61%.

Pediatric intestinal transplant patients, most achieve normal growth velocity at 2 years posttransplant. However, oral aversion is common; tube feedings are necessary for 45% of children. Sudan also reported on parental surveys of quality of life for pediatric transplant patients in which intestinal transplant patients appear to have modestly improved quality of life compared with those remaining on TPN and slightly worse than matched school-age controls without intestinal disease.

In 2022, Roberts et al conducted a multicenter international cohort study to validate the Toronto criteria (Burghadt et al 2015), a set of pediatric criteria for intestinal transplantation which included 1) two or more intensive care unit admissions requiring ventilatory or inotropic support, 2) loss of

three or more out of six central venous catheter sites, and 3) persistent elevation of conjugated bilirubin (≥ 75µmol/L) following six weeks of lipid management strategies. The Toronto criteria was based on the experiences of a single center. Roberts and colleagues aimed to prove that the data could be generalized to all pediatric patients with intestinal failure by reviewing a cohort of 443 patients who were included in the study if they were less than 18 years of age at the time of diagnosis, and with intestinal failure due to a primary gastrointestinal disorder (e.g., short bowel syndrome, motility disorder or congenital diarrhea, and enteropathy). Excluded were patients with a malignancy, metabolic, or mitochondrial disease, or any other independently life-limiting condition. Follow-up was one year, at a minimum. Patient data was collected from hospital records and included patient status at the end of the study (alive, dead or transplanted) for each of the proposed listing criteria, which was similar to the Burghadt criteria but did extend the length of lipid strategies to 8 weeks and also separated central venous catheter sites into upper and lower body sites, and upper body sites only. Validation of the criteria was done by calculating the sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV), and probability of death or transplant for each of the criteria. Median age at the diagnosis of intestinal failure was 0.1 years (Interquartile ratio (IQR) 0.03-0.14) with median follow up of 3.8 years (IQR 2.3-5.3). A total of 9% (40/443) of patients died, 12 % (53/443) were transplanted. A total of 11 patients died post-transplant. The criteria had a high predictive value of death and intestinal transplantation ($p<.0001$, 95% Confidence Interval). Authors concluded that although the study was of lower statistical power, the outcomes confirm the results of the single center cohort, thereby confirming the validity of the three proposed Toronto listing criteria for intestinal transplant in children.

Living donor isolated or combined liver/intestinal transplants have been studied in very small case studies. Typically, living donor transplants have been reserved for children who are at high risk for premature death while on the cadaveric waiting list and who have no central venous access, or for children with impending TPN-related liver failure (Gangemi 2009). A living donor liver transplant may be performed first, followed by an intestinal transplant from the same donor later. Advantages to living donors' transplants include better human leukocyte antigen (HLA) matching, reduction of cold ischemia time, and no waitlisting for a transplant; thus, the patient is less likely to die while waiting for an organ. Results from the studies showed few or no complications for the donor after transplant. Most complications for the recipient, such as diarrhea, weight loss, and nausea, were resolved within a few weeks of surgery. However, these small studies are lacking long-term follow-up of the donors.

Patient survival and graft survival for recipients of living donor combined liver/intestinal or isolated intestinal transplants has been favorable. More large studies are needed, to determine whether patient survival rate is comparable to or better than the survival rate for patients receiving cadaveric organs. Most studies suggest that living donor-transplanted organs are to be reserved for circumstances in which there is high risk for death, and no cadaveric donors are available.

PROFESSIONAL GUIDELINE(S)

In 2001, the American Society of Transplantation issued a position paper on indications for pediatric intestinal transplantation (Iyer 2022). The Society listed the following disorders in children as being potentially treatable by intestinal transplantation: short bowel syndrome, defective intestinal motility,

and impaired enterocyte absorptive capacity. Contraindications for intestinal transplants to treat pediatric patients with intestinal failure are similar to those of other solid organ transplants: profound neurologic disabilities, life-threatening comorbidities, severe immunologic deficiencies, nonresectable malignancies, autoimmune diseases, and insufficient vascular patency.

In 2022, the American Gastroenterological Association (AGA) (Iyer 2022) published a clinical practice update on the management of short bowel syndrome. The guidance recommends referral for intestinal transplantation for "patients with intestinal failure (i.e., refractory parenteral nutrition dependency) and onset of parenteral nutrition failure, especially the occurrence of progressive intestinal failure-associated liver disease or catheter related complications such as recurrent catheter-related sepsis or loss of vascular access due to thrombosis of the central veins." The guidance stresses wider adoption of pre-emptive intestinal transplant, before parenteral nutrition complications are an issue, including such patients who do not meet the strict historical criteria of parenteral nutrition failure (e.g., severe dysmotility syndromes who are not anticipated to ever wean from PN, and those with large abdominal desmoid tumors). Regarding the use of intestinal transplantation in pediatric patients, authors noted that the document focus is on adult patients, "however, some overlap with the management of pediatric short bowel syndrome may be present".

In 2001, the United Network for Organ Sharing (UNOS) indicated that asymptomatic HIV-positive patients should not necessarily be excluded from candidacy for organ transplantation, stating, "A potential candidate for organ transplantation whose test for HIV is positive but who is in an asymptomatic state should not necessarily be excluded from candidacy for organ transplantation, but should be advised that he or she may be at increased risk of morbidity and mortality because of immunosuppressive therapy."

In 2013, the American Association for the Study of Liver Diseases and the American Society of Transplantation published practice guidelines related to the evaluation of liver transplantation in adults. More than 50 recommendations were included, the strength of the recommendations were classified as strong, or weak and the quality of evidence was rated as high (A), moderate (B), or Low (C). Level 1-A recommendations include the following:

- "Evaluation for LT should be considered once a patient with cirrhosis has experienced an index complication such as ascites, hepatic encephalopathy, or variceal hemorrhage or hepatocellular dysfunction results in a MELD Score ≥ 15.
- Potential recipients with portopulmonary hypertension (POPH) should be evaluated by a pulmonary or cardiac specialist for vasodilator therapy.
- HPS is relatively common in patients evaluated for LT and should be screened by pulse oximetry.
- Renal dysfunction requires vigorous evaluation prior to LT to determine etiology and prognosis.
- Tobacco consumption should be prohibited in LT candidates.
- Candidates should undergo age and risk factor-appropriate cancer screening, e.g., colono-scopy, mammography, Papanicolaou smear.
- LT candidates should be screened for bacterial, viral, and fungal infections prior to LT.

- Vaccination should be encouraged against pneumococcus, influenza, diphtheria, pertussis, and tetanus.
- Bone densitometry should be obtained as part of transplant evaluation and treatment of osteoporosis initiated prior to LT.
- Nutritional assessment should be performed in every LT candidate.
- Patients with HIV infection are candidates for LT if immune function is adequate and the virus is expected to be undetectable by the time of LT.
- Patients should be evaluated for and meet reasonable expectations for adherence to medical directives and mental health stability as determined by the psychosocial evaluation.
- LT transplant candidates with HCV have the same indications for LT as for other etiologies of cirrhosis.
- Patients with HBV (hepatitis B) liver disease should receive antiviral therapy to suppress HBV replication pre-transplant and continued surveillance for HCC.
- LT is indicated for decompensated primary biliary cirrhosis (PBC).
- LT should be considered in patients with decompensated autoimmune hepatitis who do not respond to or are not appropriate candidates for medical therapies.
- LT is an effective therapy for decompensated liver disease due to primary sclerosing cholangitis (PSC), including bouts of recurrent cholangitis and sepsis.
- Early referral of ALD patients for initiation of LT evaluation facilitates psychosocial assessment and setting addiction treatment goals.
- Patients with acute liver failure (ALF) require immediate referral to a liver transplant center.
- Patients with acetaminophen overdose should be evaluated for and meet reasonable expectations for adherence to medical directives and mental health stability as determined by the psychosocial evaluation.
- LT is an effective therapy for Hepatocellular carcinoma (HCC) within the Milan criteria.
- LT is an effective therapy for decompensated liver disease due to non-alcoholic steatohepatitis (NASH) or cryptogenic cirrhosis.
- LT is indicated for decompensated cirrhosis due to a-1-antritrypsin deficiency.
- Screening to exclude lung disease with pulmonary function tests and chest imaging should be undertaken in patients with a-1-antritrypsin deficiency being evaluated for LT.
- Urgent LT is indicated for Wilsonian acute liver failure.
- LT is indicated in decompensated cirrhosis due to Wilson's disease unresponsive to medical therapy.
- LT is indicated for decompensated cirrhosis due to hemochromatosis.

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- Preemptive LT (prior to the development of advanced renal disease) or combined liver and kidney transplantation in the setting of ESRD are curative for primary hyperoxaluria and should be considered for patients who do not respond to medical therapy."

In 2014, the North American Society of Transplantation and the North American Society for Pediatric Gastroenterology, Hepatology & Nutrition published AASLD practice guidelines for the evaluation of the pediatric patient for liver transplant (LT) (with liver transplant included within the definition of multivisceral transplants). Over 90 recommendations were included, the strength of the recommendations were classified as strong, or weak and the quality of evidence was rated as high (A), moderate (B), or Low (C), including, but not limited to, the following:

- "A multidisciplinary pediatric LT evaluation team should be skilled in pediatric conditions and properly communicate with the family and the child, when appropriate, the processes, risks, and benefits associated with LT. (2-B)
- Immediate contact with pediatric LT center should be initiated for children with acute liver failure or acute decompensation of an established liver disease; emergent referral for LT evaluation may be required. (1-A)
- Children with liver-based metabolic crises refractory to medical and/or surgical therapy (1-B), unresectable hepatoblastoma (1-B), or evidence of hepatocellular unresectable carcinoma (1-B) should be referred urgently for LT evaluation.
- Biliary atresia (BA) patients who are post-hepatoportoenterostomy (HPE) should be promptly referred for LT evaluation if the total bilirubin is greater than 6mg/dL beyond 3 months from HPE. (1-B); liver transplant evaluation should be considered in BA patients whose total bilirubin remains between 2-6 mg/dL. (1-B)
- Referral for LT evaluation should be anticipated for children with chronic liver disease and evidence of deteriorating liver function characterized by poor weight gain, growth failure, variceal hemorrhage, intractable ascites, recurrent cholangitis, or episodes of spontaneous bacterial peritonitis, pruritus, advancing encephalopathy, and/or uncorrectable coagulopathy (1-B).
- A review of the local records by the LT team prior to LT evaluation will inform the evaluation schedule and enable affirmation of the primary diagnosis, assessment of comorbidities, and identify technical challenges related to LT. (2-B)
- In collaboration with the local primary pediatric specialist, management of the primary disease and comorbidities should be reviewed and optimized. (2-B)
- Aggressive nutritional support for children awaiting LT should be initiated to optimize outcomes (1-B); NG tube feedings and parenteral nutrition may be needed in some circumstances. (2-B)
- Two-dimensional echocardiography (2-DE) with Doppler should be performed in all patients at the time of liver transplant evaluation (2-B); if the right ventricular systolic pressure is over 50 mmHg by 2-D echo, a right-heart cardiac catheterization is necessary to establish the diagnosis of portopulmonary hypertension. (2-B)

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- Pulmonary function tests, including forced expiratory volume in one second and forced vital capacity should be performed in patients with cystic fibrosis evaluated for liver transplant. (2-B)
- Renal function should be assessed in all patients, with special emphasis on those with metabolic liver diseases associated with renal dysfunction (1-B) and those at increased risk for calcineurin inhibitor toxicity. (2-B)
- Serum creatinine alone should not be used to assess renal function (1-B); either cystatin C (2-B) or the revised Schwartz Formula (2-C) should be used to estimate the glomerular filtration rate in children with chronic liver disease.
- Children with end stage liver disease should receive a careful oral examination looking for evidence of dental caries, gingival disease, or dental abscess - referral to a pediatric dentist should occur if abnormalities are identified. (2-B)
- Completion of all age-appropriate vaccinations, for the child and family members, should occur prior to transplantation and ideally before the development of end-stage liver disease (1-B); children who have not completed the necessary vaccine schedule can receive vaccinations on an accelerated schedule. (1-B)
- Evidence of a prior Epstein-Barr virus and cytomegalovirus infection, as determined by virus-specific serological measurements, should be per-formed on all individuals evaluated for liver trans-plant, recognizing that for children less than 12-18 months of age, antibodies may have been passively transmitted to the child from the mother. (I-A)
- Families should be assessed to ensure social services and psychosocial support systems are adequate for LT-candidates in order to optimize post transplantation outcomes. (1-B)
- Patients and families at potential risk for nonadherence should be identified and receive focused psychosocial interventions prior to and following transplantation. (1-B)
- Neurocognitive testing should be performed in children awaiting LT to identify areas warranting early intervention to minimize later cognitive difficulties (2-B).
- BA patients post-HPE should be promptly referred for LT evaluation if the total bilirubin is greater than 6 mg/dL beyond 3 months from HPE (1-B); liver transplant evaluation should be considered in BA patients whose total bilirubin remains between 2-6 mg/dL (1-B), and for those with lesser bilirubin values who have unmanageable consequences of biliary cirrhosis or portal hypertension. (2-B)
- Careful assessment of cardiac and renal function should occur during LT evaluation in all liver transplant candidates. (2-B)
- Pretransplant vascular imaging of the intra-abdominal vasculature should be performed (2-B); vascular imaging of the head and neck may be considered. (2-C)”

REGULATORY STATUS

Organ transplants, as surgical procedures, do not require U.S. Food and Drug Administration (FDA) approval. The Health Resources Services Administration (HRSA) oversees the transplantation of vascularized human organs through the Organ Procurement and Transplantation Network (OPTN). For more information view the OPTN: https://www.hrsa.gov/optn [accessed 2026 February 23].

The HIV Organ Policy Equity (HOPE) Act was signed into law on November 21, 2013, and the provisions of the Act took effect on November 21,2015. The HOPE act permits donated, HIV-positive kidney and liver organs to be used for transplantation in HIV-positive patients. The HOPE Act directs the Department of Health and Human Services and the Organ Procurement Transplant Network (OPTN) to develop and institute standards for research on HIV-positive organ transplantation and permits the Secretary to permit positive-to-positive transplantation if it is determined that the results of research warrant such a change. The Secretary would be required to direct OPTN to develop standards to ensure that positive-to-positive transplantation does not impact the safety of the organ transplantation network. In addition, the Act amends federal criminal law regarding HIV transmission to clarify that such organ donations are not barred. In May of 2020, the HOPE Act was amended to include organs of any type.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
44120	Enterectomy, resection of small intestine; single resection and anastomosis
44121	Enterectomy; each additional resection and anastomosis (List separately in addition to code for primary procedure)
44125	Enterectomy, resection of small intestine; with enterostomy
44135	Intestinal allotransplantation from a cadaver donor
44136 (E/I)	Intestinal allotransplantation from a living donor
44137	Removal of transplanted intestinal allograft, complete
47135	Liver allotransplantation; orthotopic, partial or whole from cadaver or living donor, any age

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HCPCS Codes

Code	Description
S2053	Transplantation of small intestine, and liver allografts
S2054	Transplantation of multivisceral organs

ICD10 Codes

Code	Description
K72.10	Chronic hepatic failure without coma
K72.11	Chronic hepatic failure with coma
K72.90	Hepatic failure, unspecified without coma
K72.91	Hepatic failure, unspecified with coma
K91.2	Postsurgical malabsorption, not elsewhere classified

REFERENCES

American Gastroenterological Association. American Gastroenterological Association medical position statement: short bowel syndrome and intestinal transplantation. Gastroenterology. 2003 Apr;124(4):1105-10.

Benedetti E, et al. Progressive functional adaptation of segmental bowel graft from living related donor. Transplant. 2001;71(4):569-71.

Gangemi A, et al. Lessons learned in pediatric small bowel and liver transplantation from living-related donors. Transplantation. 2009 Apr 15;87(7):1027-30.

Horslen SP, et al. Isolated liver transplantation in infants with end-stage liver disease associated with short bowel syndrome. Ann Surg. 2002 Mar;235(3):435-9.

Iyer K, et al. AGA clinical practice update on management of short bowel syndrome: expert review. Clin Gastroenterol Hepatol. 2022 Oct;20(10):2185-2194.

Kaufman SS, et al. Into the indications for intestinal transplantation: consensus in the year 2019. Transplantation. 2020 May;104(5):937-946.

Kesseli S and Sudan D. Small bowel transplantation. Surg Clin North Am. 2019 Feb;99(1):103-116.

Khan FA and Selvaggi G. Overview of intestinal and multivisceral transplantation. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed May 2020.

Lee EJ, et al. Pediatric intestinal transplantation. Semin Pediatr Surg. 2022 Jun;31(3):151181.

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Martin P, et al. Evaluation for liver transplantation in adults: 2013 practice guideline by the American Association for the Study of Liver Diseases and the American Society of Transplantation. Hepatology. 2014;59(3):1144-1164.

Roberts AJ, et al. An international multicenter validation study of the Toronto listing criteria for pediatric intestinal transplantation. Am J Transplant. 2022;22:2608-2615.

Sokal EM, et al. Liver and intestinal transplantation in children: Working Group Report of the First World Congress of Pediatric Gastroenterology, Hepatology, and Nutrition. J Pediatr Gastroenterol Nutr. 2002;35 Suppl 2:S159-72.

Squires RH, et al. Evaluation of the pediatric patient for liver transplantation: 2014 practice guideline by the American Association for the Study of Liver Diseases, American Society of Transplantation and the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition. 2014;60(1):362-398.

Sudan D. Long-term outcomes and quality of life after intestine transplantation. Curr Opin Organ Transplant. 2010 Jun;15(3):357-60.

Torres C, et al. Twelve-year outcomes of intestinal failure-associated liver disease in children with short-bowel syndrome: 97% transplant-free survival and 81% enteral autonomy. JPEN J Parenter Enteral Nutr. 2022 Jan;46(1):197-206.

U. S. Department of Health and Human Services (DHHS) [Internet]. Organ Procurement and Transplantation Network National Data. 2026 [accessed 2026 Feb 09]. Available from: https://optn.transplant.hrsa.gov/data/

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Intestinal and Multi-Visceral Transplantation (260.5) [accessed 2026 Feb 09]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 2/26 **Revised**: **Reviewed**: 5/26	
Date	**Summary of Changes**
7/1/2026* *No change to effective date for this update	• Annual review; policy intent unchanged.
7/1/2026	• New

MEDICAL POLICY

Medical Policy Title	**Specialized Neuromodulation for Specific Conditions**
Policy Number	**1.01.62**
Current Effective Date	**August 1, 2026**
Next Review Date	**May 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. The following neuromodulation modalities are **investigational** for all indications:

A. Transcutaneous Afferent Patterned Stimulation (TAPS) [e.g., Cala One, Cala Trio, Felix NeuroAI];

B. Remote Electrical Neuromodulation (REN) [e.g., Nerivio].

RELATED POLICIES

Corporate Medical Policy

1.01.58 Cranial and Auricular Neurostimulation

1.01.59 Electromagnetic and Pulsed Field Stimulation

1.01.60 Implantable and Invasive Neuromodulation Systems

1.01.61 Non-Invasive Surface Electrical Stimulation for Pain and Rehabilitation

7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

7.01.10 Sacral Nerve Stimulation

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Remote Electrical Neuromodulation (REN)

REN is a nonpharmacologic abortive treatment for migraines. The Nerivio device (Theranica) was cleared by the FDA for patients aged 12 years and above. It is a wireless stimulation device applied to the lateral upper arm in 45-minute sessions and triggers weak electrical impulses to start conditioned pain modulation, a proprietary electrical signal to stimulate noxious sensory fibers and relieve acute migraine. It is controlled by a mobile app that includes a migraine diary to track

migraine headaches and treatment sessions. Each device functions for 12 treatments, after which, it is to-be disposed of and a new device is required.

Afferent Patterned Stimulation Therapy for Essential Tremor

The Cala Trio (Cala Health) is an external upper limb stimulator. It is a hand-specific device indicated to relieve tremors in adults with essential tremor. The device is worn like a wristwatch. Electrodes embedded into a disposable cloth band deliver stimulation to the median and radial nerves of the wrist after being calibrated to the specific motion of the user. The digital display provides prompts, time, offers the ability to adjust intensity and notifies the user when the band requires changing. The contained accelerometer measures the tremor and adjusts simulation. Sessions are for 40-minutes, and the device is recommended to be used twice daily prior to activities requiring use of that hand.

SUPPORTIVE LITERATURE

Remote Electrical Neuromodulation

Yarnitsky et al (2019) conducted a vendor- funded double blind RCT from involving 252 patients at 12 different sites who met the international classification of headache disorders criteria for migraine, had two to eight migraines per month and less than 12 headache days per year. The authors aimed to evaluate the efficacy and safety of REN for the acute treatment of migraine. Treatment sessions with the device were 45 minutes. Pain relief was defined as improvement from severe or moderate pain to mild or none, or improvement from mild pain to none, of which 66.7% of the active treatment group achieved pain relief at 2 hours post-treatment compared to 38% in sham group. Sustained relief (48 hours post treatment) was achieved by 39% of the treatment group, and 16% of the sham group. Adverse events were mild and rare. The authors report that the findings are equivalent to migraine relief found with triptan use. The approval of Nerivio for adolescents was based on a study by Hershey et al (2020), a vendor-funded single-arm multicenter study of 39 patients with migraine between the ages of from the ages of 12 and 17. Pain relief at 2 hours was achieved by 71% (28/39) of the patients, and 35% (14/39) were pain free within 2 hours. Study enrollment was shortened to 60% of the planned target due to the coronavirus pandemic however since pain relief at 2 hours was achieved by more than 60% it was determined to be complete. Of those that had pain relief and pain freedom, 90% had sustained relief or freedom for 24 hours. Additional symptoms of nausea, photophobia and phonophobia disappeared at 2 hours in 54%, 41% and 40% of treated individuals. There were mild and low device related adverse events for both of the studies. The writers concluded that Nerivio is both safe and effective for the treatment of acute migraine in adolescents. Longer and larger RCTs with relevant comparators are needed to determine if results can be replicated in other populations, and if the treatment is superior to the current standard of care.

Afferent Pattern Stimulation

Pahwa et al (2019) studied the use of a novel peripheral (radial and median nerves) stimulation device for the treatment of essential tremor via a RCT of 77 patients and compared to sham stimulation. Although the primary endpoint (an improvement in the Tremor Research Group Essential Tremor Rating Assessment Scale (TETRAS) Archimedes spiral scores) was not met, the authors noted significant improvements in some subject-rated tasks in activities of daily living and clinical global

impression-improvement (CGI-I) rating after stimulation. The outcomes were similar to the ranges of improvement offered by standard medications utilized for the treatment of tremor. The authors concluded that peripheral nerve stimulation may provide a safe, well-tolerated, and effective treatment for transient relief of hand tremor symptoms, however future studies over time and multiple sessions are needed.

Isaacson et al (2020) evaluated the repeated home use of an FDA-cleared wrist-worn neuromodulation device in the Prospective Study for Symptomatic Relief of Essential Tremor with Cala Therapy (PROSPECT) trial. For each active treatment session, the device electrically stimulated the median and radial nerves for 40 minutes with an alternating burst pattern tuned to the frequency of each patient's tremor. The pre-specified co-primary endpoints were improvements on the clinician-rated Tremor Research Group Essential Tremor Rating Assessment Scale (TETRAS) and patient-rated Bain & Findley Activities of Daily Living (BF-ADL) dominant hand scores. Of the 263 enrolled patients, 205 completed the visit three follow-up and were included in the primary analysis. Results revealed a significant improvement in TETRAS and BF-ADL from pre- to post-stimulation at each clinic visit ($p<.0001$ for all comparisons). Pre-stimulation tremor levels were improved from Visit 1 to 3 on both TETRAS and BF-ADL ($p<.0001$ for both). Patients rated as "severe" or moderate" improved with both TETRAS (49.3% at baseline to 21% at study exit) and BF-ADL (64.8% at baseline to 23% at study exit) scoring. Tremor power is a calculation of amplitude and frequency. Tremor power decreases with lower amplitude motions and lower frequency motions. Tremor power was also noted to significantly improve with therapy from pre- to post-stimulation ($p<.0001$). No device-related serious adverse events were reported. Non-serious device related adverse events occurred in 18% of patients (e.g., persistent skin irritation, sore/lesion, discomfort, electrical burns, and minor skin irritation). Conclusions were that the repeated in-home use of this neuromodulation device over three months was effective and safe for patients with essential tremor. Limitations identified were the open-label, single-arm design, the lack of consensus for the definition of clinically meaningful improvement in TETRAS or BF-ADL, as well as the exclusion of 58 patients who exited the study early from the pre-specified primary and secondary endpoint analyses.

PROFESSIONAL GUIDELINE(S)

Not Applicable

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates electrical stimulation devices as medical devices. All electrical stimulation devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Mar 20]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Mar 20]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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HCPCS Codes

Code	Description
A4540	Distal transcutaneous electrical nerve stimulator, stimulates peripheral nerves of the upper arm (e.g., Nerivio)
A4542 (E/I)	Supplies and accessories for external upper limb tremor stimulator of the peripheral nerves of the wrist
E0734 (E/I)	External upper limb tremor stimulator of the peripheral nerves of the wrist (e.g., Cala Trio, Felix NeuroAI)
E1399 (*E/I)	Durable medical equipment, miscellaneous (*E/I when used for any of the modalities included within this policy.)

ICD10 Codes

Code	Description
G25.0	Essential Tremor
G43.001-G43.019	Migraine without aura (code range)
R51.0-R51.9	Headache (code range)

REFERENCES

Hershey AD, et al. Remote electrical neuromodulation for acute treatment of migraine in adolescents. Headache. 2020 Nov 16;61:310-317.

Isaacson SH, et al. Prospective home-use study on non-invasive neuromodulation therapy for essential tremor. Tremor Other Hyperkinet Mov. 2020 Aug 14;10:29.

Pahwa R, et al. An acute randomized controlled trial of noninvasive peripheral nerve stimulation in essential tremor. Neuromodulation. 2019;22:537-545.

Yarnitsky D, et al. Remote electrical neuromodulation (REN) relieves acute migraine: a randomized, double-blind, placebo-controlled, multicenter trial. Headache J Head Face Pain. 2019;59:1240–52.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

External Upper Limb Tremor Stimulator Therapy (LCD L39591) [accessed 2026 Mar 09]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New:7/26

Revised:

Reviewed:

Date	Summary of Changes
8/1/2026	New policy in conjunction with other new policies 1.01.58, 1.01.59, 1.01.60, & 1.01.61, which will replace Neuromuscular/Functional Electrical Stimulation policy 1370/20.000073 which is being made obsolete.

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: SPEECH LANGUAGE/PATHOLOGY SERVICES

POLICY EFFECTIVE DATE:	3/1/2025
Policy Control #:	1370/20.000056
Next Annual Review:	March 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

92521, 92522, 92523, 92524, 92507, 92508, 92526

DESCRIPTIONS

Speech therapy services are performed to meet the functional needs of an individual who suffers from a communication impairment and/or swallowing disorder due to illness, injury, or congenital anomaly. Speech therapy services are provided as a means of medical treatment as opposed to education, training, prevention, or conditioning. Speech therapy services require the judgement, knowledge, and skills of a qualified provider of speech therapy due to the complexity and sophistication of the therapy and the physical condition of the patient.

Speech therapy services may be habilitative or rehabilitative in nature.

- **Rehabilitation services** are health care services that help a person keep, get back, or improve skills and functioning for daily living that have been lost or impaired because a person was sick, hurt, or disabled.

- **Habilitation services** are health care services that help a person keep, learn, or improve skills and functioning for daily living. They include the management of limitations and disabilities, including services or programs that help maintain or prevent deterioration in physical, cognitive, or behavioral function.
    - Refer to specific member contracts for availability of benefits, if any, relating to habilitative services.

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POLICY NAME: SPEECH LANGUAGE/PATHOLOGY SERVICES

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

- Home Care Services: Home Health Care/Telehomecare/ Personal Care/Personal Emergency Response System, 1370/20.000048

POSITION STATEMENT

CDPHP administers benefits for speech therapy services as outlined below.

Outpatient Speech Therapy

An initial speech and language evaluation is covered when ordered by a physician to determine the need for medically necessary treatment as described below.

CDPHP administers benefits for speech therapy treatment when all of the following criteria are met.

1. Speech therapy services are considered medically necessary only when such therapy is related to the treatment or diagnosis of a physical illness or injury (in the case of a covered child, this includes a medically diagnosed congenital defect.) The following are examples (not all-inclusive) of common medical disorders and resulting communication deficits that may necessitate active rehabilitative therapy:
    - Neurologic deficits as a result of a cerebral vascular accident or cerebral injury affecting swallowing, oral-motor strength and coordination, speech, or language.
    - Laryngeal cancer, laryngeal trauma, and trauma related dysphonia.
    - Oro-pharyngeal trauma or surgery affecting voice, such as laryngectomy or post-surgical vocal fold nodules.
    - Therapy for vocal cord nodules to reduce the trauma to the vocal cords caused by vocal cord apposition during phonation, and to prevent further nodule development.
    - Congenital (i.e., present at birth) anatomic defects that affect swallowing or speech where functional improvement is predicted through speech therapy (e.g., cleft palate and cleft lip).
    - Children with speech delay due to documented, acquired hearing loss (e.g., repeated ear infections resulting in hearing loss).
    - Rehabilitative therapy after cochlear implantation.
    - Acute hoarseness non-responsive to voice rest such as:
        - Sulcus vocalis
        - Dysphonia plica ventricularis
        - Early vocal fold nodule formation
        - Neurogenic, myopathic, and apraxic dysphonia
        - Spasmodic dysphonia (unresponsive to injection)

- Paradoxical vocal fold motion
- Vocal fold paralysis

2. Services are recommended by a physician.

3. Services are provided by a qualified provider of speech therapy services who is performing within the scope of license (e.g., speech therapist/pathologist, speech-language pathologist).

4. Treatment conforms to a written plan of care by a speech therapist specific to the enrollee's diagnosed impairment or condition to include the following: speech/language diagnosis with date of onset, treatment techniques and interventions to be used (amount, frequency, and duration required to achieve measurable goals), the nature, extent, and severity of the functional impairment, and an anticipated outcome.

5. Services are considered medically necessary only if there is a reasonable expectation that speech therapy will achieve measurable improvement in an enrollee's function in a reasonable and predictable period of time.

Autism Spectrum Disorder

In accordance with New York State's autism mandate, benefits are provided for covered therapeutic services, to include those for habilitative purposes, necessary to develop, maintain, or restore, to the greatest extent practicable, functioning of an individual when such services are provided by a licensed or certified speech therapist for the treatment of autism spectrum disorder. Such benefits will apply only to those plans to which the mandate applies.

POLICY CONSIDERATIONS

Benefits for speech therapy services (CPT code 92507, 92508) are subject to all applicable contract limitations and appropriate visit cost-share as stated in the enrollee's contract. Enrollee benefit period begins with the initial treatment.

The speech therapist must document objectively measurable function loss, must state objectively measurable speech therapy goals meeting and significant practical restorative need within a reasonable period of time.

Benefit coverage, for up to a maximum of six visits, will be provided for establishment of maintenance programs. However, no coverage will be provided for the continuation of maintenance programs (maintenance begins when the therapeutic goals of a treatment plan have been achieved and when no further functional progress is apparent or expected to occur).

Swallowing/feeding therapy is considered medically necessary for individuals with swallowing dysfunction (dysphagia) and children with a feeding disorder when all of the following criteria is met:

POLICY NAME: SPEECH LANGUAGE/PATHOLOGY SERVICES

- The swallowing or feeding disorder (92526) is the result of an underlying medical condition. Services performed by a speech language pathologist may include instruction and/or assistance in dietary modifications, compensatory swallowing techniques, proper head and body positioning, and facilitation exercises to improve oral-motor control.
- The medical necessity of the therapy has been demonstrated by the following:
    - an evaluation by a speech language pathologist which may document oral phase swallowing dysfunction without the need for additional testing and
    - results of testing with a videofluorographic swallowing study (VFSS) or other appropriate testing (i.e., esophageal manometry, endoscopy), as needed to document the pathology

- Meaningful improvement is expected from the therapy.

When a service or procedure that may be either habilitative or rehabilitative in nature is provided for **habilitative** purposes, the use of modifier 96 is required to indicate that the service or procedure provided was a habilitative service.

Services or procedures provided for rehabilitative purposes do not require the use of a modifier.

All speech therapy services are subject to retrospective review for medical appropriateness as defined by this policy.

Coverage will no longer be provided once the allowable maximum benefit is exhausted, even if the medical necessity criteria stated above is met.

EXCLUSIONS

Speech therapy is not considered medically necessary for dysfunctions that are self-correcting, such as language therapy for young children with natural dysfluency or developmental articulation errors that are self-correcting.

Non-skilled services. Treatments are not considered medically necessary if they do not require the skills of a qualified provider of speech therapy services and are treatments that maintain function by using routine, repetitions, and reinforced procedures that are neither diagnostic nor therapeutic or procedures that may be carried out effectively by the patient, family, or caregivers.

Maintenance programs such as drills, techniques, and exercises that preserve the enrollee's present level of function and prevent regression of that function. Maintenance begins when the therapeutic goals of a treatment plan have been achieved and when no further functional progress is apparent or expected to occur.

Speech, voice therapy, or swallowing/feeding therapy that duplicates services already being provided as part of another therapy program through another therapy discipline (i.e.,

occupational therapy). When multiple therapies are used, each must have separate written treatment plans and must provide significantly different treatments.

Speech therapy that duplicates services being provided by a federal or state governmental agency (i.e., Early Intervention Program), by a school district (Individualized Educational Program) or by a developmental learning center that are sufficient in meeting the needs of an individual.

Sensory (Auditory) Integration Therapy.

Voice therapy for muscle tension dysphonia (functional dysphonia).

Swallowing/feeding therapy for food aversion without an underlying medical condition.

Speech therapy for ankyloglossia (tongue-tie).

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy. • Benefits to include unlimited days of medically necessary speech therapy, including treatment for individuals with mental retardation when co-morbid disorders such as aphasia or dysarthria are present. Includes therapy that would otherwise be covered as an inpatient and is provided under the care of a physician pursuant to a written plan of treatment.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy. Benefit coverage includes unlimited medically necessary speech therapy visits.
SMALL GROUP/ COMMERCIAL INDIVIDUAL	Rehabilitative speech therapy services are covered only when: • Therapy is related to the treatment or diagnosis of a physical illness or injury (in the case of a covered child, this includes a medically diagnosed congenital defect); **and** • Therapy is ordered by a physician; **and** • The enrollee has been hospitalized or has undergone surgery for such illness or injury.

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	Covered speech therapy services must begin within six months of the later to occur: • The date of the injury or illness that caused the need for the therapy; • The date of discharged from the hospital where the surgical treatment was rendered; **or** • The date outpatient surgical care is rendered. Habilitation services consisting of speech therapy are covered in the outpatient department of a facility or in a health care professional's office.

SOURCES

1. Contract Language.
2. Centers for Medicare & Medicaid National Coverage Determination: Electronic Speech Aids (50.2).
3. Medicare Part B Answer Book, Rehabilitation Services, pps 20611-20612, 2000 Edition.
4. New York State Medicaid Management Information System (MMIS Manual) for Durable Medical Equipment, http://www.emedny.org/ProviderManuals/index.html
5. New York State Medicaid Redesign Team: Medicaid Managed Care Benefit Changes, 2011-2012, www.health.ny.gov
6. NHIC, Inc. Local Coverage Determination: Speech Generating Devices (L11534), revision effective date 12/1/09.
7. Linderman, T.M.; Stewart, K.B.: Sensory Integrative-based Occupational Therapy and Functional Outcomes in Young Children with Pervasive Development Disorders: a single-subject study. American Journal of Occupational Therapy – 1999 March-April; 53(2): 207-213.
8. Other payers
9. Vargas, S.; Camilli, G.: A Meta-analysis of Research on Sensory Integration Treatment. American Journal of Occupational Therapy 1999 March-April; 53(2): 189-198.
10. National Government services Local Coverage Determination: Speech-Language Pathology (L33580), effective 1/1/18: https://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/home-lob/pages/medical-policy-center/mpc-search-detail/lcd%20for%20speech-language%20pathology%20(l33580)/!ut/p/z1/pVJdb4IwFP0r2w8g9_Ih8FpBUQFB_ED6YioUJBMwaDDbr19dlpnoNrOsL829PT3n9PQChTXQmnVlwU5lU7O9qBOqbzQyHsiyhW5gywYSVwtxtAjQ6RmwgsSFRDmv7ZpA_AhNxTH-sAjC5BFA2FFa3_ILoAd22kllnTewrotjxbMyZS0XFugHydWEGphItGHftmeh6vSVT8AvKol4hnFIMC3XQmJ5oT8dWogzA-Ku5GdY1k1biYzmF8ZDWmaQ9Iyco4ZcStM0lzQZTWmbbTNJ1xVTUVWOco_D6E7hJijvW4

POLICY NAME: SPEECH LANGUAGE/PATHOLOGY SERVICES

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POLICY APPROVAL DATES

New:	04/90
Revised:	10/93, 05/95, 04/96, 03/97, 06/98, 11/00, 03/02, 01/03, 03/04, 06/04, 08/04, 05/05, 04/06, 07/09, 03/10, 03/11, 07/11, 09/11, 03/12, 09/12, 03/13, 09/13, 01/14, 03/15, 03/16, 05/16, 09/16, 03/18, 05/18, 07/18, 11/18, 03/19, 09/20, 11/20, 3/23, 5/23, 7/24, 1/25, 3/25
Reviewed:	12/91, 05/94, 02/03, 03/07, 03/08, 03/09, 03/11, 03/14, 03/17, 3/20, 3/21, 3/22, 3/24, 3/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
5/1/2025 *No change to effective date of policy	Updated information for documentation of swallowing/feeding therapy.
5/1/2025	Under exclusions section, added treatment for ankyloglossia.
6/1/2023 *No change to effective date of policy	Under swallowing therapy added examples of testing that could be performed to confirm dysphagia diagnosis.
6/1/2023	Removed specific diagnoses from the exclusion section.
1/1/21 *No change to effective date of policy	Updates did not require criteria change. Removed visit limitations under product variations as contracts are the best source for identifying limits.

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POLICY NAME: SPEECH LANGUAGE/PATHOLOGY SERVICES

1/1/21	Updated Select Plan/HARP section to indicate that speech therapy visits are now unlimited.

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MEDICAL POLICY

Medical Policy Title	**Spine Procedures for Managed Medicaid (MMC), Health and Recovery Plan (HARP), Child Health Plus (CHP), and Essential Plan (EP) Members**
Policy Number	**7.01.126**
Current Effective Date	**January 01, 2027**
Next Review Date	**September 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

SECTION LINKS

Cervical Spine Procedures:

- Arthrodesis
- Corpectomy
- Disc Arthroplasty (Replacement)
- Anterior Cervical Decompression with Fusion (ACDF) or without Fusion; **or** Posterior Cervical Decompression with or without Fusion
- Combined Anterior AND Posterior Cervical Decompression with or without Fusion

Lumbar-Sacral Spine Procedures:

- Arthrodesis
- Decompression
- Lumbar Fusion: Single Level, with or without Decompression
- Lumbar Fusion: Repeat, with or without Decompression
- Lumbar Spine Discectomy/Microdiscectomy
- Lumbar Osteotomy
- Percutaneous Lumbar Discectomy / Disc Decompression
- Pediatric Scoliosis

POLICY STATEMENT(S)

Cervical Spine Procedures

Cervical Arthrodesis

I. Cervical arthrodesis is considered **medically appropriate** when **ALL** the following are met:

A. The individual has **any** of the following cervical spine conditions:
    1. Herniated disc;
    2. Segmental instability;
    3. Spondylosis; **or**
    4. Spinal canal stenosis;

B. Clinical presentation includes **any** of the following:
    1. Myelopathy (e.g., bowel or bladder dysfunction, gait disturbance, hyperreflexia, upper extremity weakness);
    2. Measurable neurologic impairment (e.g., motor weakness, sensory loss, abnormal reflexes); **or**
    3. Radiculopathy (e.g., numbness, paresthesias, or radiating upper extremity pain);

C. Conservative management meets **either** of the following:
    1. No conservative management is required for **any** of the following:
        a. Cervical myelopathy;
        b. Progressive neurologic deterioration;
        c. Severe spinal cord compression with significant neurologic findings;
        d. Segmental instability requiring surgical stabilization;
        e. Tumor, infection or instability resulting from trauma; **or**
    2. For all other indications, conservative management must include **both** the following:
        a. Physical therapy (PT) meets **all** the following:
            i. Participation for a minimum of 6 weeks during the previous 6 months;
            ii. Symptoms or functional impairments failed to improve;
            iii. Supervised by a licensed PT, chiropractor, or through tele-rehab PT; **and**
        b. Pain management includes **all** the following:
            i. Interventional pain management strategies (e.g., epidural steroid injections, facet injections, or selective nerve root blocks) have been considered, when clinically indicated;
            ii. Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated; **and**
            iii. Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises;

D. Preoperative cervical spine imaging obtained within 6 months prior to surgery includes **any**

of the following:

1. Computed tomography (CT);
2. CT Myelogram;
3. Magnetic resonance imaging (MRI); **or**
4. Radiographs (x-rays) as supplemental (e.g., flexion/extension).

II. Cervical arthrodesis is considered **not medically necessary** for **ANY** of the following contraindications:

A. Uncontrolled diabetes with hemoglobin A1C (HbA1C) greater than 8%;

B. Medical comorbidity with increased surgical risk (e.g., anemia, malnutrition, severe cardiovascular or pulmonary disease);

C. Active infection, systemic or localized to the operative field;

D. Allergy or hypersensitivity to implant materials; **or**

E. Compromised bone integrity due to severe osteoporosis or metabolic bone disease that has not been adequately treated.

<u>Cervical Spine Corpectomy</u>

III. Anterior cervical spine corpectomy is considered **medically necessary** when **ALL** the following are met:

A. Cervical fusion is performed as part of the procedure due to instability, given fusion criteria are met;

B. A complete or partial cervical corpectomy is planned with removal of at least one-half of a vertebral body;

C. Treatment is for **one (1) or more** of the following:

1. Infection;
2. Tumor (benign or malignant);
3. Compression located at or posterior to the vertebral body level; **or**
4. Trauma.

<u>Cervical Disc Arthroplasty (CDA)</u>

IV. Cervical disc arthroplasty (artificial disc replacement) is considered **medically appropriate** when **ALL** the following are met:

A. Symptomatic cervical disc disease, evidenced by **both** of the following:

1. Documented findings correlate with neural compression at the cord or nerve root level (e.g., altered reflexes, dermatomal sensory loss, motor weakness); **and**

2. Radiculopathy and/or myelopathy attributable to degenerative disc disease at one (1) or two (2) levels between C3 and C7, with central, lateral recess, or foraminal compression (e.g., disc herniation, spondylotic osteophyte);

B. Conservative non-surgical management meets **either** of the following:

1. No conservative management is required when **any** of the following is documented:
    a. Objective neurological deterioration (e.g., increasing motor loss) across serial examinations;
    b. Myelopathy attributable to spinal cord compression (e.g., cord signal change on MRI);
    c. New-onset bowel or bladder dysfunction due to cervical spinal cord compression;
    d. Symptoms of nerve root or spinal cord compression are severe or rapidly progressive, requiring hospitalization or immediate surgery;
    e. Motor weakness is significant or rapidly progressing (e.g., motor grade ≤3/5, or interference with activities of daily living); **or**
2. For all other indications, conservative management must include **both** of the following:
    a. Physical therapy (PT) meets **all** the following:
        i. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
        ii. Participation for a minimum of 6 weeks during the previous 6 months; **and**
        iii. Symptoms or functional impairments failed to improve;
    b. Pain management includes **all** the following:
        i. Interventional pain management strategies (e.g., epidural steroid injections, facet injections, or selective nerve root blocks) have been considered, when clinically indicated;
        ii. Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated; **and**
        iii. Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises;

C. Advanced imaging (MRI or CT) demonstrate neural compression at the cord or nerve root level(s) concordant with the clinical presentation;

D. Documentation confirms skeletal maturity;

E. The cervical disc replacement device is used in accordance with U.S. Food and Drug Administration (FDA)-approved labeling.

V. Cervical disc arthroplasty (artificial disc replacement) is considered **not medically necessary** for **ANY** of the following contraindications:

A. Uncontrolled diabetes with hemoglobin A1C (HbA1C) greater than 8%;

B. Medical comorbidity with increased surgical risk (e.g., anemia, malnutrition, severe cardiovascular or pulmonary disease);

C. Active malignancy involving the cervical spine or metastatic disease;

D. Allergy or sensitivity to materials used in the implant (e.g., titanium, polyethylene, cobalt, chromium, molybdenum);

E. Immune-mediated or inflammatory arthropathy, including the spondyloarthritis, (e.g., ankylosing spondylitis, psoriatic arthritis);

F. Metabolic bone disease (e.g., Paget disease, osteomalacia);

G. Marked cervical instability (e.g., greater than 3.5 millimeters translation and/or angular difference greater than 11 degrees);

H. Clinically significant cervical anatomical deformity (e.g., fixed kyphosis);

I. Facet arthropathy graded as moderate or worse at the involved level;

J. Active infection, local or systemic;

K. Ossification of the posterior longitudinal ligament (OPLL) at the level to be treated;

L. Osteoporosis or osteopenia;

M. Severe spondylosis (e.g., bridging osteophytes, greater than 50% loss of disc height, or segmental motion less than 2 degrees) and past surgical history at the requested level; **or**

N. Structural vertebral body deficiency or deformity resulting from prior trauma (e.g., malunion, nonunion, or fracture callus).

<u>Anterior Cervical Decompression with Fusion (ACDF) or without Fusion; or Posterior Cervical Decompression with or Without Fusion</u>

VI. Anterior cervical decompression with fusion (ACDF) or without fusion; or posterior cervical decompression with or without fusion (laminectomy, laminoforaminotomy, laminoplasty) is considered **medically appropriate** when **ALL** the following are met:

A. For fusion procedures only: evidence supports that the individual is nicotine-free by **either** of the following:

1. Individual is a never smoker; **or**

2. Cotinine testing (serum, urine, or saliva) results less than or equal to 10 ng/mL, confirming the individual has refrained from nicotine use (e.g., smoking, use of smokeless tobacco products, or nicotine replacement therapy) for a minimum of six (6) weeks prior to the planned surgery;

Exception: Urgent or emergent cervical fusion is not subject to nicotine abstinence requirements when surgical delay may compromise the individual's clinical status.

B. When documentation meets **one (1)** of the following:
   1. Cervical myelopathy or radiculopathy attributed to cervical deformity, herniated disc, segmental instability, or spondylosis when **both** of the following are documented:
      a. Conservative management meets **both** of the following:
         i. Physical therapy (PT) meets **all** the following:
            a) Participation for a minimum of 6 weeks during the previous 6 months;
            b) Symptoms or functional impairments failed to improve; **and**
            c) Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
         ii. Pain management includes **all** the following:
            a) Interventional pain management strategies (e.g., epidural steroid injections, facet injections, or selective nerve root blocks) have been considered, when clinically indicated;
            b) Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated; **and**
            c) Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises;
      b. CT or MRI obtained within 6 months prior to surgery identifies neural compression at the cord or nerve root(s) levels concordant with the clinical presentation;

   OR

   2. Decompression, with or without fusion, may be performed as an initial surgical intervention without a trial of conservative management when **all** the following are documented:
      a. Symptoms of cervical myelopathy associated with spinal cord compression;
      b. Neurological impairments are progressing/worsening; **and**
      c. Objective clinical findings include **any** of the following:
         i. Clonus;
         ii. Hyperreflexia (exaggerated deep tendon reflexes);
         iii. Impaired walking or loss of coordination;
         iv. Motor weakness; **or**
         v. Positive Babinski or Hoffmann sign;

   OR

   3. Decompression with fusion may be performed as an initial surgical intervention without

a trial of conservative management when **all** the following are documented:

a. Significant neural compression (spinal cord or nerve root) from infection, trauma, or tumor, which may be demonstrated by spinal canal narrowing and/or clinical findings (e.g., loss of hand dexterity or gait/balance impairment); **and**

b. X-rays identify fracture or segmental instability, defined by **either** of the following:

i. C1-level subluxation with an atlantodental interval greater than 3 mm in an adult or 5 mm in a child; **or**

ii. Sagittal plane measurement, demonstrating **either** of the following:

a) Angulation greater than 11 degrees at a single motion segment; **or**

b) Anterior translation greater than 3.5 mm accompanied by spinal cord dysfunction or radiculopathy;

OR

4. Decompression without fusion may be performed as an initial surgical intervention without a trial of conservative management when **all** the following are documented:

a. Imaging (X-ray) confirms no segmental instability; **and**

b. Significant neural compression (spinal cord or nerve root) from infection, trauma, or tumor, which may be demonstrated by spinal canal narrowing and/or clinical findings (e.g., loss of hand dexterity or gait/balance impairment).

VII. Cervical decompression or fusion is considered **not medically necessary** for **EITHER** of the following:

A. Decompression performed without fusion, when the spinal deformity requires stabilization (fusion);

B. The presence of **any** of the following contraindications:

1. Uncontrolled diabetes with hemoglobin A1C (HbA1C) is greater than 8%;

2. Medical comorbidity with increased surgical risk (e.g., anemia, malnutrition, severe cardiovascular or pulmonary disease);

3. Clinically insignificant or minimally symptomatic disease that does not produce a meaningful functional limitation (e.g., incidental imaging findings);

4. Neck pain in the absence of neurologic impairment, with no radiographic evidence of spinal cord or nerve root compression; **or**

5. Imaging findings are not consistent with the individual's reported symptoms or objective clinical examination findings.

<u>Combined Anterior AND Posterior Cervical Decompression, with or without Fusion</u>

VIII. Anterior and posterior cervical spine decompression, with or without fusion, is considered

medically appropriate when **ALL** the following are met:

A. Comorbid conditions are optimally managed;

B. Conservative management meets **both** of the following:

1. Physical therapy (PT) meets **all** the following:

a. Participation for a minimum of 6 weeks during the previous 6 months;

b. Symptoms or functional impairments failed to improve; **and**

c. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;

2. Pain management includes **all** the following:

a. Interventional pain management strategies (e.g., epidural steroid injections, facet injections, or selective nerve root blocks) have been considered, when clinically indicated;

b. Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated; **and**

c. Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises;

C. Imaging (CT, MRI, X-ray) reveals segmental instability or disc pathology;

D. Axial and non-radicular neck pain;

E. Anatomic source of pain (e.g., cervical facet [zygapophyseal] joint) has been identified and treated;

F. No more than two (2) levels are affected;

G. For fusion procedures only: evidence supporting that the individual is nicotine-free by **either** of the following:

1. Individual is a never smoker; **or**

2. Cotinine testing (serum, urine, or saliva) results less than or equal to 10 ng/mL, confirming the individual has refrained from nicotine use (e.g., smoking, use of smokeless tobacco products, or nicotine replacement therapy) for a minimum of six (6) weeks prior to the planned surgery;

Exception: Urgent or emergent cervical fusion is not subject to nicotine abstinence requirements when surgical delay may compromise the individual's clinical status.

IX. Cervical spine decompression or fusion is considered **not medically necessary** for the following:

A. Stand-alone decompression (without fusion) for spinal deformity (e.g. cervical kyphosis) requiring stabilization (fusion);

B. For **any** of the following contraindications:
   1. Uncontrolled diabetes with hemoglobin A1C (HbA1C) is greater than 8%;
   2. Medical comorbidity with increased surgical risk (e.g., anemia, malnutrition, severe cardiovascular or pulmonary disease);
   3. Clinically insignificant or minimally symptomatic disease that does not produce a meaningful functional limitation (e.g., incidental imaging findings);
   4. Neck pain in the absence of neurologic impairment, with no radiographic evidence of spinal cord or nerve root compression; **or**
   5. Imaging findings are not consistent with the individual's reported symptoms or objective clinical examination findings.

Lumbar-Sacral Spine Procedures

Lumbar Arthrodesis

X. Lumbar arthrodesis is considered **medically appropriate** when **ALL** the following are met:
   A. The individual has evidence of **any** of the following:
      1. Symptomatic degenerative spondylolisthesis;
      2. Neurogenic claudication or radiculopathy attributable to degenerative disease;
      3. Recurrent lumbar disc herniation necessitating segmental stabilization;
      4. Persistent, clinically significant axial low back pain accompanied by **either** of the following:
         a. Degenerative spondylolisthesis; **or**
         b. Neurogenic claudication
      5. Segmental instability demonstrated on imaging (e.g., abnormal motion on flexion-extension views); **or**
      6. Spinal deformity with associated symptoms (e.g., scoliosis);
   B. Symptom burden includes **either** of the following:
      1. Clinically significant pain; **or**
      2. Functional impairment that interferes with activities of daily living;
   C. Conservative management meets **either** of the following:
      1. No requirement for conservative management for **any** of the following indications:
         a. Cauda equina syndrome;
         b. Deteriorating or marked motor/sensory deficit (e.g., weakness, foot drop);
         c. Instability or neurologic impairment secondary to spinal infection or tumor for which

surgical intervention is indicated; **or**

d. Traumatic spinal instability;

OR

2. For all other indications, conservative management includes **both** of the following:
   a. Physical therapy (PT) meets **all** the following:
      i. Participation for a minimum of 6 weeks during the previous 6 months;
      ii. Symptoms or functional impairments failed to improve; **and**
      iii. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
   b. Pain management includes **all** the following:
      i. Interventional pain management strategies (e.g., epidural steroid injections, facet injections, or selective nerve root blocks) have been considered, when clinically indicated;
      ii. Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated; **and**
      iii. Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises;

D. Preoperative lumbar spine imaging includes **both** of the following:
   1. Findings consistent with clinical presentation; **and**
   2. Obtained within 6 months prior to surgery using **any** of the following:
      a. CT;
      b. CT myelogram;
      c. MRI; **or**
      d. X-ray.

XI. Lumbar arthrodesis is considered **not medically necessary** for **ANY** of the following contraindications:
   A. Uncontrolled diabetes with hemoglobin A1C (HbA1C) is greater than 8%;
   B. Medical comorbidity with increased surgical risk (e.g., anemia, malnutrition, severe cardiovascular or pulmonary disease);
   C. Clinically insignificant or minimally symptomatic disease that does not produce a meaningful functional limitation (e.g., incidental imaging findings);
   D. Active infection, systemic or localized to the operative field, except when the fusion is intended to treat the infection; **or**

E. Compromised bone integrity due to severe osteoporosis or metabolic bone disease that has not been adequately treated.

Lumbar Spine Decompression

XII. Lumbar decompression (facetectomy, foraminotomy, laminectomy, laminotomy) is considered **medically appropriate** when **ALL** the following are met:

A. Subjective symptoms include **either** of the following:

1. Significant level of pain on a daily basis; **or**
2. Significant functional impairment impacting activities of daily living (e.g., household tasks, prolonged standing, walking);

B. Preoperative lumbar spine imaging (e.g., CT, MRI) includes **both** of the following:

1. Obtained within 6 months prior to surgery; **and**
2. Stenosis (central canal, lateral recess, or foraminal) at the identified level(s) is consistent with clinical presentation and findings;

C. Documentation confirms **either** of the following clinical presentations:

1. Neurogenic claudication includes **all** the following:
    a. Symptoms involve the low back, buttocks, or legs, with **at least one (1)** of the following documented:
        i. cramping;
        ii. decreased strength,
        iii. heaviness;
        iv. numbness
        v. pain; **or**
        vi. paresthesia;
    b. Functional impairment related to limitations in ambulation or standing;
    c. Symptom relief from sitting or lumbar flexion; **and**
    d. Symptom exacerbation with standing or walking;

OR

2. Radiculopathy secondary to lumbar stenosis includes **all** the following symptoms:
    a. Pain radiating into the buttock or legs is ongoing;
    b. A symptom pattern that follows the distribution of the involved nerve root; **and**
    c. Documentation of **one (1) or more** of the following:

i. Sensory loss in a dermatomal pattern;
ii. Nerve root–specific muscle weakness;
iii. Reproduction of symptoms with the contralateral (crossed) straight leg raise;
iv. Positive femoral nerve stretch maneuver;
v. Positive straight leg raise (SLR) or comparable nerve tension sign; **or**
vi. Reflex abnormality (e.g., absent or diminished);

D. Conservative management meets **either** of the following:
1. No requirement for conservative management for **any** of the following indications:
a. Cauda equina syndrome;
b. Neurologic deterioration over time (e.g., declining functional capacity, new/worsening foot drop or motor strength);
c. Motor deterioration progressed over a short period of time;
d. Significant motor weakness of 3/5 or less on manual muscle testing; **or**
e. Significant neurologic compromise resulting from lumbar neural compression, supported by imaging findings consistent with the clinical presentation;

OR

2. For all other indications, conservative management includes **both** of the following:
a. Physical therapy (PT) meets **all** the following:
i. Participation for a minimum of 6 weeks during the previous 6 months;
ii. Symptoms or functional impairments failed to improve; **and**
iii. Supervised by a licensed PT, chiropractor, or through tele-rehab PT;
b. Pain management includes **all** the following:
i. Interventional pain management strategies (e.g., epidural steroid injections, facet injections, or selective nerve root blocks) have been considered, when clinically indicated;
ii. Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated; **and**
iii. Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises.

XIII. Lumbar decompression (facetectomy, foraminotomy, laminectomy, laminotomy) is considered **not medically necessary** for **EITHER** of the following contraindications:

A. Uncontrolled diabetes with hemoglobin A1C (HbA1C) is greater than 8%;

B. Medical comorbidity with increased surgical risk (e.g., anemia, malnutrition, severe cardiovascular or pulmonary disease).

Lumbar Fusion: Single Level, with or without Decompression

XIV. Single level lumbar fusion, with or without decompression (laminectomy, laminotomy, facetectomy, foraminotomy) is considered **medically appropriate** when **EITHER** of the following are met:

A. For chronic axial low back pain attributed to degenerative disc disease and a condition requiring spinal stabilization when **all** the following are met:

1. Axial low back pain without primary symptoms of radiculopathy has persisted for a minimum of 6 months;
2. Conservative management includes **both** the following:
    a. Physical therapy (PT) meets **all** the following:
        i. Participation for a minimum of 6 weeks during the previous 6 months;
        ii. Symptoms or functional abilities failed to improve; **and**
        iii. Supervised by a licensed PT, chiropractor, or through tele-rehab PT; **and**
    b. Pain management includes **all** the following:
        i. Interventional pain management trial (e.g., epidural steroid injections, facet injections, or selective nerve root blocks), unless documentation supports rationale for why trial is not appropriate;
        ii. Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated; **and**
        iii. Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises;
3. Preoperative imaging (e.g., CT, MRI, X-rays) obtained within 6 months prior to the procedure confirms a structural abnormality at the requested fusion level that concordant with reported symptoms, objective examination findings, and overall clinical picture;
4. Documented objective findings confirming a structural abnormality for which fusion is needed to restore segmental stability, evidenced by **any** of the following:
    a. Spondylolisthesis accompanied by instability on dynamic or side-by-side comparative imaging;
    b. Abnormal segmental motion, defined as more than 3 mm of translational displacement between flexion and extension views on dynamic X-rays; **or**
    c. Symptomatic, localized spinal deformity that requires operative stabilization;

5. Evidence supporting that the individual is nicotine-free by **either** of the following:
    a. Individual is a never smoker; **or**
    b. Cotinine testing (serum, urine, or saliva) results less than or equal to 10 ng/mL, confirming the individual has refrained from nicotine use (e.g., smoking, use of smokeless tobacco products, or nicotine replacement therapy) for a minimum of six (6) weeks prior to the planned surgery.

    Exception: Urgent or emergent lumbar fusion is not subject to nicotine abstinence requirements when surgical delay may compromise the individual's clinical status.

OR

B. For lumbar fusion as first line treatment, without a trial of non-surgical conservative management, when **both** of the following are met:
    1. **All** the following are met:
        a. Documentation of **any** of the following conditions:
            i. Cauda equina syndrome with bowel or bladder dysfunction accompanied by neurologic deficits;
            ii. Acute, progressive and significant neurological impairment (e.g., motor weakness, reflex changes); **or**
            iii. Spinal infection, tumor or malignancy;
        b. Preoperative imaging obtained within 6 months prior to the procedure confirms a structural abnormality at the requested fusion level concordant with reported symptoms and objective examination findings; **and**
        c. Evidence confirms that fusion is necessary to restore segmental stability; **and**
    2. Evidence supporting that the individual is nicotine-free by **either** of the following:
        a. Individual is a never smoker; **or**
        b. Cotinine testing (serum, urine, or saliva) results less than or equal to 10 ng/mL, confirming the individual has refrained from nicotine use (e.g., smoking, use of smokeless tobacco products, or nicotine replacement therapy) for a minimum of six (6) weeks prior to the planned surgery.

    Exception: Urgent or emergent lumbar fusion is not subject to nicotine abstinence requirements when surgical delay may compromise the individual's clinical status.

<u>Repeat Lumbar Fusion at the Same Level</u>

XV. Repeat lumbar fusion (arthrodesis) (with or without decompression) at the same level in adult patients is considered **medically necessary** for **EITHER** of the following indications:
    A. For malposition or failure of implant/instrumentation or structural bone graft, when the

following criteria are met:

1. Post-operative imaging shows evidence of malposition or failure of the implant/instrumentation or structural bone graft (e.g., migration, pedicle screw breakage, pedicle screw loosening, dislodged hooks, rod breakage, rod bending, rod loosening, loss of curve correction, decompensation, etc.);

OR

B. For symptomatic Pseudoarthrosis when **all** the following criteria are met:
   1. Greater than 6 months since the prior lumbar fusion;
   2. Subjective symptoms include significant level of pain on a daily basis defined as clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing, etc.);
   3. Post-operative physical exam findings are concordant with the individual's symptoms;
   4. Less than clinically meaningful improvement with 6 weeks of non-surgical treatment with **both** of the following (unless contraindicated):
      a. Prescription strength analgesics, steroids, gabapentinoids or NSAIDs; **and**
      b. Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician;
   5. Post-operative imaging (performed at no less than six (6) months after the lumbar fusion) shows pseudoarthrosis at the requested level(s);
   6. Post-operative MRI/CT findings are concordant with the individual's symptoms;
   7. Evidence supporting that the individual is nicotine-free by **either** of the following:
      a. Individual is a never smoker; **or**
      b. Cotinine testing (serum, urine, or saliva) results less than or equal to 10 ng/mL, confirming the individual has refrained from nicotine use (e.g., smoking, use of smokeless tobacco products, or nicotine replacement therapy) for a minimum of six (6) weeks prior to the planned surgery.

      Exception: Urgent or emergent lumbar fusion is not subject to nicotine abstinence requirements when surgical delay may compromise the individual's clinical status.

<u>Lumbar Spine Discectomy/Microdiscectomy</u>

XVI. A lumbar discectomy/microdiscectomy is considered **medically appropriate** when **either** of the following is met:

A. For urgent conditions, microdiscectomy is indicated as first-line treatment without a trial of conservative management when **either** of the following is documented:
   1. Cauda equina syndrome (e.g., saddle anesthesia, bowel or bladder dysfunction); **or**

2. Motor impairment is severe (e.g., weakness ≤3/5) or worsening over a short period of time (e.g., across several examinations);

OR

B. For intervertebral disc herniation, when **all** the following are met:
   1. MRI confirms a disc herniation that is concordant with the clinical presentation;
   2. Functional impairment is attributable to radiculopathy;
   3. Conservative management meets **both** of the following:
      a. Physical therapy (PT) meets **all** the following:
         i. Participation for a minimum of 6 weeks during the previous 6 months;
         ii. Symptoms or functional limitations failed to improve; **and**
         iii. Supervised by a licensed PT, chiropractor, or through tele-rehab PT; **and**
      b. Pain management includes **all** the following:
         i. Interventional pain management strategies (e.g., epidural steroid injections, facet injections, or selective nerve root blocks) have been considered, when clinically indicated;
         ii. Non-steroidal anti-inflammatory drugs (NSAIDs) for a minimum of 4 weeks, unless contraindicated; **and**
         iii. Non-pharmacologic pain management such as activity modification, rest periods, splinting, or therapeutic exercises.

XVII. A lumbar discectomy/microdiscectomy is considered **not medically necessary** for **ANY** of the following contraindications:
   A. Uncontrolled diabetes with hemoglobin A1C (HbA1C) is greater than 8%;
   B. Medical comorbidity with increased surgical risk (e.g., anemia, malnutrition, severe cardiovascular or pulmonary disease);

<u>Lumbar Osteotomy</u>

XVIII. Lumbar spinal osteotomy is considered **medically appropriate** when **ALL** the following are met:
   A. Spinal alignment abnormality includes **both** of the following:
      1. Documented for a minimum of 6 months; **and**
      2. Standing X-rays confirm the presence **of any** of the following:
         a. Flatback deformity;
         b. Fixed kyphotic deformity;

c. Fixed sagittal-plane deformity;
d. Moderate-to-severe sagittal malalignment;
e. Sagittal malalignment following prior fusion that causes functional impairment; **or**
f. Symptomatic spinal deformity for which surgical correction is indicated;

B. Associated symptoms include **any** of the following:
1. Neurologic impairment confirmed by objective findings on physical examination;
2. Radicular symptoms that correspond with findings on diagnostic imaging;
3. Neurogenic claudication;
4. Chronic midline (axial) low back pain caused by the deformity;
5. Difficulty walking, including decreased tolerance;
6. Impaired ability to remain upright;
7. Impaired ability to maintain a horizontal gaze due to deformity; **or**
8. Meaningful loss of function affecting the performance of activities of daily living;

C. Preoperative imaging includes **all** the following:
1. Obtained within 3 to 6 months prior to surgery;
2. Advanced imaging of the lumbar spine (CT or MRI);
3. Standing X-rays document the presence of a spinal alignment abnormality; and
4. Correlation between imaging findings, clinical findings, and the planned corrective procedure;

D. Conservative management meets **either** of the following:
1. No conservative management is required for **any** of the following:
a. Cauda equina syndrome;
b. Bowel or bladder dysfunction caused by compression of neural structures;
c. Neurologic deficit continues to worsen over time; **or**
d. Neurologic decline occurring over a short interval;
2. For all other indications, conservative pain management includes **all** the following:
a. Pharmacological treatment with **either** of the following, as clinically indicated:
i. Analgesics or anti-inflammatory medication (e.g., NSAIDs); **or**
ii. Corticosteroid injection(s);
b. Participation in **at least one (1)** of the following treatments:

i. Activity modification and/or avoidance of aggravating activities;
ii. Acupuncture;
iii. Biofeedback techniques;
iv. Cognitive behavioral therapy (CBT);
v. Transcutaneous electrical nerve stimulation (TENS);

c. Physical therapy (PT) meets **all** the following:
i. Participation for a minimum of 6 weeks during the previous 6 months;
ii. Symptoms or functional limitations failed to improve; **and**
iii. Supervised by a licensed PT, chiropractor, or through tele-rehab PT.

XIX. Lumbar spinal osteotomy is considered **not medically necessary** for **ANY** of the following contraindications:

A. Uncontrolled diabetes with hemoglobin A1C (HbA1C) is greater than 8%;
B. Medical comorbidity with increased surgical risk (e.g., anemia, malnutrition, severe cardiovascular or pulmonary disease);
C. Bleeding disorder that cannot be adequately corrected;
D. Compromised bone integrity, including severe osteoporosis.
E. Hypersensitivity to bone cement or osseointegration/augmentation materials; **or**
F. Unresolved infection, including infection in the bloodstream;

<u>Percutaneous Lumbar Disc Decompression / Discectomy</u>

XX. Percutaneous lumbar disc decompression or discectomy procedures are considered **investigational**, include but are not limited to:

A. Automated percutaneous lumbar discectomy (APLD) (e.g., Nucleotome);
B. Mechanical percutaneous discectomy (e.g., Dekompressor);
C. Percutaneous laser disc decompression (PLDD);
D. Nucleoplasty (also known as plasma disc decompression [PDD], radiofrequency coblation disc decompression, or plasma-mediated ablation; e.g., SpineWand);
E. Targeted disc decompression (TDD).

<u>Pediatric Scoliosis</u>

XXI. Surgical management of scoliosis in the pediatric population is considered **medically appropriate** when **ALL** of the following are met:

A. The clinical presentation meets **all** the following:

1. Physical examination findings include **any** of the following:
    a. Unequal shoulder or pelvic (iliac crest) heights;
    b. Trunk shift or lateral lean in posture;
    c. Paraspinal/rib prominence elicited on the Adams forward-bend maneuver;
    d. Asymmetric waist contour or hip alignment; **or**
    e. Clinically apparent curvature of the spine;
2. Diagnostic imaging obtained within the preceding 12 months confirms **any** of the following:
    a. Cobb measurement of 50 degrees or more in a child at or approaching the end of skeletal growth (maturity);
    b. Early-onset scoliosis exhibiting a curve exceeding 40 degrees with substantial remaining growth potential;
    c. Documented curve advancement to a Cobb measurement of 45 degrees or more despite a trial of non-operative conservative management;
    d. Worsening deformity producing truncal imbalance, loss of function, or a demonstrable likelihood of continued progression;
3. Preoperative imaging includes **all** the following:
    a. Obtained within the last 12 months of the planned procedure;
    b. Documentation of the measured Cobb angle;
    c. Imaging findings are concordant with the diagnosed deformity and planned surgical correction;
    d. X-rays including standing PA and lateral spine; **and**
    e. MRI has been obtained when **any** of the following are identified:
        i. Abnormal findings on neurologic examination;
        ii. Atypical curve features; **or**
        iii. Rapid curve progression;

B. Treatment includes **both** of the following:
1. Non-surgical conservative management includes **both** of the following:
    a. Ongoing use of brace or spinal orthosis until **either** of the following:
        i. The individual reaches skeletal maturity prior to surgical consideration; **or**
        ii. Until the curve advances beyond 45 degrees; **and**
    b. Physical therapy (PT) meets **all** the following:

i. Participation for a minimum of 6 weeks during the previous 6 months;

ii. Symptoms or functional impairments failed to improve; **and**

iii. Supervised by a licensed PT, chiropractor, or through tele-rehab PT; **and**

2. Surgical management includes **any** of the following:
   a. Posterior instrumented spinal fusion indicated for curves in the range of approximately 45 to 50 degrees or greater;
   b. Vertebral body tethering (VBT) when **all** the following are present:
      i. Cobb measurement between 35 and 65 degrees;
      ii. Bracing has failed, is not tolerated, or is otherwise unsuitable; **and**
      iii. Skeletal immaturity with meaningful growth remaining; **or**
   c. In early-onset disease with a curve exceeding 40 degrees and substantial residual growth, a growth-preserving construct (traditional growing rods or magnetically controlled growing rods).

RELATED POLICIES

Corporate Medical Policy

7.01.122 Interventional Pain Management for Managed Medicaid (MMC), Health and Recovery Plan (HARP), Child Health Plus (CHP), and Essential Plan (EP) Members

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

The cervical and lumbar-sacral spine are common sites of degenerative, structural, and traumatic disease that can compress the spinal cord and nerve roots or destabilize the spinal column. When these conditions produce pain, neurologic impairment, or functional limitation that does not respond to appropriate non-surgical treatment, or when urgent neurologic compromise is present, surgical intervention may be used to relieve pressure on neural structures (decompression), stabilize abnormal motion (fusion/arthrodesis), replace a diseased disc (arthroplasty), or correct structural deformity (osteotomy or scoliosis correction).

Common Clinical Conditions

- Cauda equina syndrome (CES) is a surgical emergency caused by severe compression of the bundle of nerve roots at the base of the spine, producing new bowel and/or bladder dysfunction, saddle anesthesia, and frequently bilateral lower-extremity pain, numbness, or weakness. CES requires urgent decompression and is exempt from conservative care and other elective requirements.

- Degenerative disc disease (DDD) is the age-related deterioration of an intervertebral disc, with loss of disc height, dehydration, bulging, or herniation. Although commonly associated with aging, surgical treatment is generally considered only when degeneration is associated with nerve compression, instability, or other clinically significant pathology that correlates with symptoms.
- A herniated disc is displacement of the inner disc material beyond its normal boundary, which may press on a nerve root or the spinal cord.
- Myelopathy is dysfunction of the spinal cord itself from compression. Signs include problems with balance or walking, loss of hand dexterity, overactive reflexes, and in severe cases bowel or bladder dysfunction. It is generally progressive and typically warrants more urgent evaluation and treatment than isolated radiculopathy.
- Pseudarthrosis (failed fusion) is the failure of a prior fusion to heal into solid bone, which can cause recurrent pain and instability and may warrant a repeat operation.
- Scoliosis is an abnormal lateral and rotational curvature of the vertebral column. Adolescent idiopathic scoliosis is the most common form of idiopathic scoliosis. Severe progressive thoracic deformities may be associated with cardiopulmonary compromise. Diagnosis is made clinically and radiographically.
    - The curve is measured by the Cobb angle, which is the angle formed between intersecting lines drawn perpendicular to the top of the vertebrae of the curve and the bottom vertebrae of the curve.
    - The Risser sign measures remaining spinal growth by progressive anterolateral to posteromedial ossification. Risser sign ranges from 0 (no ossification) to 5 (full bony fusion of the apophysis). Immature patients will have 0% to 25% ossification (Risser grade 0 or 1), while 100% ossification (Risser grade 5) indicates maturity with no spinal growth remaining. Children may progress from a Risser grade 1 to grade 5 over a brief (eg, 2-year) period.
- Radiculopathy refers to symptoms caused by compression or irritation of a single nerve root. Symptoms typically include pain, numbness, tingling, or weakness that follows the path of that nerve into the arm (cervical) or leg (lumbar).
- Segmental instability is abnormal, excessive movement between two (2) vertebrae that may be demonstrated by dynamic imaging studies (e.g., flexion-extension radiographs) and can cause pain or neural compromise.
- Spinal stenosis is narrowing of the spinal canal or the openings where nerves exit (foramina), most often from degeneration, that can compress neural structures.
- Spondylolisthesis is forward (or backward) slippage of one vertebra relative to the one below it, which may narrow the canal and destabilize the segment.
- Spondylosis is general degenerative "wear-and-tear" arthritis of the spine, including bone spurs (osteophytes) and joint degeneration that can narrow the spaces around the spinal cord and

nerves.

Cervical Spine Procedures

- Cervical arthrodesis is the permanent joining of two or more vertebrae so they heal into a single bone, eliminating motion at the painful or unstable segment. It is used for instability, deformity, or to stabilize the spine after decompression or removal of disc or bone.
- Cervical corpectomy involves removal of all or part of a vertebral body and adjacent discs to decompress the spinal cord or nerve roots when compression is located behind the vertebral body itself, such as from tumor, infection, trauma, or extensive spondylosis. Because structural bone is removed, fusion and reconstruction are required.
- Cervical disc arthroplasty (CDA), also known as artificial/cervical disc replacement, is a motion-preserving alternative to ACDF for selected one- or two-level disc disease between C3 and C7. The diseased disc is removed and replaced with an FDA-approved artificial disc intended to decompress the nerves or spinal cord while maintaining cervical motion. Appropriate candidates require skeletal maturity and suitable anatomy, including adequate bone quality and the absence of significant deformity, instability, or facet arthropathy.
- Anterior cervical discectomy and fusion (ACDF) is the most established operation for symptomatic cervical disc disease. Through the front of the neck, the surgeon removes the diseased disc and any associated bone spurs to decompress the nerves or spinal cord, then fuses the segment to restore height, alignment, and stability.
- Posterior cervical decompression, with or without fusion, relieves pressure on the spinal cord or nerve roots through the back of the neck by removing bone or ligament. Techniques include laminectomy (removal of the lamina), laminoforaminotomy (enlargement of the nerve root exit), and laminoplasty (reshaping or hinging the lamina to expand the spinal canal while preserving motion). Fusion may be added when the segment is unstable or expected to become unstable.
- Combined anterior and posterior decompression and fusion uses both front and back surgical approaches and is generally reserved for complex disease, such as multilevel compression or deformity, when a single approach cannot adequately decompress or stabilize the spine.

Lumbar-Sacral Spine Procedures

- Lumbar arthrodesis permanently joins lumbar vertebrae to eliminate painful or unstable motion. Indications include degenerative spondylolisthesis, segmental instability, deformity, and recurrent disc herniation requiring stabilization. Fusion may be performed alone or combined with decompression through anterior, posterior, or lateral surgical approaches depending on the clinical situation.
- Single-level lumbar fusion, with or without decompression, treats a structurally confirmed abnormality at a single motion segment, such as spondylolisthesis associated with instability or abnormal segmental motion, or, in selected circumstances, carefully evaluated chronic axial low back pain associated with single-level degenerative pathology.

- Repeat (revision) lumbar fusion at the same level may be performed when a previous fusion has failed because of hardware failure, hardware malposition, or a symptomatic non-union (pseudarthrosis) confirmed on imaging.
- Lumbar decompression relieves pressure on the nerve roots or cauda equina in individuals with neurogenic claudication or radiculopathy caused by spinal stenosis. Techniques include laminectomy, laminotomy, foraminotomy, and facetectomy to enlarge the spinal canal or nerve root openings.
- Lumbar discectomy or microdiscectomy removes the herniated portion of a disc that is compressing a nerve root, typically for radiculopathy that has not improved with conservative management or, more urgently, for cauda equina syndrome or severe or progressive weakness. The term "microdiscectomy" refers to the use of magnification and smaller surgical exposures.
- Lumbar osteotomy involves surgical cutting and realignment of one or more vertebrae to correct a fixed spinal deformity, such as flatback deformity or fixed sagittal imbalance, that impairs standing, walking, or horizontal gaze. It is typically performed as part of a larger spinal reconstruction.
- Pediatric scoliosis surgery corrects spinal curvature in children and adolescents. Surgical options include posterior instrumented spinal fusion for larger curves, growth-preserving instrumentation such as traditional or magnetically controlled growing rods for early-onset scoliosis with substantial growth remaining, and vertebral body tethering in appropriately selected skeletally immature patients.
- Percutaneous lumbar disc decompression / discectomy are needle-based techniques that remove or shrink disc material through a small puncture under imaging guidance, including automated percutaneous lumbar discectomy (e.g., Nucleotome), mechanical percutaneous discectomy (e.g., Dekompressor), percutaneous laser disc decompression (PLDD), nucleoplasty/plasma (coblation) disc decompression, and targeted disc decompression.

<u>Cross-Cutting Concepts in the Criteria</u>

- Conservative (non-surgical) management for non-urgent conditions aims to relieve pain, improve or restore function, and allow an appropriate trial of non-operative treatment before surgical intervention is considered. Conservative therapy may include a documented trial of supervised physical therapy and pain management (e.g., medications, interventional injections, and non-pharmacologic measures). This requirement is waived for urgent or emergent presentations, such as cauda equina syndrome, progressive neurologic deficit, significant motor weakness, myelopathy with cord compression, or instability/compression related to trauma, tumor, or infection.
- Imaging concordance requires that advanced imaging (MRI, CT, or CT myelogram), supplemented by X-rays when needed, demonstrate a structural abnormality that correlates with the patient's symptoms and physical examination findings. Surgery is not supported when imaging findings do not correlate with the clinical presentation.

- Nicotine abstinence is required for fusion procedures because nicotine is associated with impaired bone healing and increased risk of non-union. Fusion criteria generally require the patient to be nicotine-free, which may be confirmed through cotinine testing. This requirement does not apply to urgent or emergent fusion procedures when delaying treatment would compromise the patient's condition.

Standardized Spine Assessments

- modified Japanese Orthopaedic Association (mJOA) score grades cervical myelopathy severity (motor, sensory, and bladder function) and is used to categorize myelopathy as mild, moderate, or severe, and informs urgency and timing of decompression.
- Neck Disability Index (NDI) is the cervical counterpart of the ODI, a 10-item questionnaire scored 0–100% measuring how neck pain limits daily function. It is used to document disability for cervical conditions and procedures (e.g., ACDF).
- Numeric Rating Scale (NRS) is a simple 0–10 verbal or written pain rating, often used interchangeably with the VAS to document pain intensity at rest and with activity.
- Oswestry Disability Index (ODI) is a 10-item questionnaire scored 0–100% that measures how low back pain limits daily activities (lifting, walking, sitting, sleep, personal care). It is the most widely used measure of lumbar-related disability, documenting functional impairment and improvement.
- Roland-Morris Disability Questionnaire (RMDQ) is a 24-item yes/no measure of low back pain–related disability, an alternative to the ODI for tracking functional limitation.
- Visual Analog Scale (VAS) is a patient-reported pain score, typically marked on a 0–100 mm line or rated 0–10, used to quantify back, neck, arm, or leg pain before and after treatment.

SUPPORTIVE LITERATURE

Cervical Arthroplasty

Early pivotal United States Food and Drug Administration (FDA) Investigational Device Exemption (IDE) randomized controlled trials (RCTs) demonstrated that cervical disc arthroplasty (CDA) preserves segmental motion and provides clinical outcomes comparable to anterior cervical discectomy and fusion (ACDF) in appropriately selected patients with symptomatic cervical degenerative disc disease. Evidence from single-level and multilevel studies supports durable improvements in pain, disability, and neurologic outcomes (Heller 2009; Zigler 2013; Burkus 2014).

Kim et al (2021) reported the 10-year outcomes from the prospective multicenter Mobi-C FDA IDE clinical trial in patients undergoing one- or two-level CDA. Patients maintained significant improvement from baseline in NDI, neck and arm pain, neurologic function, and segmental range of motion (ROM) through 10 years, with only two subsequent surgeries reported after 7 years. The authors concluded that CDA remained a safe and effective treatment for one- and two-level cervical degenerative disc disease through 10 years of follow-up.

Sasso et al (2024) reported 20-year outcomes from the prospective randomized FDA IDE trial comparing BRYAN CDA with ACDF in 47 patients with single-level cervical radiculopathy. Follow-up was available for 91.3% of participants, with both groups demonstrating sustained, statistically significant improvement in NDI and VAS neck and arm pain from baseline. There was no significant difference between CDA and ACDF in 20-year NDI, VAS neck pain, or VAS arm pain scores. Reoperation was reported in 10.0% of CDA patients and 41.7%, ACDF patients (P = 0.039), with no arthroplasty device failures requiring index-level device reoperation. The authors concluded that both CDA and ACDF were effective treatments for cervical radiculopathy, with CDA demonstrating lower reoperation rates over long-term follow-up.

Foley et al (2024) reported the corresponding 20-year radiographic outcomes from the BRYAN FDA IDE trial. The study found that CDA maintained index-level ROM (P = 0.952) and preserved greater overall cervical ROM than ACDF (47.8° vs. 33.4°, P = 0.005). CDA was also associated with significantly lower rates of adjacent-segment degeneration (P < 0.005) and adjacent-level ossification (P < 0.001).

Yakdan et al (2025) performed a systematic review and meta-analysis of 25 RCTs (35 studies) comparing CDA (n=2,449) and ACDF (n=2,081) for degenerative disc disease. CDA demonstrated higher rates of neurological and overall success, lower rates of adjacent level disease and reoperation, greater ROM at the operated level, and higher rates of heterotopic ossification. Operative times were significantly longer than with ACDF. Despite identified study limitations (e.g., inclusion of myelopathic patients and variations in follow-up between treatment groups contributed to heterogeneity among studies), the authors concluded the study found CDA showed comparable or potentially more favorable outcomes in achieving overall and neurological success, with a lower incidence of adjacent-level degeneration, and reoperation rates, but longer operative time.

Lumbar Discectomy / Microdiscectomy

Overall, in patients with lumbar radiculopathy with disc herniation who receive discectomy, there is sufficient evidence to support the use of discectomy in patients who have not responded to usual care for 6 weeks, but the net benefit is uncertain because of the lack of a robust RCT comparing discectomy with a comprehensive conservative treatment program. The evidence is limited by a lack of high-quality trials. In most trials, a high percentage of patients in the conservative care group crossed over to surgery.

Weinstein et al (2006) reported on SPORT, a moderately-large trial that compared discectomy to non-operative care in patients with lumbar disc herniation and included both a randomized and a non-randomized component. The RCT included 501 patients randomized to discectomy or to usual care. Discectomy was performed by the open technique, and, in some cases, the medial border of the superior facet joint was removed. Crossover was allowed during the trial; 107 of the 245 patients assigned to usual care underwent surgery, and 140 of the 245 patients assigned to surgery underwent surgery. The main outcomes were changes from baseline in the bodily pain and physical function subscales of the SF-36, and the modified Oswestry Disability Index (ODI) measured at time points up to two years. Secondary outcomes included self-reported improvement, work status, satisfaction with care, and a symptom severity measure (Sciatica Bothersomeness Index). For the

primary outcomes evaluated using ITT analysis, improvements in ODI scores were superior for the surgery group at three months, but, at the one- and two-year follow-ups, there were no significant group differences on either primary outcome. For secondary outcomes, there were significant improvements for the surgery group on the Sciatica Bothersomeness Index at all time points, and satisfaction with care was superior for the surgery group at three (3) months, but not at longer time points. A secondary analysis was performed on a treatment-received basis, and this analysis showed significantly greater improvements for the surgery group at all time points. The estimated treatment effects for the SF-36 bodily pain and physical function subscales were 15.0 and 17.5, respectively, on a 0-to-100 scale. The estimated change in the ODI score was -15.0 on a 0 to 100 scale.

Clark et al (2020) published a systematic review assessing the efficacy, safety, and cost of surgical versus nonsurgical management of lumbar radiculopathy. The systematic review included seven RCTs (5 discectomy and/or microdiscectomy; 2 percutaneous disc decompression with or without coblation) published between January 2007 and April 2019. Results revealed that surgery reduced VAS-leg pain scores as compared to nonsurgical management at up to week 26; however, the differences in these scores did not persist at 1 year or later. Regarding function and disability, the evidence was mixed with minimal differences between surgical and nonsurgical management at 2 years. Comparable improvements in quality of life, neurologic symptoms, and return to work were seen with no surgical deaths and infrequent surgical morbidity reported. The authors of the systematic review rated 5 included RCTs as having a high risk of bias due to inadequate methods of randomization or allocation concealment, lack of blinding, crossover, and attrition.

Bailey et al (2020) published a prospective RCT from a single Canadian site involving 128 patients with persistent sciatica lasting 4 to 12 months and lumbar disc herniation. Enrolled patients were randomly assigned to undergo microdiscectomy or receipt of 6 months of standardized nonoperative care (education regarding day-to-day functioning, activity and exercise, oral analgesics, active physiotherapy, epidural glucocorticoid injections) followed by surgery if necessary. Follow-up was performed at 6 weeks, 3 months, 6 months, and 1 year after enrollment. Results revealed that the surgical group experienced a significant reduction in the VAS-leg pain intensity score at 6 months as compared to the nonsurgical group. At 1 year, a continued reduction in leg-pain intensity, as well as ODI score and pain, was observed in the surgical group. There was a potential impact on external validity with this trial as both surgeons and patients may have been less inclined to undertake nonsurgical care if severe sciatica was present. Additionally, the generalizability of this study may be diminished due to its single-center nature and up to 20% of the data for the primary outcome were absent. A total of 22 patients from the nonsurgical group ultimately crossed over to surgery due to intractable sciatic pain.

Smoking

Tobacco use is considered a risk factor for poor healing and is associated with non-union. It is well-established that smoking is a preventable cause of morbidity and mortality. Lumbar fusion is in most situations an elective surgery; it is strongly recommended that individuals be in the best physical condition prior to undergoing surgery.

Cotinine, the primary metabolite of nicotine, is currently regarded as the best biomarker of tobacco

smoke exposure. Measuring cotinine is preferable to measuring nicotine because cotinine persists longer in the body. Non-smokers exposed to typical levels of second-hand smoke have serum cotinine levels lower than one ng/ml, with heavy exposure to second-hand smoke producing levels in the 1-10 ng/ml range. Active smokers almost always have levels higher than 10 ng/ml and sometimes higher than 500 ng/ml. Therefore, non-smoking is defined as a serum cotinine level of less than or equal to 10 ng/ml.

Khalid et al (2022) evaluated 31,935 patients undergoing single-level lumbar fusion , including active smokers, patients receiving smoking cessation therapy, and patients without a smoking history.. Patients undergoing smoking cessation therapy had lower odds of any postoperative complication compared with active smokers (OR 0.86, 95 % CI: 0.80 to 0.93) The authors concluded smoking cessation therapy within 90 days of surgery decreased the likelihood of all-cause post-operative complications. However, there were no between-group differences in the likelihood of pseudarthrosis, revision surgery, or re-admission within 90 days.

In a retrospective database study, Connor et al (2022) 703,051 patients who underwent elective spine surgery with discectomy, fusion, or decompression for degenerative cervical or thoracolumbar spine disorders. After adjustment for patient and hospital characteristics, tobacco use was independently associated with re-admission at 90 days (OR 1.05, 95 % CI: 1.03 to 1.07, $p < 0.0001$), but not 30 days (OR 1.02, 95 % CI: 1.00 to 1.05, $p = 0.045$). Postoperative infection was the most common reason for both 30- and 90-day readmissions. The authors concluded that tobacco use is a known risk factor for adverse health events and should be considered when selecting patients for spine surgery

Annular Repair Following Spinal Surgery

Thome et al (2018) conducted a randomized controlled trial at 21 European centers to determine whether adding a bone-anchored annular closure device (ACD) to limited microdiscectomy reduced reherniation and reoperation rates and improved overall success compared with microdiscectomy alone. A total of 554 patients were randomized to the ACD group (n=267) or control (n=283). Eligible patients were 21 to 75 years of age with imaging-confirmed single-level lumbar disc herniation between L1 and S1, disc height of 5 mm or greater, and failure of at least 6 weeks of nonsurgical treatment. At 2 years, symptomatic reherniation was lower in the ACD group (12% vs. 25%; p<.001), as was reoperation (5% vs. 13%; p=.0001), with no difference in all-cause serious adverse events between groups.

Longer-term follow-up reinforced these findings. At 3 years, ACD discectomies resulted in fewer symptomatic reherniations (15% vs. 30%) and fewer reoperations (11% vs. 19%), with modest improvements in disability and quality-of-life scores favoring the ACD group (Kienzler, 2019). Four-year reoperation rates were 14.4% with ACD versus 21.1% with control (Nanda et al., 2019). At 5 years, outcomes remained lower in ACD patients, with reduced risk of symptomatic reherniation (18.8% vs. 31.6%; p<.001) and reoperation (16.0% vs. 22.6%; p=.03) (Thome, 2021). A notable limitation of this body of evidence is that investigators were not blinded to treatment assignment, and only patients at select sites were blinded.

Miller LE et al (2020) published a systematic review and meta-analysis of the annular closure device in patients at high risk for lumbar disc reherniation, including four trials (two randomized controlled trials). The 2018 Thome trial was the only study to demonstrate a statistically significant reduction in symptomatic reherniation or reoperation at 2 years. The other three trials showed nonsignificant reductions for both outcomes. Overall, the meta-analysis favored use of the annular device for post-discectomy patients with large annular defects.

Stabilization/Distraction Implants

Schmidt et al. (2018) reported results of a randomized controlled trial in 225 patients with moderate-to-severe lumbar spinal stenosis and back pain, with or without spondylolisthesis, who underwent open microsurgical decompression with interlaminar stabilization using the coflex device (n=110) or decompression alone (n=115). At 24 months, composite clinical success was significantly higher in the coflex group than in the decompression-alone group (58.4% vs. 41.7%; p=.017), primarily driven by fewer epidural steroid injections (4.5% vs. 14.8%; p=.010). No statistically significant differences were observed in ODI success among patients censored for secondary interventions (75.6% vs. 70.4%; p=.47), overall ODI success (55% vs. 44%; p=.091), or other clinical outcomes, including ZCQ and VAS scores. Limitations included potential bias, inconsistent reporting of intention-to-treat analyses, and incomplete outcome reporting, with primary outcome data available for 204 of 254 randomized patients. The impact of the missing data on study results was not reported.

Li et al (2023) conducted a systematic review and meta-analysis to investigate evidence for the comparison of lumbar dynamic stabilization device Coflex with posterior lumbar fusion for lumbar spinal stenosis. A total of 26 studies were included and relational databases were searched up to October 2022. Lumbar dynamic stabilization device Coflex had shorter operation time (mean P <0.00001), less intraoperative blood loss (P < 0.00001), and shorter hospital stays (P < 0.00001). The Japanese Orthopedic Association (JOA) score and ODI score were higher in the Coflex group during early follow-up. There was no significant difference between the two groups with the extension of follow-up time. Moreover, the Coflex group had a lower VAS score than fusion treatment (P < 0.00001). Finally, the Coflex group had lower total complications rate (P= 0.03), lower ASD rate (P=0.001), and higher range of motion (P < 0.00001), but there was no significant difference in reoperation rate and internal fixation problems rate.

Xin et al (2023) conducted a meta-analysis of eight randomized controlled trials including 852 patients to evaluate the safety and effectiveness of interspinous spacers compared with decompressive surgery for lumbar spinal stenosis. Outcomes were generally comparable between groups with respect to hospital stay, blood loss, spinous process fracture, disc height loss, VAS pain scores, ODI scores, and Zurich Claudication Questionnaire symptom severity scores. However, interspinous spacer implantation was associated with a higher rate of reoperation than decompressive surgery. Limitations included the relatively small, pooled population and limited long-term follow-up. The authors concluded that additional well-designed studies with longer follow-up are needed to further evaluate the efficacy and safety of interspinous spacers.

Disc Herniation/Degenerative Disc Disease (DDD)

Current evidence, which includes a large, multi-center, randomized, controlled trial (RCT) by Weinstein (2006) known as Spine Patient Outcomes Research Trial (SPORT), supports that surgical treatment with discectomy improves outcomes for lumbar disc herniation with radiculopathy. However, there is no evidence to support that the addition of spinal fusion to discectomy improves outcomes in patients with the sole indication of lumbar disc herniation without instability.

Spinal Stenosis with Spondylolisthesis

The SPORT RCT (Weinstein 2007 and 2009) compared surgical and nonsurgical treatment for lumbar degenerative spondylolisthesis. All patients had neurogenic claudication or radicular leg pain associated with neurologic signs, spinal stenosis shown on cross-sectional imaging, and degenerative spondylolisthesis shown on lateral radiographs, with symptoms persisting for at least 12 weeks. There were 304 patients in a randomized cohort and 303 patients in an observational cohort. About 40% of the randomized cohort crossed over in each direction by two years of follow-up. At the four-year follow-up timepoint, 54% of patients randomized to non-operative care had undergone surgery. Five percent of the surgically treated patients received decompression only, and 95% underwent decompression with fusion. Analysis was by the treatment that was received, due to the high percentage of crossovers. This analysis, controlled for baseline factors, showed a significant advantage for surgery at up to four years of follow-up for all primary and secondary outcome measures.

Scoliosis

Treatment of scoliosis currently depends on three factors: etiology (idiopathic, congenital, secondary), curve severity (Cobb angle), and the remaining skeletal growth at presentation. Progression risk rises with larger curves and greater skeletal immaturity, with curves in the 25°–40° range in a patient with substantial growth remaining (e.g., low Risser/Sanders stage, open triradiate cartilage) carries a meaningfully elevated risk of progression. Since large curves, particularly thoracic curves, may progress into adulthood and large thoracic deformities can compromise pulmonary function, and because untreated scoliosis is associated with increased back pain in adulthood, surgical correction with spinal fusion is generally recommended once curves progress to approximately 45°–50° or more.

Kolenko et al (2020) states that children who have curves approaching 50° should be referred to an orthopedic surgeon for consultation. The goals of surgical treatment include preventing curve progression while obtaining spinal correction, realignment, and multilevel fusion. Corrective surgeries most frequently follow a posterior approach, but anterior and a combination of anterior and posterior surgery are dependent on surgeon preference and curve type. Current techniques aim to either fuse the spine or modulate growth. Both posterior and anterior spinal fusions use a combination of implants to provide surgical correction and result in 15% to 48% Cobb angle improvement on the coronal plane.

Abdelaal et al (2025) published a systematic review and meta-analysis comparing anterior vertebral body tethering (VBT) with posterior spinal fusion (PSF) for adolescent idiopathic scoliosis. Ten comparative cohort studies comprising 1168 patients were included. At 2-year follow-up, VBT was

associated with less radiographic correction than PSF in the main thoracic curve and proximal thoracic curve, while no significant differences were observed in main thoracic Cobb angle overall or in lumbar curve correction. VBT also demonstrated perioperative advantages, including significantly shorter operative time, less blood loss, and shorter hospital stay. However, VBT carried a significantly higher revision surgery risk compared with PSF. Study authors concluded that while VBT offers meaningful perioperative and recovery advantages and comparable short-term patient-reported outcomes in selected skeletally immature patients, it results in less consistent radiographic correction and substantially higher revision rates than PSF.

Dynamic Stabilization Systems/Devices

The available evidence does not demonstrate that spinal dynamic stabilization devices improve health outcomes compared with the established standard of instrumented fusion. The highest-quality data, including a multicenter double-blind randomized trial (Meyer 2022), show outcomes comparable to fusion without proven long-term superiority. The evidence is largely confined to the lumbar spine and is limited by short follow-up, heterogeneity, and publication bias. No clinical practice guideline endorses dynamic stabilization as superior to or a substitute for fusion. Larger randomized trials with longer follow-up are needed before these devices can be recommended over the established fusion standard.

Interspinous Fixation Devices (IFDs)

There is a lack of high-quality comparative evidence on the efficacy of IFDs in combination with interbody fusion. Reported risks include, while a potential benefit is a reduction in adjacent segment degeneration. Randomized trials with longer follow-up are needed to evaluate the risks and benefits following use of IFDs compared with the established standard (pedicle screw with rod fixation).

PROFESSIONAL GUIDELINE(S)

Cervical Arthroplasty (Replacement)

The North American Spine Society (NASS) coverage policy for Cervical Artificial Disc Replacement (2015; revised Feb 2024) indicates that cervical artificial disc replacement may be indicated for the following diagnoses with qualifying criteria, when appropriate:

- Radiculopathy related to nerve root compression from one- or two- level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-7 in the following scenarios:
    - Persistent symptoms despite at least 6 weeks of nonoperative management.
    - Progressive or functionally limiting weakness correlating with the compressed nerve root.
    - Inability to perform normal work duties or necessary activities of daily living because of severity of symptoms, despite nonoperative management.
- Myelopathy or myeloradiculopathy related to central spinal stenosis from one- or two-level degenerative disc disease from (either herniated disc or spondylotic osteophyte) C3-4.
- There is no significant evidence at this time to support the following:

- Its use for 3 or more levels.
- It's use for isolated axial neck pain. Neck pain along with radiculopathy/myeloradiculopathy, is not an exclusionary criterion. There is early evidence for use in treatment of adjacent segment disease following an index fusion.

Lumbar Arthrodesis

In 2011, the North American Spine Society (NASS) issued evidence-based guidelines on the diagnosis and treatment of degenerative lumbar spinal stenosis. The guidelines stated that patients with mild symptoms of lumbar spinal stenosis are not considered surgical candidates; however, decompressive surgery was suggested to improve outcomes in patients with moderate-to-severe symptoms of lumbar spinal stenosis (grade B recommendation). NASS also indicated that current evidence was insufficient to recommend for or against the placement of interspinous process spacing devices to treat spinal stenosis. A 2013 update of this guideline from the Degenerative Lumbar Spinal Stenosis Work Group of the NASS notes the same recommendations.

In July 2018, the National Institute for Health and Care Excellence (NICE) provided evidence-based recommendations on transaxial interbody lumbosacral fusion for low back pain in adults. The recommendation, based on a literature review conducted in December 2017, states, "Evidence on the safety of transaxial interbody lumbosacral fusion for severe chronic low back pain shows that there are serious but well-recognized complications. Evidence on efficacy is adequate in quality and quantity. Therefore, this procedure may be used provided that standard arrangements are in place for clinical governance, consent and audit. This procedure should only be done by a surgeon with specific training in the procedure, who should carry out their initial procedures with an experienced mentor."

Lumbar Decompression

In 2022, NASS issued coverage policy recommendations related to lumbar decompression and included the following diagnoses with qualifying criteria: Lumbar spinal stenosis (primary or recurrent); Synovial facet cyst associated with either radiculopathy or neurogenic claudication; cauda equina syndrome caused by prominent compression of the thecal sac in the lumbar spine, with resultant saddle anesthesia, new onset loss of bowel/bladder function, or new onset of lower extremity neurologic deficits not explained by a more proximal lesion; tumor; fracture; epidural/subdural hematoma, infection, degenerative/isthmic spondylolisthesis; or additional diagnoses requiring non-decompressive laminectomies/laminotomies or other dorsal approaches.

Lumbar Discectomy

The North American Spine Society (NASS, 2019) coverage policy for lumbar discectomy recommends that primary or recurrent lumbar disc herniation with radiculopathy indicated when both criteria are met:

- Lumbar radiculopathy is present, and a correlative lesion is present on advanced imaging.
- Presence of symptoms for at least 6 weeks and inability to tolerate or failure to respond to 4 weeks of nonsurgical care, including but not limited to physical therapy, chiropractic treatment,

and/or fluoroscopic-guided epidural steroid injections

Bone-Anchored Annular Closure Device (ACD)

In 2025, the International Society for the Advancement of Spine Surgery (ISASS) updated recommendations for bone-anchored annular closure device as follows: "Based on the accumulating clinical evidence, ISASS reiterates its position that in patients with symptomatic lumbar disc herniation (LDH) with radiculopathy undergoing primary discectomy with large (≥6 mm wide) annular defects, bone-anchored annular closure may be used to sustain the treatment benefits of discectomy by reducing the risk of recurring LDH and the need for reoperation." ISASS recommends consideration of annular closure devices in:

- "Symptomatic LDH with radiculopathy, confirmed by clinical history, physical examination, and imaging.
- Single-level disc herniation L4 to L5 or L5 to S1.
- Moderately preserved disc height: ≥5 mm posterior disc height.
- Large annular defect (between 4 and 6 mm tall and between 6 and 10 mm wide) visualized intraoperatively after discectomy."

Percutaneous Lumbar Discectomy / Disc Decompression

In 2022, the American Society of Pain and Neuroscience (ASPN) (Deer 2022) published a consensus guideline outlining best practices for minimally invasive lumbar spinal stenosis treatment. The following recommendation was provided with regard to the use of percutaneous image-guided lumbar decompression: "Percutaneous image- guided decompression should be considered for the treatment of symptomatic lumbar spinal stenosis with the presence of neurogenic claudication, with less than or equal to a grade 2 spondylolisthesis, and with a ligamentum flavum hypertrophy greater than or equal to 2.5mm." Grade A; Level of certainty high; Level of evidence 1-A.

Pre-operative Optimization

Harrop et al (2021) published the Congress of Neurological Surgeons (CNS) evidence-based guideline for preoperative surgical risk assessment, with the following findings

- Individuals undergoing spinal fusion surgery who are active smokers should be counseled regarding the increased risk of reoperation. (Grade B)
- There is insufficient evidence that cessation of smoking before spine surgery decreases the risk of reoperation; however, patients should be counseled to abstain from smoking before and after spinal fusion surgery. (Grade Insufficient)
- Diabetic individuals undergoing spine surgery should have a preoperative HbA1c test and be counseled regarding the increased risk of reoperation or infection when HbA1c is greater than 7.5%. (Grade B)
- There is conflicting evidence regarding the association between elevated BMI and reoperation or surgical site infection; however, patients with elevated BMI should be counseled regarding the

potential increased risk. (Grade Insufficient)

According to the 2025 NASS clinical guidelines for antithrombotic therapies for adults undergoing spine surgery:

- There is fair evidence suggesting that chemoprophylaxis is not associated with increased hemorrhagic complication rates in patients undergoing elective spine surgery. (Grade B)
- It is suggested that the use of chemoprophylaxis is not associated with an increased hemorrhagic complication rate in patients undergoing surgery for spine trauma. (Grade B)

Stabilization / Distraction Implants

In 2025, the North American Spine Society (NASS) published three coverage recommendations for interspinous devices: interspinous decompression devices, interspinous devices without fusion and without decompression, and interspinous fusion devices.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates spinal implants and spinal fixation and instrumentation used during spine procedures as medical devices. All require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Oct 1]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls-and-early-alerts [accessed 2026 Oct 1]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
22207	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (e.g., pedicle/vertebral body subtraction); lumbar
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar

22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar
22526 (E/I)	Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-C1-C2 (atlas-axis), with or without excision of odontoid process
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace
22590	Arthrodesis, posterior technique, craniocervical (occiput-C2)
22595	Arthrodesis, posterior technique, atlas-axis (C1-C2)
22600	Arthrodesis, posterior or posterolateral technique, single interspace; cervical below C2 segment
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with lateral transverse technique, when performed)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments

22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments
22843	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (List separately in addition to code for primary procedure)
22849	Reinsertion of spinal fixation device
22850	Removal of posterior nonsegmental instrumentation (e.g., Harrington rod)
22852	Removal of posterior segmental instrumentation
22855	Removal of anterior instrumentation
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
62287 (E/I)	Decompression, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle-based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar.
62330	Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (i.e., CT or fluoroscopy), bilateral; one interspace, lumbar
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated

	intervertebral disc, 1 interspace, lumbar
63001	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; cervical
63005	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; lumbar, except for spondylolisthesis
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), 1 or 2 vertebral segments; sacral
63012	Laminectomy with removal of abnormal facets and/or pars interrticularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (Gill type procedure)
63015	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; cervical
63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (e.g., spinal stenosis), more than 2 vertebral segments; lumbar
63020	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, cervical
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (List separately in addition to code for primary procedure)
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; lumbar

63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; cervical
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [e.g., spinal or lateral recess stenosis]), single vertebral segment; lumbar
63050	Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments;
63051	Laminoplasty, cervical, with decompression of the spinal cord, 2 or more vertebral segments; with reconstruction of the posterior bony elements (including the application of bridging bone graft and non-segmental fixation devices [e.g., wire, suture, mini-plates], when performed)
63056	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (e.g., far lateral herniated intervertebral disc)
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace
63081	Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, single segment
63102	Vertebral corpectomy (vertebral body resection), partial or complete, lateral extracavitary approach with decom-pression of spinal cord and/or nerve root(s) (e.g., for tumor or retropulsed bone fragments); lumbar, single segment
63300	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; extradural, cervical
63304	Vertebral corpectomy (vertebral body resection), partial or complete, for excision of intraspinal lesion, single segment; intradural, cervical

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HCPCS Codes

Code	Description
S2350	Diskectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; lumbar, single interspace

ICD10 Codes

Code	Description
C72.0	Malignant neoplasm of spinal cord
C79.40	Secondary malignant neoplasm of unspecified part of nervous system
G06.1	Intraspinal abscess and granuloma
D16.6	Benign neoplasm of vertebral column
D32.1	Benign neoplasm of spinal meninges
D33.4	Benign neoplasm of spinal cord
M40.35-M40.37	Flatback syndrome: thoracolumbar, lumbar or lumbosacral region (code range)
M41.05-M41.9	Scoliosis (code range: codes ending in 5 are thoracolumbar, ending in 6 are lumbar and ending in 7 are lumbosacral)
M43.00-M43.07	Spondylolysis: thoracolumbar, lumbar or lumbosacral region (code range)
M43.10-M43.19	Spondylolisthesis (code range)
M43.27	Fusion of spine, lumbosacral region
M48.00-M48.08	Spinal stenosis (code range)
M51.06	Intervertebral disc disorders with myelopathy, lumbar region
M51.16-M51.17	Intervertebral disc disorders with radiculopathy, lumbar/lumbosacral regions
M51.26-M51.27	Other intervertebral disc displacement, lumbar/lumbosacral regions
M51.36-M51.37	Other intervertebral disc degeneration, lumbar/lumbosacral regions
M51.46-M51.47	Schmorl's nodes, lumbar/lumbosacral regions
M51.86-M51.87	Other intervertebral disc disorders, lumbar/lumbosacral regions
M53.2X5-M53.2X7	Spinal instabilities: thoracolumbar, lumbar or lumbosacral region (code range)

Code	Description
M53.86-M53.87	Other specified dorsopathies, lumbar or lumbosacral region (code range)
M54.16-M54.17	Radiculopathy, lumbar/lumbosacral regions
M54.5	Low back pain
M79.604-M79.609	Pain in leg/limb (code range)
M79.651-M79.676	Pain in thigh/lower leg/foot/toes (code range)
M96.0	Pseudarthrosis after fusion or arthrodesis
M96.1	Postlaminectomy syndrome, not elsewhere classified
M99.23	Subluxation stenosis of neural canal of lumbar region
M99.33	Osseous stenosis of neural canal lumbar region
M99.43	Connective tissue stenosis of neural canal of lumbar region
M99.53	Intervertebral disc stenosis of neural canal of lumbar region
M99.63	Osseous and subluxation stenosis of intervertebral foramina of lumbar region
M99.73	Connective tissue and disc stenosis of intervertebral foramina of lumbar region
S32.000A-S32.059S	Fracture of lumbar spine (code range)

REFERENCES

Reference Links:

- Cervical Arthrodesis, including ACDF
- Cervical Corpectomy
- Cervical Arthroplasty
- Anterior Cervical Decompression without Fusion; Posterior Cervical Decompression ± Fusion
- Anterior AND Posterior Cervical Decompression with or without Fusion
- Lumbar Arthrodesis, including Repeat Lumbar Fusion ± Decompression
- Lumbar Decompression

- Lumbar Discectomy / Microdiscectomy
- Lumbar Osteotomy
- Percutaneous Lumbar Discectomy / Disc Decompression
- Pediatric Scoliosis
- Stabilization/Distraction Implants
- Preoperative Optimization

Cervical Arthrodesis, including ACDF

Boddapati V, et al. Are outpatient three- and four-level anterior cervical discectomies and fusion safe? Spine J. 2021;21(9):231-238.

Gardocki RJ, et al. Degenerative disorders of the cervical spine. In: Azar FM, Beaty JH, editors. Campbell's Operative Orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1682-1718.e5.

Huynh K, et al. Airway management in acute hematoma formation following anterior cervical spine surgery. Orthop Rev (Pavia). 2024;16(3):1-4.

Kerolus MG, et al. Posterior percutaneous and minimally invasive approaches to decompression and arthrodesis of the cervical spine. In: Benzel's Spine Surgery. 5th ed. Philadelphia (PA): Elsevier; 2022. p. 949-956.e3.

Lee BS, et al. Management of cervical spondylotic myelopathy. In: Schmidek and Sweet: Operative Neurosurgical Techniques. 7th ed. Philadelphia (PA): Elsevier; 2022. p. 1650-1663.e3.

Resnick DK, et al. Update on spinal fusion. Neurol Clin. 2022;40(2):261-268.

Tavanaei R, et al. Postoperative complications of anterior cervical discectomy and fusion: a comprehensive systematic review and meta-analysis. N Am Spine Soc J. 2025;21:100596.

Williams KD. Fractures, dislocations, and fracture-dislocations of the spine. In: Azar FM, Beaty JH, editors. Campbell's Operative Orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1832-1923.

Wolfa CE, et al. Posterior subaxial and cervicothoracic instrumentation. In: Winn HR, editor. Youmans and Winn Neurological Surgery. 8th ed. Philadelphia (PA): Elsevier; 2023. p. 2807-2814.e2.

Cervical Corpectomy

Foreman M, et al. Management considerations for cervical corpectomy: updated indications and future directions. Life (Basel). 2024;14(6):651.

Gardocki RJ, et al. Degenerative disorders of the cervical spine. In: Azar FM, Beaty JH, editors. Campbell's Operative Orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1682-1718.e5.

Lee BS, et al. Management of cervical spondylotic myelopathy. In: Schmidek and Sweet: Operative Neurosurgical Techniques. 7th ed. Philadelphia (PA): Elsevier; 2022. p. 1650-1663.e3.

Williams KD. Fractures, dislocations, and fracture-dislocations of the spine. In: Azar FM, Beaty JH, editors. Campbell's Operative Orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1832-1923.

Cervical Arthroplasty

Alves O. Cervical total disc replacement: expanded indications. Neurosurg Clin N Am. 2021;32(4):437-448.

Burkus JK, et al. Clinical and radiographic analysis of an artificial cervical disc: 7-year follow-up from the prestige prospective randomized controlled clinical trial. J Neurosurg Spine. 2014 Oct;21(4):516-28.

Callanan G, et al. Cervical total disc replacement: long-term outcomes. Neurosurg Clin N Am. 2021;32(4):461-472.

Heller JG, et al. Comparison of BRYAN cervical disc arthroplasty with anterior cervical decompression and fusion: clinical and radiologic results of a randomized, controlled, clinical trial. Spine 2009 Jan 15;34(2):101-7.

Kim K, et al. Ten-year outcomes of 1- and 2-level cervical disc arthroplasty from the Mobi_C investigational device exemption clinical trial. Neurosurgery. 2021 Mar; 88 (3): 497-505.

Lin BHH, et al. Cervical arthroplasty for myelopathy: a systematic review. Semin Spine Surg. 2023;35(1):101012.

North American Spine Society (NASS) [Internet]. Coverage policy recommendation. Cervical artificial disc replacement. 2024 Feb [accessed 2026 Oct 1]. Available from: https://www.spine.org/Coverage

Nunley P, et al. Cervical total disc replacement: indications and technique. Neurosurg Clin N Am. 2021;32(4):419-424.

Quinto ES Jr, et al. Ten-year outcomes of cervical disc arthroplasty versus anterior cervical discectomy and fusion: a systematic review with meta-analysis. Spine (Phila Pa 1976). 2024 Apr 1;49(7):463-469. Epub 2023 Nov 29.

Rossi V, et al. Cervical spine surgery: arthroplasty versus fusion versus posterior foraminotomy. Neurosurg Clin N Am. 2021;32(4):483-492.

Sasso WR, et al. 20-year clinical outcomes of cervical disk arthroplasty: a prospective, randomized, controlled trial. Spine (Phila Pa 1976). 2024 Jan 1;49(1):1-6.

Yakdan S, et al. Randomized controlled trials comparing cervical disc arthroplasty and anterior cervical discectomy and fusion outcomes in degenerative spine disease: a systematic review and meta-analysis. J Neurosurg Spine. 2025 Aug 29;43(6):703-716.

Zigler JE, et al. ProDisc C and ACDF as surgical treatment for single level cervical symptomatic degenerative disc disease: Five-year results of an FDA study. Spine. 2013 Feb;38(3):203-209.

Anterior Cervical Decompression without Fusion; Posterior Cervical Decompression ± Fusion

Badhiwala JHA, et al. Evaluation and treatment of degenerative cervical myelopathy. In: Winn HR, editor. Youmans and Winn Neurological Surgery. 8th ed. Philadelphia (PA): Elsevier; 2023. p. 2517-2525.e4.

Cheng J, et al. Neck pain. In: Firestein GS, Budd RC, editors. Firestein & Kelley's Textbook of Rheumatology. Philadelphia (PA): Elsevier; 2024. p. 697-713.

Gardocki RJ, et al. Degenerative disorders of the cervical spine. In: Azar FM, Beaty JH, editors. Campbell's Operative Orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1682-1718.e5.

Kerolus MG, et al. Posterior percutaneous and minimally invasive approaches to decompression and arthrodesis of the cervical spine. In: Benzel's Spine Surgery. 5th ed. Philadelphia (PA): Elsevier; 2022. p. 949-956.e3.

Lee BS, et al. Management of cervical spondylotic myelopathy. In: Schmidek and Sweet: Operative Neurosurgical Techniques. 7th ed. Philadelphia (PA): Elsevier; 2022. p. 1650-1663.e3.

Margetis K and Donnally CJ III. Cervical myelopathy. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Aug 2 [accessed 2026 Oct 2] Available from: https://www.ncbi.nlm.nih.gov/books/NBK482312/

Renehan J, et al. Cervical laminoplasty. Semin Spine Surg. 2020;32(1):100777.

Rossi V, et al. Cervical spine surgery: arthroplasty versus fusion versus posterior foraminotomy. Neurosurg Clin N Am. 2021;32(4):483-492.

Valero-Moreno F. Radiculopathy from foraminal stenosis. In: Chaichana KL, Quiñones-Hinojosa A, editors. Comparative Management of Spine Pathology. Philadelphia (PA): Elsevier; 2023. p. 88-93.

Weinberg DS, et al. Cervical laminoplasty: indication, technique, complications. J Spine Surg. 2020;6(1):290-301.

William J, et al. Degenerative cervical myelopathy. Orthop Clin North Am. 2022;53(4):509-521.

Wolfa CE, et al. Posterior subaxial and cervicothoracic instrumentation. In: Winn HR, editor. Youmans and Winn Neurological Surgery. 8th ed. Philadelphia (PA): Elsevier; 2023. p. 2807-2814.e2.

Zhang AS, et al. Cervical myelopathy: diagnosis, contemporary treatment, and outcomes. Am J Med. 2022;135(4):435-443.

Anterior AND Posterior Cervical Decompression with or without Fusion

Strenge KB, et al. Three-level anterior cervical discectomy and fusion with or without an investigational posterior stabilization system assessed through 24 months: a multicenter randomized controlled trial. Spine (Phila Pa 1976). 2025 Sep 1;50(17):1161-1170.

Wolfa CE, et al. Posterior subaxial and cervicothoracic instrumentation. In: Winn HR, editor. Youmans and Winn Neurological Surgery. 8th ed. Philadelphia (PA): Elsevier; 2023. p. 2807-2814.e2.

Lumbar Arthrodesis, including Repeat Lumbar Fusion ± Decompression

Austevoll IM, et al. Decompression with or without fusion in degenerative lumbar spondylolisthesis. N Engl J Med. 2021;385:526-538.

Chang L, et al. Posterior thoracic and lumbar instrumentation. In: Winn HR, editor. Youmans and Winn Neurological Surgery. 8th ed. Philadelphia (PA): Elsevier; 2023. p. 2830-2830.e14.

Donnally CJ, et al. Current incidence of adjacent segment pathology following lumbar fusion versus motion-preserving procedures: a systematic review and meta-analysis of recent projections. Spine J. 2020 Oct;20(10):1554-1565.

Gadjradj PS, et al. Decompression alone versus decompression with fusion in patients with lumbar spinal stenosis with degenerative spondylolisthesis: a systematic review and meta-analysis. Eur Spine J. 2023;32(3):1054-1067.

Gardocki RJ, et al. Degenerative disorders of the thoracic and lumbar spine. In: Azar FM, Beaty JH, editors. Campbell's Operative Orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1719-1801.e9.

Goldberg JL, et al. Algorithmic patient selection for minimally invasive versus open lumbar interbody fusion surgery. Neurosurg Clin N Am. 2023;34(4):599-607.

Howell HJ, et al. Evidence-based guidelines for the surgical management of degenerative lumbar spondylolisthesis. Neurosurg Clin N Am. 2026;37(1):1-25.

Inose H, et al. Comparison of decompression, decompression plus fusion, and decompression plus stabilization: a long-term follow-up of a prospective, randomized study. Spine J. 2022 May;22(5):747-755. Epub 2021 Dec 25.

International Society for the Advancement of Spine Surgery (ISASS) [Internet]. Policy statement for lumbar spinal fusion surgery 2011 Jul 15. [accessed 2026 Oct 2]. Available from: https://isass.org/advocacy/

Khalid SI, et al. The impact of smoking cessation therapy on lumbar fusion outcomes. World Neurosurg. 2022;164:e119-e126.

Martirosyan NL, et al. Anterior and lateral lumbar instrumentation. In: Winn HR, editor. Youmans and Winn Neurological Surgery. 8th ed. Philadelphia (PA): Elsevier; 2023. p. 2822-2829.e2.

National Institute for Health and Clinical Excellence (NICE) [Internet]. Transaxial interbody lumbosacral fusion for severe chronic low back pain. 2018 Jul [accessed 2026 Oct 13]. Available from: https://www.nice.org.uk/guidance/htg478.

North American Spine Society (NASS) [Internet]. Clinical guidelines. Diagnosis and treatment of degenerative lumbar spondylolisthesis. 2014 Revised [accessed 2026 Oct 2]. Available from: https://www.spine.org/Research/Clinical-Guidelines

North American Spine Society (NASS) [Internet]. Current recommendations: Lumbar fusion. 2021 Jun [accessed 2026 Oct 2]. Available from: https://www.spine.org/coverage

Resnick DK, et al. Update on spinal fusion. Neurol Clin. 2022;40(2):261-268.

Saadeh YS, et al. Evaluation and treatment of degenerative lumbar spondylolisthesis. In: Winn HR, editor. Youmans and Winn Neurological Surgery. 8th ed. Philadelphia (PA): Elsevier; 2023. p. 2510-2516.e2.

Weinstein JN, et al. Surgical compared with nonoperative treatment for lumbar degenerative

spondylolisthesis. Four-year results in the Spine Patient Outcomes Research Trial (SPORT) randomized and observational cohorts. J Bone Joint Surg Am. 2009 Jun;91(6):1295-304.

Weinstein JN, et al. Surgical versus nonoperative treatment for lumbar disc herniation: four-year results for the Spine Patient Outcomes Research Trial (SPORT). Spine. 2008 Dec 1;33(25):2789.

Williams KD. Fractures, dislocations, and fracture-dislocations of the spine. In: Azar FM, Beaty JH, editors. Campbell's Operative Orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1832-1923.

Lumbar Decompression

Austevoll IM, et al. Decompression with or without fusion in degenerative lumbar spondylolisthesis. N Engl J Med. 2021;385:526-538.

Chen KT, et al. Current indications for spinal endoscopic surgery and potential for future expansion. Neurospine. 2023;20(1):33-42.

Gadjradj PS, et al. Decompression alone versus decompression with fusion in patients with lumbar spinal stenosis with degenerative spondylolisthesis: a systematic review and meta-analysis. Eur Spine J. 2023;32(3):1054-1067.

Howell HJ, et al. Evidence-based guidelines for the surgical management of degenerative lumbar spondylolisthesis. Neurosurg Clin N Am. 2026;37(1):1-25.

Hutchins TA, et al. ACR appropriateness criteria: low back pain. J Am Coll Radiol. 2021;18(11 Suppl):S361-S379.

Inose H, et al. Comparison of decompression, decompression plus fusion, and decompression plus stabilization: a long-term follow-up of a prospective, randomized study. Spine J. 2022 May;22(5):747-755. Epub 2021 Dec 25.

Miller JK, et al. Cauda equina syndrome. Br J Hosp Med (Lond). 2023;84(11):1-7.

National Health Service England. National suspected cauda equina syndrome pathway [Internet]. 2023 [cited 2026 May]. Available from: https://gettingitrightfirsttime.co.uk/surgical_specialties/spinal-surgery/

North American Spine Society (NASS) [Internet]. Clinical guidelines. Diagnosis and treatment of degenerative lumbar spondylolisthesis. 2014 Revised [accessed 2026 Oct 2]. Available from: https://www.spine.org/Research/Clinical-Guidelines

North American Spine Society (NASS) [Internet]. Coverage policy recommendations. Lumbar decompression: laminectomy, laminotomy & foraminotomy. 2022 Jan [accessed 2026 Oct 7] Available from: https://www.spine.org/coverage

Webb CW, et al. Lumbar spinal stenosis: diagnosis and management. Am Fam Physician. 2024;109(4):350-359.

Weinstein JN, et al. Surgical versus nonoperative treatment for lumbar disc herniation: four-year results for the Spine Patient Outcomes Research Trial (SPORT). Spine. 2008 Dec 1;33(25):2789.

Yoon WW, et al. Herniated discs: when is surgery necessary? EFORT Open Rev. 2021;6(6):526-530.

Lumbar Discectomy / Microdiscectomy

Bailey, CS et al. Discectomy compared with standardized nonoperative care for chronic sciatica due to a lumbar disc herniation. JBJS. 2021;103(23):2161-2169.

Bailey CS, et al. Surgery versus conservative care for persistent sciatica lasting 4 to 12 months. N Engl J Med. 2020 Mar 19;382(12):1093-1102.

Butler AJ, et al. Diskectomy. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 [cited 2026 May]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK544281/

Clark R, et al. Surgical management of lumbar radiculopathy: a systematic review. J Gen Intern Med. 2020 Mar;35(3):855-864. Epub 2019 Nov 11.

Chen KT, et al. Current indications for spinal endoscopic surgery and potential for future expansion. Neurospine. 2023;20(1):33-42.

Gardocki RJ, et al. Degenerative disorders of the cervical spine. In: Azar FM, Beaty JH, editors. Campbell's Operative Orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1682-1718.e5.Lorio M, et al. International Society for the Advancement of Spine Surgery policy 2019-surgical treatment of lumbar disc herniation with radiculopathy. Int J Spine Surg 2020 Feb 29;14(1):1-17.

Lorio MP, et al. ISASS recommendations and coverage criteria for bone-anchored annular defect closure following lumbar discectomy: coverage indications, limitations, and/or medical necessity-an ISASS 2025 policy update on the use of bone-anchored annular closure to prevent reherniation in high-risk lumbar discectomy patients. Int J Spine Surg. 2025 Sep 2;19(4):444-451.

Miller LE, et al. Expert review with meta-analysis of randomized and nonrandomized controlled studies of Barricaid annular closure in patients at high risk for lumbar disc reherniation. Expert Rev Med Devices. 2020 May;17(5):461-469.

National Health Service England. National suspected cauda equina syndrome pathway [Internet]. 2023 [cited 2026 May]. Available from: https://gettingitrightfirsttime.co.uk/surgical_specialties/spinal-surgery/

North American Spine Society (NASS) [Internet]. Clinical guidelines. Diagnosis and treatment of lumbar disc herniation with radiculopathy. 2012 Revised [accessed 2026 Oct 2]. Available from: https://www.spine.org/Research/Clinical-Guidelines

North American Spine Society (NASS) [Internet]. Coverage policy recommendations. Lumbar discectomy. 2019 Dec [accessed 2026 Oct 7]. Available from: https://www.spine.org/coverage

Weinstein JN, et al. Surgical versus nonoperative treatment for lumbar disc herniation: four-year results for the Spine Patient Outcomes Research Trial (SPORT). Spine. 2008 Dec 1;33(25):2789.

Wilby MJ, et al. Microdiscectomy compared with transforaminal epidural steroid injection for persistent radicular pain caused by prolapsed intervertebral disc: the NERVES RCT. Health Technol Assess. 2021 Apr;25(24):1-86.

Yoon WW, et al. Herniated discs: when is surgery necessary? EFORT Open Rev. 2021;6(6):526-530.

Lumbar Osteotomy

Chang L, et al. Posterior thoracic and lumbar instrumentation. In: Winn HR, editor. Youmans and Winn Neurological Surgery. 8th ed. Philadelphia (PA): Elsevier; 2023. p. 2830-2830.e14.

Cheung JPY. The importance of sagittal balance in adult scoliosis surgery. Ann Transl Med. 2020;8(2):35. doi:10.21037/atm.2019.10.19.

Joiner EF, et al. Posterior-based osteotomies for deformity correction. Neurosurg Clin N Am. 2023;34(4):555-566.

Gardocki RJ, et al. Degenerative disorders of the cervical spine. In: Azar FM, Beaty JH, editors. Campbell's Operative Orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1682-1718.e5.

Hu WH, et al. Osteotomy Techniques for Spinal Deformity. Chin Med J (Engl). 2016;129(21):2639 2641.

Metkar US, et al. Spinal alignment and surgical correction in the aging spine and osteoporotic patient. N Am Spine Soc J. 2024;19:100531.

Sorour O, et al. Enhanced recovery after surgery protocols and spinal deformity. Neurosurg Clin N Am. 2023;34(4):677-687.

Percutaneous Lumbar Discectomy / Disc Decompression

Butler AJ, et al. Diskectomy. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2024 Apr 16 [accessed 2026 Oct 2]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK544281/

Chen KT, et al. Current indications for spinal endoscopic surgery and potential for future expansion. Neurospine. 2023;20(1):33-42.

Deer TR, et al. Best Practices for minimally invasive lumbar spinal stenosis treatment 2.0 (MIST): consensus guidance from the American Society of Pain and Neuroscience (ASPN). J Pain Res. 2022 May 5;15:1325-1354.

Yoon WW, et al. Herniated discs: when is surgery necessary? EFORT Open Rev. 2021;6(6):526-530.

Pediatric Scoliosis

Abdelaal M, et al. Anterior vertebral body tethering versus posterior spinal fusion in adolescent idiopathic scoliosis: a systematic review and meta-analysis of comparative outcomes. J Clin Med. 2025 Sep 23;14(19):6707.

DePaola K, et al. Pediatric spine disorder. Pediatr Clin North Am. 2020;67(1):185-204.

De Varona-Cocero, A., et al Sagittal alignment outcomes following two-row vertebral body tethering versus posterior spinal fusion in adolescent idiopathic scoliosis: a multicenter two-year study. Eur Spine J (2026).

Dunn J, et al. Screening for adolescent idiopathic scoliosis: evidence report and systematic review for the US Preventive Services Task Force. JAMA. 2018 Jan 9;319(2):173-187.

Dolan LA, et al. Bracing in Adolescent Idiopathic Scoliosis Trial (BrAIST): development and validation of a prognostic model in untreated adolescent idiopathic scoliosis using the simplified skeletal maturity system. Spine Deform. 2019 Nov;7(6):890-898.e4.

Groves ML, et al. Neurosurgical evaluation and management of adults with achondroplasia. Neurosurg Clin N Am. 2022;33(1):25-35.

Hammad AM, et al. Vertebral body tethering: an alternative to posterior spinal fusion in idiopathic scoliosis? Front Pediatr. 2023;11:1133049.

Jinnah AH, et al. Adolescent idiopathic scoliosis: advances in diagnosis and management. Curr Rev Musculoskelet Med. 2025 Feb;18(2):54-60. Epub 2024 Dec 30.

Joiner EF, et al. Posterior-based osteotomies for deformity correction. Neurosurg Clin N Am. 2023;34(4):555-566.

Kolenko AM, et al. Pediatric idiopathic scoliosis diagnosis and management. Physician Assist Clin. 2020;441-453.

Negrini S, et al. 2016 SOSORT guidelines: orthopaedic and rehabilitation treatment of idiopathic scoliosis during growth. Scoliosis Spinal Disord. 2018 Jan 10;13:3.

Payares-Lizano M, et al. Pediatric orthopedic examination. Pediatr Clin North Am. 2020;67(1):1-21.

Richardson BM, et al. Common pediatric musculoskeletal issues. Prim Care. 2021;48(3):417-428.

Sorour O, et al. Enhanced recovery after surgery protocols and spinal deformity. Neurosurg Clin N Am. 2023;34(4):677-687.

Warner WC, et al. Scoliosis and kyphosis. In: Azar FM, Beaty JH, editors. Campbell's Operative Orthopaedics. 14th ed. Philadelphia (PA): Elsevier; 2021. p. 1998-2196.e28.

Weinstein SL, et al. Effects of bracing in adolescents with idiopathic scoliosis. N Engl J Med. 2013 Oct 17;369(16):1512-21.

Stabilization/Distraction Implants

Deer TR, et al. Best Practices for minimally invasive lumbar spinal stenosis treatment 2.0 (MIST): consensus guidance from the American Society of Pain and Neuroscience (ASPN). J Pain Res. 2022 May 5;15:1325-1354.

Li T, et al. Efficacy and safety of lumbar dynamic stabilization device coflex for lumbar spinal stenosis: a systematic review and meta-analysis. World Neurosurg. 2023 Feb;170:7-20. Epub 2022 Dec 6.

Meyer B, et al.; DYNORFUSE Study Group; DYNORFUSE Study Group. Lumbar dynamic pedicle-based stabilization versus fusion in degenerative disease: a multicenter, double-blind, prospective, randomized controlled trial. J Neurosurg Spine. 2022 Apr 22;37(4):515-524.

North American Spine Society (NASS) [Internet]. Coverage policy recommendations. Interspinous device for fusion. 2025 Mar [accessed 2026 Oct 15] Available from: https://www.spine.org/coverage

North American Spine Society (NASS) [Internet]. Coverage policy recommendations. Interspinous device with decompression. 2025 Mar [accessed 2026 Oct 15] Available from: https://www.spine.org/coverage

North American Spine Society (NASS) [Internet]. Coverage policy recommendations. Interspinous device without Fusion & without Decompression. 2025 Mar [accessed 2026 Oct 15] Available from: https://www.spine.org/coverage

Schmidt S, et al. Prospective, randomized, multicenter study with 2-year follow-up to compare the performance of decompression with and without interlaminar stabilization. J Neurosurg Spine. 2018 Apr;28(4):406-415.

Xin JH, et al. Effectiveness and safety of interspinous spacer versus decompressive surgery for lumbar spinal stenosis: A meta-analysis of randomized controlled trials. Medicine (Baltimore). 2023 Nov 17;102(46):e36048.

Preoperative Optimization

Achilihu H, et al. Tobacco use classification by inexpensive urinary cotinine immunoassay test strips. J Anal Toxicol. 2019;43(2):149-153.

American Academy of Orthopaedic Surgeons (AAOS) [Internet]. Preoperative risk factors. No date [accessed 2026 Oct 2]. Available from: https://www.aaos.org/quality/quality-programs/quality-toolkits/smoking/

Benowitz NL, et al. Biochemical verification of tobacco use and abstinence: 2019 update. Nicotine Tob Res. 2020;22(7):1086-1097.

Connor M, et al. Tobacco use is associated with increased 90-day readmission among patients undergoing surgery for degenerative spine disease. 2022;12(5):787-794.

Cooke F, et al. Diagnostic accuracy of NicAlert cotinine test strips in saliva for verifying smoking status. Nicotine Tob Res. 2008;10(4):607-612.

Diltz ZR, et al. Perioperative management of comorbidities in spine surgery. Orthop Clin North Am. 2023;54(3):349-358.

Harrop JS, et al. Congress of neurological surgeons systematic review and evidence-based guidelines for perioperative spine: preoperative surgical risk assessment. Neurosurgery. 2021 Oct 13;89(Suppl 1):S9-S18.

Khalid SI, et al. The impact of smoking cessation therapy on lumbar fusion outcomes. World Neurosurg. 2022;164:e119-e126.

North American Spine Society (NASS) [Internet]. Clinical guidelines. Antithrombotic therapies for adults undergoing spine surgery. 2025 [accessed 2026 Oct 15] Available from: https://www.spine.org/Research/Clinical-Guidelines

Wang TY, et al. Preoperative optimization for patients undergoing elective spine surgery. Clin Neurol Neurosurg. 2021;206:106445.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Cervical Fusion (LCD L39770) [accessed 2026 Sep 24]

Facet Joint Interventions for Pain Management (LCD L35936) [accessed 2026 Oct 2]

Laser Procedures (NCD 140.5) [accessed 2026 Sep 10]

Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis (NCD 150.13) [accessed 2026 Sep 10]

Thermal Intradiscal Procedures (TIPs) (NCD 150.11) [accessed 2026 Sep 10]

The following are not specifically addressed in National or Regional Medicare coverage determinations or policies:

- Artificial cervical intervertebral disc
- Interspinous process decompression devices
- Lumbar decompression, fusion, posterior column osteotomy (PCO), three-column osteotomy, microdiscectomy
- Minimally Invasive/Minimal Access Lumbar Interbody Fusion

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates
01/01/27

Date	Summary of Changes
01/01/27	• Original effective date

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: STEREOTACTIC RADIOSURGERY (SRS) & STEREOTACTICBODY RADIATION THERAPY (SBRT)

POLICY EFFECTIVE DATE:	3/1/2025
Policy Control #:	1370/20.000434
Next Annual Review:	November, 2026

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

PROCEDURE CODES

Stereotactic radiosurgery: 61796, 61797, 61798, 61799, 61800, 63620, 63621, 77371, 77372, 77432, C9795, G0339, G0340, G0563
Stereotactic body radiosurgery: 77373, 77435

DESCRIPTIONS

Stereotactic radiosurgery (SRS) is a technique that utilizes precisely targeted radiation to a tumor while minimizing radiation to adjacent normal tissue. It is used for the non-invasive destruction of intracranial lesions and some extracranial lesions that may be inaccessible or unsuitable for open surgery. In order to localize the treatment target and to achieve precise delivery of radiation, SRS relies on stereotactic guidance (using cerebral angiography, computerized tomography, and/or magnetic resonance imaging) and the use of a positioning frame to restrict head movement. Stereotactic body radiation therapy (SBRT) is used to treat extracranial sites as opposed to stereotactic radiosurgery which is used to treat intra-cranial and spinal targets.

Radiosurgery can be performed with:

- High energy X-rays produced by linear accelerators that are frame-based or robotically targeted (e.g., LINAC and CyberKnife®).
- Gamma rays (e.g., Gamma Knife®)

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- With charged particle beams of protons, neutrons, or helium ions.

The three methods of radiation delivery differ technically in the source of radiation, size and shape of radiation field, and the range of radiation doses.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policy:

- Proton Beam Therapy, 1370/20.000495

POSITION STATEMENT

CDPHP considers stereotactic radiosurgery (SRS) and stereotactic body radiation therapy (SBRT) medically necessary when performed in accordance with the Centers for Medicare and Medicaid coverage determination as outlined below:

Indications for SRS/SBRT (for Cranial and Spinal Lesions):

- Primary central nervous system malignancies, generally used as a boost or salvage therapy for lesions < 5 cm.
- Primary and secondary tumors involving the brain or spine parenchyma, meninges/dura, or immediately adjacent bony structures.
- Benign brain tumors and spinal tumors such as meningiomas, acoustic neuromas, other schwannomas, pituitary adenomas, pineocytomas, craniopharyngiomas, glomus tumors, hemangioblastomas.
- Cranial arteriovenous malformations, cavernous malformations, and hemangiomas
- Other cranial non-neoplastic conditions such as trigeminal neuralgia and select cases of medically refractory epilepsy. As a boost treatment for larger cranial or spinal lesions that have been treated initially with external beam radiation therapy or surgery (e.g., sarcomas, chondrosarcomas, chordomas, and nasopharyngeal or paranasal sinus malignancies).
- Metastatic brain or spine lesions, with stable systemic disease, Karnofsky Performance Status 40 or greater (or expected to return to 70 or greater with treatment), and otherwise reasonable survival expectations, OR an Eastern Cooperative Oncology Group (ECOG) Performance Status of 3 or less (or expected to return to 2 or less with treatment). Note that the higher a Karnofsky Performance Status is, the better a patient is doing. However, the lower an Eastern Cooperative Oncology Group (ECOG) Performance Status is, the better a patient is doing.
- Relapse in a previously irradiated cranial or spinal field where the additional stereotactic precision is required to avoid unacceptable vital tissue radiation.
- Choroidal and other ocular melanomas.

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Indications for Stereotactic Body Radiation Therapy (SBRT):

- Primary tumors and tumors metastatic to the lung, liver, kidney, adrenal gland, or pancreas.
- Pelvic and head and neck tumors that have recurred after primary irradiation.
- For patients with clinically localized, low- to intermediate-risk prostate cancer.
- SBRT treatment, of anybody site or internal organ, is indicated for treatment of recurrence in or near previously irradiated regions when a high level of precision and accuracy or a high dose per fraction is indicated to minimize the risk of injury to surrounding normal tissues and treatment with conventional methods is not appropriate or safe for the particular patient (medical records must describe the specific circumstances, see documentation requirements below).

POLICY CONSIDERATIONS

A neuro-surgical consult is required prior to the initiation of stereotactic radiosurgery in an effort to provide the patient with all available treatment options related to their diagnosis.

SRS/SBRT procedures include the following components:

- Planning
- Position stabilization (attachment of a frame or frameless)
- Imaging for localization (CT, MRI, angiography, PET, etc.)
- Computer assisted tumor localization (i.e., "Image Guidance")
- Treatment planning – number of isocenters, number, placement and length of arcs or angles, number of beams, beam size and weight, etc.
- Isodose distributions, dosage prescription and calculation
- Setup and accuracy verification testing
- Simulation of prescribed arcs or fixed portals
- Radiation treatment delivery

SBRT is only indicated as primary treatment for tumor types or locations where the available published literature supports an outcome advantage over other conventional radiation modalities.

SBRT may be delivered in one to five sessions (fractions). Each fraction requires an identical degree of precision, localization, and image guidance.

SRS is typically performed in a single session, using a rigidly attached stereotactic guiding device, other immobilization technology and/or a stereotactic-guidance system.

The Karnofsky Performance Scale Index and Eastern Cooperative Oncology Group (ECOG) Performance Status allows patients to be classified as to their functional impairment, and is often used to compare effectiveness of different therapies and to assess the prognosis in individual patients.

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- Karnofsky Performance Scale Index
- ECOG Performance Status

EXCLUSIONS

SRS/SBRT (for Cranial and Spinal Lesions)
SRS is not considered medically necessary under the following circumstances:

- Treatment for anything other than a severe symptom or serious threat to life or critical functions.
- Treatment unlikely to result in functional improvement or clinically meaningful disease stabilization, not otherwise achievable.
- Patients with wide-spread cerebral or extra-cranial metastases with limited life expectancy unlikely to gain clinical benefit within their remaining life.
- Patients with poor performance status (Karnofsky Performance Status less than 40 or an ECOG Performance greater than 3). Note that the higher a Karnofsky Performance Status is, the better a patient is doing. However, the lower an Eastern Cooperative Oncology Group (ECOG) Performance Status is, the better a patient is doing.
- Cobalt-60 pallidotomy is non-covered.

Stereotactic Body Radiation Therapy (SBRT):
SBRT is not considered medically necessary under the following circumstances for any condition:

- Treatment is unlikely to result in clinical cancer control and/or functional improvement.
- The tumor burden cannot be completely targeted with acceptable risk to critical normal structures.
- The patient has a poor performance status (Karnofsky Performance Status less than 40 or Eastern Cooperative Oncology Group (ECOG) Status of 3 or worse). Note that the higher a Karnofsky Performance Status is, the better a patient is doing. However, the lower an Eastern Cooperative Oncology Group (ECOG) Performance Status is, the better a patient is doing.
- Recurrent (other than pelvic and head and neck tumors) or metastatic disease could be treated by conventional methods (record must describe why other radiation therapy measures are not appropriate or safe for the particular patient).
- Since the goal of SBRT is to maximize the potency of the radiotherapy by completing an entire course of treatment within an extremely accelerated time frame, any course of radiation treatment extending beyond five fractions is not considered SBRT. SBRT is meant to represent a complete course of treatment and not to be used as a boost following a conventionally fractionated course of treatment.
- Primary treatment of lesions of bone, breast, uterus, ovary, and other internal organs not listed earlier in this policy as covered is not considered medically necessary.

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CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. Bhatnager AK, Cyberknife frameless radiosurgery for the treatment of extracranial benign tumors. Technol Cancer Res Treat. 2005;4(5):57 1-6.
2. Chang SD, Main W, Martin DP, et al. An analysis of the accuracy of the CyberKnife: a robotic frameless stereotactic radiosurgical system. Neurosurgery. 2003; 52(1):140-6.
3. Degen JW, Cyberknife stereotactic radiosurgical treatment of spinal tumors for pain control and quality of life. J Neurosurg Spine. 2005; 2(5): 540-549.
4. Dodd RL, Cyberknife radiosurgery for benign intradural extramedullary spinal tumors. Neurosurgery. 2006; 58(4): 674-85.
5. Empire Medicare services, LCD for Radiation Oncology. Revised date: 1/1/06. http://www.empiremedicare.com/nyorkpolicya/12908_final.htm
6. Gerszten PC, Evaluation of Cyberknife frameless real-time image-guided stereotactic radiosurgery for spinal lesions. Stereotact Funct Neurosurg. 2003; 81(1-4): 84-89.
7. Giller CA, Berger BD, Pisenmaa DA, et al, Robotically guided radiosurgery for children. Pediatrric Blood Center. 2005; 45(3): 304-10.
8. Hamamoto Y, Manabe T, Nishizaki, O, et al, Influence of collimater sizeon three dimensional conformal radiotherapy of the cyberknife. Radiat Med. 2004; 22(6): 442-448.
9. Hayes Medical Technology Directory. Stereotactic radiosurgery for trigeminal neuralgia and movement disorders. Winifred S. Hayes Inc. Lansdale, PA. July 2002; Updated June, 2005.
10. Hayes Medical Technology Directory. Robotically Assisted Stereotactic Surgery. Winifred S. Hayes Inc. Lansdale, PA. October 2004; Updated November, 2005.
11. HealthNow New York, Inc., Upstate medicare Division. Stereotactic Radiosurgery. Effective 8/9/05,http://www.umd.nycpic.com/cgi-bin/bookmgr/bookmgr.exe/BOOKS/SU010E00/FRONT
12. Kajiwara K, Image-guided stereotactic radiosurgery with the cyberknife for pituitary adenomas. Minimum Invasive neurosurg. 2005; 48(2): 91-6.
13. Lim M, Cyberknife radiosurgery for idiopathic trigeminal neuralgia. Neurosurg Focus. 2005; 18(5): E9.
14. King CR, Cyberknife radiotherapy for localized prostate cancer: rationale and technical feasibility. Technol Cancer Res treat. 2003: 2(1) 25-30.
15. Other payers

16. International RadioSurgery Association (IRSA) Practice Guideline: Stereotactic Radiosurgery for Patients with Intractable Typical Trigeminal Neuralgia Who Have Failed Medical Management, January 2009, http://www.irsa.org/trigeminal_neuralgia.html
17. International Radiosurgery Association Practice Guidelines, http://www/irsa.org/guidelines.html
18. ASTRO Model Policy: Stereotactic Radiatiotherapy: https://www.astro.org/uploadedFiles/_MAIN_SITE/Daily_Practice/Reimbursement/Model_Policies/Content_Pieces/ASTROSRSModelPolicy.pdf
19. ASTRO Model Policy: Stereotactic Body Radiotherapy, https://www.astro.org/uploadedFiles/Main_Site/Practice_Management/Reimbursement/2013HPcoding%20guidelines_SBRT_Final.pdf
20. National Government Services Local Coverage Determination: Stereotactic Radiation Therapy:
Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) (L35076):
https://www.ngsmedicare.com/ngs/portal/ngsmedicare/newngs/home-lob/pages/medical-policy-center/mpc-search-detail/lcd%20for%20stereotactic%20radiation%20therapy%20stereotactic%20radiosurgery%20(srs)%20and%20stereotactic%20body%20radiation%20therapy%20(sbrt)%20(l35076)/!ut/p/z1/rVRdc6IwFP0r7EMfM0kgSnjEoGAVwQ-K5KWDfC1Wg1WmtvvrN7U73R0Yy-64PMDcO-eee-7JJZDDNeQifimLuC4rEe9kHPH-IzHHQ4wZmngW1pE5IT5yVh6yezoMGwDqIAmwTGLObM1bIsi_qDd6rXrNo8gko4FlzX3NHqh_V4-uPGZn_wcYWTA6hWnF5y0xLTT_NzNaAP611hDyRou2nQ0AG5rSL2vWn5kj7KFeC9A2tEtFJKfQfzPYaDKQGvyALqwlpi6G4UuZnWEgquNersjynfGQlCmM1ExNjTzVgJobMSCEaIDGBga6qvc32FDzRDeg0-rQ8Mlvd4jY5xk1aIEPy_kYGevEcVTb125U16Cn7lJF5nl0tjx7gGx2K_191z7KH67cPj9zE_KkEnX2WsO1KE77LC2T-JhdcqIW2fkO_ZG-xIdqVyZvd-gjuVM-YiWR-OyoAGUXi7QUhXKIi-x0Bfa4fVIkTNn235WoR5e5hRwwrr-DUuQVXHdVNf1jEyaPZ-q7sxFDaK5f98_IjcwwUh3QNCWA6FQF8YZqACOakCzBRL46Nmf6n-npaiHVT9zpQzCmGrJvpb_vvECGn3vOMTzsgyAQbyV4Wjg_BjNgs3zPNvS8yvchrS_fX2Hw7Sfm1SlN/dz/d5/L2dBISEvZ0FBIS9nQSEh/

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: STEREOTACTIC RADIOSURGERY (SRS) & STEREOTACTICBODY RADIATION THERAPY (SBRT)

POLICY APPROVAL DATES

New:	09/06
Revised:	06/07, 05/08, 07/08, 05/09, 11/09, 07/11, 7/12, 07/15, 03/18, 11/19, 7/21, 1/24, 3/25
Reviewed:	07/09, 07/13, 07/14, 07/16, 07/17, 07/18, 07/19, 07/20, 7/22, 7/23. 7/24, 11/25

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
3/1/2025	Added new code G0563 to procedure codes list.
1/1/2024	Added new code C9795 to policy.
8/1/21	Added additional indication for SRS/SBRT for cranial and spinal lesions.
1/1/20	Revised entire policy to align with CMS regulations for all LOB.

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MEDICAL POLICY

Medical Policy Title	**Surgical Management of Sleep Disorders**
Policy Number	**7.01.41**
Current Effective Date	**January 1, 2027**
Next Review Date	**January 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Nasal Surgery

A. Nasal surgery is **medically appropriate** to correct a nasal obstruction that prohibits the use of continuous positive airway pressure (CPAP) device and bilevel positive airway pressure (BiPAP).

B. Septoplasty, turbinate reduction, and polypectomy are **not medically necessary** for obstructive sleep apnea (OSA).

II. Surgical Bypass of the Airway Tracheostomy

A. Tracheostomy is **medically appropriate** for the treatment of severe, life threatening OSA.

III. Upper Airway Surgery

A. Palatopharyngoplasty (e.g., Uvulopalatopharyngoplasty (UPPP), Uvulopharyngoplasty) **AND** Hyoid Suspensions for the treatment of OSA are **medically appropriate** when the following criteria are met:

1. Documented OSA with an apnea-hypopnea index (AHI) or respiratory disturbance index (RDI) of 15 or greater events per hour, regardless of symptoms; **or**
2. Documented OSA with an AHI or RDI of five (5) to 14 events per hour, accompanied by symptoms of excessive daytime sleepiness, impaired cognition, mood disorders, insomnia, or documented cardiovascular diseases, including hypertension and ischemic heart disease; **and**
3. Failure of all forms of medical management of OSA, including documented intolerance to positive airway pressure (e.g., CPAP, BiPAP) or intolerance.

B. Tonsillectomy and Adenoidectomy:

1. Tonsillectomy and adenoidectomy are **medically appropriate** for the following indications:
   a. treatment of OSA; **or**
   b. to correct an upper airway obstruction that prohibits the use of CPAP/BiPAP.

C. Radiofrequency Ablation or Somnoplasty of Palatal Tissues is **not medically necessary** for the treatment of OSA.

D. Laser-assisted Uvulopalatoplasty (LAUP) is **not medically necessary** for the treatment of OSA.

E. Expansion Sphincter Pharyngoplasty/Expansion Sphincteroplasty (ESP) is **investigational.**

F. Injection Snoreplasty:

1. Injection Snoreplasty is **not medically necessary** for the treatment of snoring alone.
2. Injection Snoreplasty is **investigational** for the treatment of OSA.

G. Cautery-Assisted Palatal Stiffening Operation (CAPSO):

1. CAPSO is **not medically necessary** for snoring alone.
2. CAPSO is **investigational** for the treatment of OSA.

H. Palatal Implant System (e.g., Pillar Palatal Implant):

1. Palatal Implant Systems are **not medically necessary** for snoring alone.
2. Palatal Implant Systems are **investigational** for the treatment of OSA.

IV. Lower Airway Surgery

A. Jaw Realignment Surgery (e.g., inferior sagittal mandibular osteotomy, genioglossal advancement, hyoid myotomy and suspension, maxillomandibular osteotomy and advancement)*:*

1. Jaw realignment surgery is **medically appropriate** for the treatment of OSA in individuals who meet the criteria for UPPP, as stated in Policy Statement III.A.

B. Radiofrequency Ablation or Somnoplasty of the Base of the Tongue is **not medically necessary** for the treatment of OSA.

C. Tongue Suspension Suture Systems (e.g., AIRvance [formerly known as the Repose System], Encore System) are **investigational** for the treatment of OSA.

V. Hypoglossal Nerve/Upper Airway Stimulation

A. The approved United States Food and Drug Administration (FDA) hypoglossal nerve upper airway stimulation (e.g**.**, Inspire II Upper Airway Stimulation system, Inspire 3028 System for Upper Airway Stimulation (UAS) Therapy) device is **medically appropriate** for the treatment of moderate-to-severe OSA, when **ALL** the following criteria are met for each listed age group:

1. Adult ($\geq$ 18 years):

a. AHI $\geq$ 15 and $\leq$ 100;

b. $\leq$ 25% central apneas and mixed apneas (e.g., AHI and apneas confirmed with a in facility or attended polysomnography);

c. documentation of failure or inability to use or tolerate CPAP (e.g., residual AHI ≥ 15 or failure to use CPAP ≥ 4 hours per night for ≥ 5 nights per week);

d. documentation of all previous treatment measures and why they have been unsuccessful;

e. absence of complete concentric collapse of the soft palate; **and**

f. Body Mass Index (BMI) < 40km/m2;

2. Adolescents or young adults (aged 13 to 18 years) with Down Syndrome:

a. AHI > 10 and less than ≤ 50;

b. ≤ 25% central or mixed apneas;

c. are either contraindicated for adenotonsillectomy or do not respond effectively to the procedure;

d. do not have complete concentric collapse at the soft palate level on drug induced sleep endoscopy;

e. Body Mass Index ≤ 95th percentile for age;

f. have either a tracheotomy or have been confirmed to fail, or cannot tolerate, PAP therapy despite attempts to improve compliance; **and**

g. have followed standard of care in considering all other alternative/adjunct therapies.

B. Upper airway stimulation therapy is **contraindicated** when the individual:

a. has any condition or procedure that would affect neurological control of the upper airway;

b. is unable or does not have the necessary assistance to operate the sleep remote;

c. is pregnant or plans to become pregnant;

d. has an implantable device that may have unintended interactions with the upper airway stimulation system (e.g., Inspire system).

C. Hypoglossal nerve/upper airway treatment of OSA that does not meet the above listed criteria in PS V.A. or B. is considered **investigational**.

VI. Surgical treatment for snoring without polysomnographic evidence of OSA is considered **not medically necessary**.

VII. Cardiac pacing or atrial overdrive pacing is **investigational** for the treatment of OSA.

VIII. Device Repair

A. Repair of a medically necessary device or components not under warranty will be considered **medically appropriate** when the following criteria are met:

1. Physician documentation includes **ALL** the following:

a. date of device implantation/initiation;

b. manufacturer warranty information, if applicable;

c. attestation that the individual has been compliant with the use of device and will continue to benefit from the use of device;

2. The device is no longer functioning adequately; and **BOTH** of the following criteria are met:

a. inadequate function interferes with activities of daily living; **and**

b. repair is expected to make the equipment fully functional (as defined by manufacturer).

B. Repair of equipment damaged due to the individual neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage.**

RELATED POLICIES

Corporate Medical Policy

1.01.06 Positive Airway Pressure Devices CPAP, BIPAP, APAP, and Noninvasive Positive Pressure Ventilators (NIV)

1.01.07 Medical Management Obstructive Sleep Apnea (OSA)

7.01.05 Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy

7.01.99 Sinus Excision/Destruction, Implants, and Repair

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Surgery is not the first treatment of choice for OSA. It is reserved for individuals who have failed all forms of medical management of OSA, or are intolerant of CPAP, BiPAP, or oral appliances.

II. In severe OSA disease, surgery may not be curative, and follow-up studies may be warranted post-operatively.

III. For those individuals who have been found to have multiple levels or anatomical sites (e.g., hypopharyngeal, retropalatal, and/or retro lingual) of OSA on clinical evaluation, a simultaneous combination of surgical procedures may be appropriate for the best surgical outcome and to minimize operative risk. Nasal surgery is not considered part of a multi-level surgery to correct OSA. If a nasal obstruction precludes the use of CPAP, then nasal surgery to allow the use of CPAP should be performed first.

DESCRIPTION

Obstructive sleep apnea (OSA) is the cessation of airflow through the nose and mouth for at least 10 seconds with a respiratory effort noted and is usually associated with a reduction in blood oxygen

saturation. Features of OSA include daytime somnolence, disordered sleep, and a variety of clinical symptoms. It is also common to find decreased motor and perceptual skills while awake, which correlates with the severity of hypoxia during sleep. The syndrome is most common in middle-aged, obese, male smokers.

In individuals with OSA, the normal pharyngeal narrowing is accentuated by anatomic factors, such as a short neck, elongated palate and uvula, or large tonsillar pillars with redundant lateral pharyngeal wall mucosa. OSA may also be associated with a wide variety of craniofacial abnormalities, including micrognathia, retrognathia or maxillary hypoplasia.

When anatomical obstructions exist, surgical interventions are used. Obstruction can occur at several different locations along the airway, and in specific circumstances, combined surgical procedures can offer a higher overall success rate than one single procedure alone. Due to the complexity of airway narrowing or collapse during sleep, one surgical procedure may not eradicate the person's sleep apnea. Procedures such as septoplasty, nasal turbinectomies or nasal polypectomies may be indicated for correction of nasal airway obstruction, their role in treating multi-level OSA is very limited.

When individuals with OSA are not able achieve benefit with non-invasive positive pressure therapy (PAP) or fail the gold standard of treatment in the form of CPAP, a second-line treatment may be a surgical option.

The goal of surgery is to enlarge the airway and prevent airway collapse and oxygen desaturation, to prevent the clinical symptoms of OSA: excessive daytime sleepiness, impaired cognition, and mood disorders. Surgery is site-specific, performed to enlarge a certain portion of the airway.

Types of Nasal Surgery

- Septoplasty corrects a deviated septum, which may obstruct the nasal airway.
- Turbinate reduction reduces the size of one of the three turbinate in each nostril, which can improve the size of the nasal airway. The surgery may be performed with lasers, cautery, or radiofrequency ablation.
- Polypectomy removes nasal polyps that obstruct the nasal airways.

Upper Airway Surgery

- Uvulopalatopharyngoplasty (UPPP) involves the removal of the uvula and trimming of the lower edge of the soft palate. The surgery may include several technical variations. All techniques include the basic UPPP procedure, but often additional surgery is performed, such as tonsillectomy. UPPP with inferior sagittal osteotomy with hyoid suspension is one variation proposed to improve the surgical outcome.
- Radio-frequency ablation of soft palate tissue, or somnoplasty system, uses a device consisting of an electrosurgical (RF) generator and tissue-coagulating electrodes that ablate soft tissues in the palate or uvula.
- Laser-assisted uvulopalatoplasty (LAUP) involves the progressive removal of the back edge of the palate and reduction in the size of the uvula. It is most frequently performed with a carbon

dioxide laser and is typically performed over several surgical sessions in an outpatient setting.

- Expansion sphincter pharyngoplasty/expansion sphincteroplasty (ESP) is a modification of a UPPP in which the lateral pharyngeal wall is stiffened to prevent collapse. ESP consists of a tonsillectomy, expansion pharyngoplasty, rotation of the palatopharyngeal muscle, partial uvulectomy, and closure of the anterior and posterior tonsillar pillars.
- Tonsillectomy and adenoidectomy are, respectively, procedures to remove enlarged tonsils, which may narrow the width of the upper airway, and the adenoids, which are at the back of the nose and may obstruct the nasal airway. Removal of tonsils and adenoids is performed most often in children with sleep apnea. Adenoids usually shrink with age and only rarely require removal in adults.
- Injection snoreplasty involves the injection of a sclerosing agent (tetradecyl sulfate/Sotradecol) into the soft palate, which causes scarring and subsequent stiffening of the soft palate. This is thought to reduce the flutter of the soft palate, which is the cause of primary snoring.
- Cautery-assisted palatal stiffening operation (CAPSO) is a procedure in which electrocautery is utilized to remove a portion of the soft palate and uvula. It is carried out under local anesthesia, on an outpatient basis.
- Palatal implant system involves insertion of three narrow bands of braided polyester under the skin of the soft palate using a delivery tool. The implant has been proposed for the treatment of snoring and for the treatment of palate-related mild to moderate sleep apnea. Once in place, the implant stiffens the palate by mechanical means and induces a fibrotic response that incapsulates and secures the implants, further stiffening the palatal tissue. Palatal implants, though designed to be permanent, are removable. Implantation is carried out under local anesthesia.

<u>Lower Airway Surgery</u>

- Jaw realignment surgery (e.g., inferior sagittal mandibular osteotomy, genioglossal advancement, hyoid myotomy and suspension, maxillomandibular osteotomy and advancement) is a more aggressive surgical procedure than UPPP. It has been used to relieve obstruction in OSA individuals who meet the criteria for UPPP.
- A tongue suspension suture system (e.g., Airvance, Medtronic, Inc) involves preventing the tongue from falling back during sleep. The Airvance System uses a titanium screw in the chin, which is attached to a permanent stitch through the tongue to pull it forward. The Encore System is similar to the Airvance System but creates a suture loop within the tongue without having to create penetrations through the mucosal surface of the tongue.
- Radiofrequency ablation, or Somnoplasty System, uses a device consisting of an electrosurgical (RF) generator and tissue-coagulating electrodes that ablate soft tissues, creating volumetric tissue reduction of the tongue.

<u>Surgical Bypass of the Airway</u>

- A tracheostomy bypasses the narrow segments of the airway that cause obstruction and creates

an opening in the neck that allows the individual to breathe unobstructed at night. This is done in severe, life-threatening cases of sleep apnea.

Hypoglossal Nerve/Upper Airway Stimulation

- Electrical stimulation of the hypoglossal nerve has been proposed as a method of maintaining upper airway patency by augmenting tone to the upper airway. The implant device, which consists of a pulse generator, a stimulation lead, and a sensing lead, is designed to detect the respiratory effort and maintain airway patency with mild stimulation of the hypoglossal nerve. Therapy settings are stored in the pulse generator and configured by the physician using an external programmer. The individual uses a remote to start therapy before going to sleep and to stop therapy when awakened. The sleep remote also provides the ability to pause therapy and to adjust stimulation amplitude within physician-defined limits.

Atrial Overdrive Pacing

- It has been found that bradycardia frequently occurs during episodes of apnea. Therefore, atrial overdrive pacing after implantation of a pacemaker has been proposed as a treatment to reduce the incidence of obstructive sleep apnea events.

SUPPORTIVE LITERATURE

Candidates for surgical options require appropriate selection. Factors to consider are the polysomnographic report, age, BMI, and objective upper airway evaluation measures.

Kent et al (2021) conducted a systematic review and meta-analysis to support the development of the American Academy of Sleep Medicine clinical practice guidelines on when to refer adults with OSA for surgical consultation. Findings show that surgical therapy (upper airway or bariatric surgery) is associated with clinically significant improvements in excessive daytime sleepiness, snoring, AHI, RDI, ODI, blood pressure and quality of sleep. The AASM guideline recommendations are based on a systematic review and meta-analysis of 274 studies of surgical interventions, including procedures such as Uvulopalatopharyngoplasty (UPPP), modified UPPP, MMA, tongue base suspension, and hypoglossal nerve stimulation (Kent et al 2021). The systematic review deemed most studies included data of low quality, consisting of mostly observational data.

LAUP studies have shown that a large proportion of patients post-operatively developed significant worsening of objective sleep parameters. Camacho et al (2017) conducted a systematic review and meta-analysis on the effectiveness and the outcomes of LAUP as a treatment for OSA. The review evaluated pre-and-post-operative outcomes such as AHI, oxygen saturation levels, and quality of life measurements. Twenty-three adult studies (717 patients) reported outcomes. LAUP reduced AHI by 32% among all participants. Individual participant data analyses demonstrated a 23% success rate (≥ 50% reduction in AHI and < 20 events/hour) and an 8% cure rate. A total of 44% of patients had worsening of their AHI after LAUP. Lowest oxygen saturation (LSAT) improved minimally. Recommendations suggest that LAUP should be performed with caution or not perform at all given the unfavorable results of study.

Snoreplasty and CAPSO are intended treatment therapies for snoring, and not for the treatment of OSA (Lee et al 2014). Most published studies on this treatment have been non-randomized,

observational studies with highly selected enrolled participants. These studies also fail to report long-term outcomes or recurrence rates.

The Pillar Palatal Implant received FDA approval for the treatment of snoring in 2003 and as a treatment for OSA in September 2004. There is insufficient peer-reviewed evidence to support the use of the Pillar implant as a treatment for OSA. The literature consists of small case series investigating its use for snoring. Studies with OSA patients had very small sample sizes and limited follow-up, and were vendor sponsored (Nordgard et al (2006); Friedman et al (2006)).

Many individuals with OSA also suffer from nocturnal bradycardia or tachyarrhythmias. It has been observed that, in some patients, the use of a pacemaker to increase the heart rate and cardiac function during sleep could also reduce the incidence of apneic episodes. Although a clinical study by Garrigue et al (2002) found that atrial overdrive pacing significantly reduced the number of episodes of central and obstructive sleep apnea, but these positive findings have not been validated in any of the newer, well-designed studies. Atrial overdrive pacing has not been found to reduce the number of apnea and/or hypopnea events in patients with OSA (Krahn et al (2006); Unterberg et al (2005); Luthje et al (2005); Simantirakis et al (2005); Pepin et al (2005)).

Upper airway stimulation (UAS) leads to significant reductions in the AHI, the ODI, and the ESS in older patients, despite higher age with multiple co-morbidities. Advanced age was not a limiting factor for surgical procedure or treatment outcomes. The main result of this study is a significant reduction of the AHI in younger and older subjects: 84% decrease in younger subjects and 80.8% decrease in older subjects where the AHI declined below a level of 15 events per hour (the generally accepted values that define mild sleep apnea). Furthermore, the level of daytime sleepiness also declined in 69.6% of younger and in 72% of older subjects where the value of ESS was below 10 points. (Zhu et al 2018).

The largest cohort study done to date, which focused exclusively on UAS therapy outcomes, consisted of a study of 47 patients, 30 of whom had undergone a previous surgery and 16 of whom had not suffered from moderate-to-severe OSA, but were surgical candidates for Hypoglossal Nerve Stimulation (HNS_ therapy). The study examined AHI and nadir oxyhemoglobin saturation (NOS) as measured by polysomnography; secondary measures included ESS. The study revealed an overall reduction in AHI by 90%, which translated to a success rate of 96% and cure rate of 81%. (Mahmoud et al 2018).

Patients with moderate-to-severe OSA and an inability to adhere to positive pressure therapy, who underwent HGNS, were compared to a historical cohort of patients who were intolerant of CPAP who underwent UPPP. Data included BMI, as well as pre- and post-implant AHI. UAS resulted in an approximately 90% reduction in AHI, while traditional airway surgery resulted in an approximately 30% reduction in AHI. In addition, 65% of the patients in the UAS cohort demonstrated a reduction in AHI from the moderate-to-severe range into the normal range (AHI < 5), compared to only 20% of the patients in the UPPP group. (Shah et al 2018).

Liu et al (2022) published a systematic review investigating HNS in adolescents with Down Syndrome and OSA. A total of nine studies were included with a follow up period ranging from two to 58 months; six studies had sample sizes fewer than ten patients. The largest of the included studies was

a prospective cohort study published by Yu et al (2022), which is summarized below. In an analysis that included 104 patients, AHI scores were significantly reduced in patients after HNS (mean AHI reduction, 17.43 events/h; 95% CI, 13.98 to 20.88events/h; p<.001). Similarly, in an analysis that included 88 patients, OSA-18 survey scores were significantly reduced after HNS (mean OSA-18 reduction, 1.67; 95% CI, 1.27 to 2.08; p<.001).

Yu et al (2022) reported on the safety and effectiveness of HNS in 42 adolescents with Down Syndrome and severe OSA (AHI of 10 events/h or greater). This was a single-group, multicenter, cohort study with a 1-year follow-up that included non-obese (BMI < 95%) children and adolescents aged 10 to 21 years who were refractory to adenotonsillectomy and unable to tolerate CPAP. Patients who were included had an AHI between 10 and 50 on baseline polysomnography (PSG); the mean baseline AHI was 23.5 (SD, 9.7). All patients included tolerated HNS without any intraoperative complications. The most common complication was tongue or oral discomfort or pain, which occurred in 5 (11.9%) patients and was temporary, lasting weeks or rarely, months. Four patients (9.5%) had device extrusion resulting in readmissions to replace the extruded device. At 12 months, there was a mean decrease in AHI of 12.9 (SD, 13.2) events per hour (95% CI, -17.0 to -8.7 events/h). At the 12-month PSG, 30 of 41 patients (73.2%) had an AHI of less than 10 events/h, 14/41 patients (34.1%) had an AHI of less than 5 events/h, and 3/41 patients (7.3%) had an AHI of less than 2 events/h. There was also a significant improvement in quality-of-life outcomes. The mean improvement in the OSA-18 total score was 34.8 (SD, 20.3;95% CI, -42.1 to -27.5) and the ESS improved by 5.1 (SD, 6.9; 95% CI, -7.4 to -2.8).

Alrubasy et al (2024) evaluated the efficacy of Apnex, Inspire, and ImThera HNS devices in changing the severity of OSA in adults (> 18). The efficacy of each device was assessed individually, and the reported outcomes were analyzed at short-term (≤ 1 year) and long term (> 1 year) intervals. Data was based on a total of 549 middle aged (55 ± 9.2) overweight (BMI=29 ± 3.9) individuals. The Inspire device significantly reduced the AHI by -20.14 events/hour (h) in the short term and -15.91 events/h in the long term. ODI decreased by -14.16 events/h (short term) and -12.95 events/h (long term). Patient-reported outcomes showed decreased ESS scores by -5.02 (short term) and -4.90 (long term) and FOSQ scores by 3.58 (short term) and 3.28 (long term). The Apnex device and the ImThera devices featured similar improvements but to a lesser extent. No significant differences in efficacy were observed among the three devices. Study findings were consistent with previous meta-analyses examining the effects of HNS on OSA.

Kim et al (2023) compared HNS to other OSA treatments in a systematic review and meta-analysis. Studies included measured polysomnography parameters and assessed sleep apnea-related quality of life (Epworth Sleepiness Scale (ESS)) both before and after HNS, and compared these outcomes with control, CPAP, or airway surgery (uvulopalatopharyngoplasty, expansion sphincter pharyngoplasty, or tongue base surgery) groups. A total of 10 studies with 2209 patients (mean BMI ≤ 30 kg/m2 in every study) who were treated with HNS or alternative interventions. HNS improved post-treatment AHI < 10 and < 15 events/hour compared with other surgical options including uvulopalatopharyngoplasty, expansion sphincterpharyngoplasty, or tongue-based surgery (odds ratio [OR]; 5.33;95% CI, 1.21 to 23.42).

ImThera Medical Targeted Hypoglossal Neurostimulation Study #3 (THN3) investigated the efficacy

and safety of targeted HNS of the proximal hypoglossal nerve in individuals with moderate-to-severe OSA (AHI 20-60 events per hour) and a BMI of 35 kg/m2 or less (Schwartz et al. 2023). This was a multicenter, randomized trial where all individuals (N=138) were implanted with the HNS system (aura6000; ImThera Medical) and randomly assigned 2:1 to HNS device activation at one or four months after implant for the treatment and control groups, respectively. Efficacy was measured at month four, and after 11 months of therapy (study months 12 and 15 for treatment and control groups, respectively). The study included mostly males (86.2%) and Caucasian individuals (91.3%). The results demonstrated that at month four, the treatment group had significantly better outcomes compared to the control group for AHI and oxygen desaturation index (ODI) scores. After 11 months of active therapy, the difference between the treatment and control groups was not statistically significant for AHI (RR, -7.5; 95% CI, -16 to 1.4) but remained significant for ODI (RR, 10.4; 95% CI, 1.6 to 18.8). The authors noted that the results should only be applied to individuals with moderate to severe OSA and a BMI of 35 kg/m2 or less.

Woodson et al (2024) published the DREAM study, which aimed to evaluate the safety and efficacy of a novel bilateral hypoglossal nerve stimulation device (HNSBL), the Genio device. Adult patients with moderate-to-severe obstructive sleep apnea who refused, failed, or did not tolerate positive airway pressure therapy underwent implantation and nightly use of the Genio system. The Genio system was implanted in 113 participants. Eleven serious adverse events occurred in ten (8.7%) participants. AHI and oxygen desaturation index responses were achieved in 63.5% (73/115, P = .002) and 71.3% (82/115, P < .001), respectively. Secondary endpoint analysis revealed significant changes in mean AHI (218.3 ± 11.8 events/h, P < .001), oxygen desaturation index (217.7 ± 14.6 events/h, P < .001), and sleep time with blood oxygen saturation less than 90% (6.9 ± 10.7%, P < .001). The study design had several limitations including a small sample size, homogeneous study sample, industry sponsorship and lack of follow up or study completion by 27 participants.

PROFESSIONAL GUIDELINE(S)

National Institute for Health and Care Excellence 2017 recommendation states that HNS for moderate to severe obstructive sleep apnea should only be used with special arrangements for clinical governance, in clinical trials, stating the evidence on the safety and efficacy of the HNS is limited in quantity and quality.

The AASM (2021) strongly recommends that clinicians discuss a referral to a sleep surgeon with adults with OSA and body mass index (BMI) < 40 kg/m2 who are intolerant or unaccepting of PAP. The AASM makes a conditional recommendation that clinicians discuss referral to a sleep surgeon with adults with OSA, BMI < 40 kg/m2, and persistent inadequate PAP adherence due to pressure-related side effects. The available data (very low-quality), suggests that upper airway surgery has a moderate effect in reducing minimum therapeutic PAP level and increasing PAP adherence. In adults with OSA and obesity (class II/III, BMI > 35) who are intolerant or unaccepting of PAP, the AASM strongly recommends discussion of referral to a bariatric surgeon, along with other weight-loss strategies.

The American Academy of Otolaryngology - Head and Neck Surgery (AAO-HNS; 2021) position statement supports surgical management of OSA when part of a comprehensive approach in the

medical and surgical management of adults with OSA. Approved treatments include:

- Tracheostomy
- Nasal and pharyngeal airway surgery
- Tonsillectomy and adenoidectomy
- Palatal advancement
- UPPP
- Genioglossal advancement
- Hyoid myotomy
- Midline glossectomy
- Tongue suspension
- Maxillary and mandibular advancement
- Hypoglossal nerve stimulation as an effective second-line treatment of moderate-to-severe OSA.

According to the 2021 American Academy of Sleep Medicine (AASM) clinical practice guidelines, PAP therapy is strongly recommended as the first-line treatment for adults with OSA, especially those experiencing excessive daytime sleepiness. The guidelines support initiating PAP therapy using either auto-adjusting PAP (APAP) at home or in laboratory titration and recommend ongoing treatment with CPAP or APAP. The guidelines highlight that the clinical effectiveness of PAP therapy may be limited for individuals who struggle with adherence or do not experience sufficient therapeutic benefit. In such situations, alternative treatment options including surgical interventions may be more suitable, depending on the individual's specific circumstances and needs.

The AASM holds the position that while home sleep apnea testing (HSAT) is appropriate for diagnosing OSA in select adult populations, in laboratory PSG remains the preferred standard for more complex clinical scenarios, particularly when:

- Precise measurement of the Apnea-Hypopnea Index (AHI) is required;
- Exclusion of central sleep apnea is clinically important; or
- When advanced therapies such as HNS (e.g., Inspire therapy) are being considered.

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates sleep devices and appliances as medical devices. All sleep devices and appliances including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Dec 11]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 Dec 11]

On April 30, 2014, the FDA granted pre-market approval for the Inspire Upper Airway Stimulation (UAS) system (Inspire Medical Systems) for use in treating a subset of individuals, aged 22 years and older, with moderate-to-severe obstructive sleep apnea (AHI of 20 to 65) who have failed or could not tolerate CPAP treatments, who do not have complete concentric collapse at the level of the soft palate and a body mass index (BMI) less than 32.

In June 2023, the FDA expanded indications for Inspire UAS system. The update increased the upper limit of the AHI to 100 events per hour from 65 and raised the BMI warning from 32 to 40. The FDA lowered the age to 18 years old for individuals with moderate to severe OSA. The FDA added indications for pediatric individuals aged 13-18 years old with Down Syndrome and who have an AHI greater than 10 and less than 50. Inspire Medical Systems, Inc. [Internet] [accessed 2025 Dec 11] Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130008S090A.pdf

On August 8, 2025, the FDA granted premarket approval for the Genio system for a subset of patients who meet specific criteria.

The FDA defines positive airway pressure (PAP) failure as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage), and PAP intolerance is defined as:

1. Inability to use PAP (greater than five (5) nights per week of usage; usage defined as greater than four (4) hours of use per night); or
2. Unwillingness to use PAP (for example, an individual returns the PAP system after attempting to use it).

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
21141-21155, 21193-21206, 21244	Jaw realignment surgery (code ranges)
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
30620	Septal or other intranasal dermatoplasty (does not include obtaining graft)
31600	Tracheostomy, planned (separate procedure)

Code	Description
41512 (E/I)	Tongue base suspension, permanent suture technique
41530 (NMN)	Submucosal ablation of the tongue base, radiofrequency, one or more sites, per session
42145	Palatopharyngoplasty (e.g., uvulopalatopharyngoplasty, uvulopharyngoplasty)
42820	Tonsillectomy and adenoidectomy; younger than age 12
42821	Tonsillectomy and adenoidectomy; age 12 or over
64568	Open implantation cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
64582	Open implantation of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
64583	Revision or replacement of hypoglossal nerve neurostimulator array and distal respiratory sensor electrode or electrode array, including connection to existing pulse generator
64584	Removal of hypoglossal nerve neurostimulator array, pulse generator, and distal respiratory sensor electrode or electrode array
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95976	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95977	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex cranial nerve neurostimulator pulse generator/transmitter programming by

Code	Description
	physician or other qualified health care professional

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HCPCS Codes

Code	Description
C1823	Generator, neurostimulator (implantable), non-rechargeable, with transvenous sensing and stimulation leads
C9727 (E/I)	Insertion of implants into the soft palate; minimum of three implants
S2080 (NMN)	Laser-assisted uvulopalatoplasty (LAUP)

ICD10 Codes

Code	Description
F51.8	Other sleep disorders not due to a substance or known physiological condition
G47.00	Insomnia, unspecified
G47.10	Hypersomnia, unspecified
G47.20	Circadian rhythm sleep disorder, unspecified type
G47.30-G47.39	Sleep apnea (code range)
G47.69	Other sleep related movement disorders
G47.8-G47.9	Other and unspecified sleep disorders (code range)

REFERENCES

Algethami MR, et al. Perception of surgical treatments for obstructive sleep apnea among sleep medicine physicians: A cross-sectional study. J Family Med Prim Care. 2020 Aug 25;9(8):4401-4405.

Alrubasy WA, et al. Hypoglossal nerve stimulation for obstructive sleep apnea in adults: An updated systematic review and meta-analysis. Respir Med. 2024 Nov-Dec; 234:107826.

American Academy of Otolaryngology-Head and Neck Surgery [Internet]. Nasal surgery and OSAS. Position statement. [Updated 2021 Apr 22; accessed 2025 Dec 11]. Available from: https://www.entnet.org/resource/position-statement-nasal-surgery-and-osas/

American Academy of Otolaryngology-Head and Neck Surgery. [Internet] Position statement: hypoglossal nerve stimulation for treatment of obstructive sleep apnea (OSA). [Updated 2021 Apr 22; accessed 2025 Dec 11]. Available from: https://www.entnet.org/resource/position-statement-hypoglossal-nerve-stimulation-for-treatment-of-obstructive-sleep-apnea-osa

American Academy of Otolaryngology-Head and Neck Surgery. [Internet]. Surgical management of

obstructive sleep apnea. Position statement. [Updated 2021 Apr 22; accessed 2025 Dec 11]. Available from: https://www.entnet.org/resource/position-statement-surgical-management-of-obstructive-sleep-apnea/

American Academy of Otolaryngology – Head and Neck Surgery. [Internet]. Tongue suspension. Position statement. [Updated 2021 Apr 22; accessed 2025 Dec 11]. Available from https://www.entnet.org/resource/position-statement-tongue-suspension/

American Academy of Otolaryngology-Head and Neck Surgery [Internet]. Uvulopalatopharyngoplasty. Position statement. [Updated 2021 Apr 22; accessed 2025 Dec 11]. Available from http://www.entnet.org/node/896

American Academy of Sleep Medicine. [Internet]. Practice parameters for the use of laser-assisted uvulopalatoplasty. An update for 2000. [accessed 2025 Dec 11] Available from: https://aasm.org/resources/practiceparameters/pp_uvulopalatoplasty.pdf

Bestourous D, et al. Adverse events associated with the Inspire implantable hypoglossal nerve stimulator: A MAUDE database review. Am J Otolaryngol. 2020 Nov-Dec;41(6):102616.

Braun M, et al. Patient-reported outcomes with hypoglossal nerve stimulation for treatment of obstructive sleep apnea: a systematic review and meta-analysis. Eur Arch Otorhinolaryngol. 2023 Oct;280(10):4627-4639.

Camacho M, et al. Laser-Assisted uvulopalatoplasty for obstructive sleep apnea: a systematic review and meta-analysis. Sleep. 2017 Mar 1;40(3).

Caples SM, et al. Use of polysomnography and home sleep apnea tests for the longitudinal management of obstructive sleep apnea in adults: an American academy of sleep medicine clinical guidance statement. J Clin Sleep Med. 2021 Jun 1;17(6):1287-1293.

Friedman M, et al. Patient selection and efficacy of pillar implant technique for treatment of snoring and obstructive sleep apnea/hypopnea syndrome. Otolaryngol Head Neck Surg. 2006 Feb;134(2):187-96.

Kang KT, et al. Effect of sleep surgery on blood pressure in adults with obstructive sleep apnea: A systematic review and meta-analysis. Sleep Med Rev. 2022 Apr:62:101590.

Kent D, et al. Referral of adults with obstructive sleep apnea for surgical consultation: an American Academy of Sleep Medicine systematic review, meta-analysis, and GRADE assessment. J Clin Sleep Med. 2021 Dec 1;17(12):2507-2531.

Kim DH, et al. Comparative effectiveness of hypoglossal nerve stimulation and alternative treatments for obstructive sleep apnea: a systematic review and meta-analysis. J Sleep Res. May 2024; 33(3): e14017.

Krahn AD, et al. Physiologic pacing in patients with obstructive sleep apnea: a prospective, randomized crossover trial. J Am Coll Cardiol 2006 Jan 17;47(2):379-83.

Lee LA, et al. Comparative effects of snoring sound between two minimally invasive surgeries in the treatment of snoring: a randomized controlled trial. PLoS One. 2014 May 9;9(5):e97186.

Liu P, et al. Hypoglossal nerve stimulation in adolescents with down syndrome and obstructive sleep apnea: a systematic review and meta-analysis. Front Neurol. 2022 Oct; 13:1037926.

Luthje L, et al. Atrial overdrive pacing in patients with sleep apnea with implanted pacemaker. Am J Respir Crit Care Med 2005 Jul 1;172(1):118-22.

Mahmoud AF, et al. Outcomes of hypoglossal nerve upper airway stimulation among patients with isolated retropalatal collapse. Otolaryngology– Head and Neck Surgery. 2019;160(6):1124–1129.

National Institute for Health and Care Excellence. [Internet]. Hypoglossal nerve stimulation for moderate to severe obstructive sleep apnoea (IPG598). 2017 Nov 22 [accessed 2025 Dec 11]. Available from: https://www.nice.org.uk/guidance/ipg598/chapter/1-Recommendations

Neruntarat C, et al. Barb reposition pharyngoplasty versus expansion sphincter pharyngoplasty: a meta-analysis. Laryngoscope. 2021 Jun;131(6):1420-1428.

Nordgard S, et al. One-year results: palatal implants for the treatment of obstructive sleep apnea. Otolaryngol Head Neck Surg. 2007 May;136(5):818-22.

Pepin JL, et al. Overdrive atrial pacing does not improve obstructive sleep apnea syndrome. Eur Resp J .2005 Feb;25(2):343-7.

Rodriguez-Lara F, et al. Advances in the use of hypoglossal nerve stimulator in adolescents with Down Syndrome and persistent obstructive sleep apnea-a systematic review. Ann Otol Rhinol Laryngol. 2024 Mar;133(3):317-324.

Schwartz AR, et al. Targeted hypoglossal nerve stimulation for patients with obstructive sleep apnea: a randomized clinical trial. JAMA Otolaryngol Head Neck Surg. 2023 Jun 1;149(6):512-520.

Shiffman HS, et al. Invasive combined Nd: YAG and Er: YAG laser-assisted uvulopalatoplasty for treatment of obstructive sleep apnea. Photobiomodul Photomed Laser Surg. 2021 Aug;39(8):550-557.

Simantirakis EN, et al. Atrial overdrive pacing for obstructive sleep apnea-hypopnea syndrome. NEJM. 2005 Dec 15;353(24):2568-77.

Unterberg C, et al. Atrial overdrive pacing compared to CPAP in patients with obstructive sleep apnoea syndrome. Eur Heart J. 2005 Dec;26(23):2568-75.

U.S. Food & Drug Administration Inspire Upper Airway Stimulation – P130008/S090. [Internet] [Updated 2023 Jul 13; accessed 2025 Dec 11]. Available from: https://www.fda.gov/medical-devices/recently-approved-devices/inspire-upper-airway-stimulation-p130008s090

Woodson TB, et al. Bilateral hypoglossal nerve stimulation for obstructive sleep apnea: a nonrandomized clinical trial. J Clin Sleep Med. 2025 Nov;21(11):1883-1891.

Yu PK, et al. Evaluation of upper airway stimulation for adolescents with down syndrome and obstructive sleep apnea. JAMA Otolaryngol Head Neck Surg. 2022 Jun;148(6): 522-528.

SEARCH TERMS

Airvance, Atrial overdrive pacing, Aura6000 System, CAPSO, Encore, HGNS, Hypoglossal Nerve

Stimulation, Inspire II Upper Airway Stimulation System, LAUP, Pillar, Repose, Snoreplasty, Somnoplasty, UPPP

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Surgical management of obstructive sleep apnea is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

Policy/Procedure Name: Sylvant (siltuximab) **Control Number: 1350/20.000586**

Disclaimer Notice

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Background

Castleman disease is a rare blood disease defined by enlarged lymph nodes with a particular appearance when reviewed under the microscope and a broad range of symptoms and laboratory findings. Castleman disease is first classified based on the number of regions of enlarged lymph nodes that have these abnormal features. Unicentric Castleman disease (UCD) involves a single region of enlarged lymph nodes whereas multicentric Castleman disease (MCD) involves multiple regions of enlarged lymph nodes and body-wide inflammation. People with MCD often develop drenching night sweats, fatigue, unexplained weight loss, rash, fevers, shortness of breath, or swelling. The inflammation can take the form of blood count abnormalities, fluid accumulation in the legs, lungs, or abdomen, rash, kidney failure, or other blood test abnormalities.

A 2014 study estimated an incidence of 6500-7700 cases/year of CD in the United States, with approximately 75% estimated to have unicentric disease and the remaining 25% to be split between HHV-8-associated MCD or HHV-8-negative/iMCD. However, more recent data from a 2022 study estimated that 40% of incident cases are UCD and 50% are idiopathic MCD (iMCD). The prevalence of iMCD is estimated at 6.9-9.7 cases per million in the US.

Although all subtypes of Castleman disease have had reports of cases with elevated levels of interleukin 6 (IL-6), IL-6 is not elevated or the pathologic driver in all cases. However, IL-6 does appear to drive symptomatology in idiopathic (non-HHV-8) MCD (iMCD), with anti-IL-6 therapy showing effective symptom reduction and lymph node shrinking in some patients.

Sylvant (siltuximab) is an IL-6 antagonist and is the only FDA-approved agent for treatment of iMCD. For patients with severe disease manifestations, chemotherapy and high-dose corticosteroids are recommended if the patient's disease progresses while on siltuxumab. Approximately half of iMCD patients do not improve with anti-IL-6 therapy. For these patients, there is no consensus standard of treatment though rituximab, sirolimus, ruxolitinib, adalimumab, and a combination of thalidomide/cyclophosphamide/dexamethasone have all been used.

Summary

Effective Date of Policy:	2/12/2026
Indications	Treatment of patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative
ICD10 Diagnosis Codes	D47.Z2
HCPCS Code	J2860
Availability	Single dose vial of 100 mg or 400 mg lyophilized powder
Duration	Initial: 1 year Continuation: 1 year

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy

Indication	Inclusion Criteria	Dosing Regimen
Indication Treatment of patients with multicentric Castleman's disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative ICD10: D47.Z2	• Must be prescribed by an oncologist or hematologist • Must have a diagnosis of Multicentric Castleman's disease (MCD) with pathological confirmation on biopsy of involved tissue AND • Must be human immunodeficiency virus (HIV) negative and human herpesvirus-8 (HHV-8) negative	• 11 mg/kg given over 1 hour by intravenous infusion every 3 weeks

Continuation Criteria

- Recertification will be for 1 year
- Further approval will require submission of documentation supporting the absence of disease progression (defined as increase in symptoms, radiologic progression, or deterioration in performance status)

Considerations

- Patient must have medical drug coverage administered by CDPHP.
- Prior authorization is obtained through the CDPHP pharmacy department.

References

		Updated	Accessed
1	Sylvant [prescribing information]. Recordati Rare Diseases Inc. Bridgewater, NJ	6/2024	1/2026
2	Castleman Disease. National Organization for Rare Disorders (NORD). Available at: https://rarediseases.org/rare-diseases/castlemans-disease/	5/2025	1/2026

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 2/12/2026

New: 2/2026

Revised	Reviewed

Revision Date	Changes Made

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

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POLICY NAME: TECHNOLOGY ASSESSMENT & POLICY DEVELOPMENT

POLICY EFFECTIVE DATE:	10/1/2025
Policy Control #:	1370/20.000407
Next Annual Review:	March 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

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DESCRIPTION

Technology assessment is the evaluation of a medical or behavioral health procedure, test, therapy, device, or pharmaceutical for safety and efficacy. CDPHP follows a technology review process to determine whether a technology, or new applications to an existing technology, is to be included in its benefit plan.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

- Experimental, Investigational, and Non-Standard Treatments, 1370/20.000152.
- Non-Covered Technologies, 1370/20.000444.
- Out of Network Care, 1370/20.000145.

Payment Policy:

- Mandated Benefits for State Funded Programs, 1550/20.000188

Pharmacy Policies:

- Pharmacy and Therapeutics Committee, Role & Function, 1350/20.000022.
- Prescription Drug Formulary, 1350/20.000033.

POLICY NAME: TECHNOLOGY ASSESSMENT & POLICY DEVELOPMENT

POSITION STATEMENT

procedures, pharmaceuticals, and devices. Published scientific evidence must demonstrate a procedure, pharmaceutical, or device is safe and efficacious otherwise it will not be considered eligible for coverage.

CDPHP utilizes **all** of the following criteria to reach decisions regarding eligibility for coverage of new medical and behavioral healthcare procedures, pharmaceuticals and devices, or for new applications to existing technologies:

1. The CDPHP provides systematic and timely review of evolving medical and behavioral health care technology must have final approval from government regulatory bodies.
   - This criteria applies to drugs, biological products, devices, diagnostic technologies, and any other product or procedure that must have final approval to market from the Food and Drug Administration or any other governmental body with authority to regulate the technology.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
   - The evidence should consist of high-quality scientific studies published in peer reviewed journals.
   - The evidence should demonstrate that the technology can measure or alter the physiological changes related to a disease, injury, illness, or condition. In addition, there should be evidence based on established scientific evidence that use of this service affects health outcomes.

3. The technology must improve the net health outcome.
   - The technology's beneficial effects on health outcomes must outweigh any harmful effects on health net outcomes.

4. The technology must be as beneficial as any established alternatives.
   - The technology should improve the net health outcome as much as, or more than, established standard alternative therapies.

5. The technology is not cosmetic in nature and is required for reasons other than convenience.

Technology Review Process

Technology assessment is performed in an ongoing process to evaluate new developments in medical and behavioral healthcare procedures, devices, and pharmaceuticals, as well as new applications to existing technology, to determine eligibility for coverage as non-investigational.

The review of current technology, and its applications, is conducted by the CDPHP technology

assessment team. The team consists of medical directors and medical policy manager(s) with additional appointees as directed. The medical policy manager(s) researches and compiles up-to-date information from computerized searches of the sources of evidence noted below, for review and consideration by the CDPHP technology assessment team. Board certified consultants in medicine and behavioral health may be utilized during the review process when additional expertise is needed regarding a newly emerging medical technology. Final determinations, as to whether a technology meets the above criteria, is based upon the professional assessment of the supporting evidence by the technology assessment team. In addition, the CDPHP medical director may conduct an assessment of a technology for a case specific review, utilizing the same sources of evidence in making the determination. Upon written approval by the CDPHP medical directors, the technology is presented for review, as appropriate, to the policy committee, utilization and management committee, and/or pharmacy and therapeutics committee. Outcomes of a technology assessment team decision may include the development of a new policy, or revision to an existing policy, to address a future covered benefit or to address non-coverage of a reviewed new technology.

Sources of Evidence

- Evidence published in peer-reviewed clinical and scientific literature.
- Opinions and evaluations from professional societies and associations (e.g., American Medical Association, American Psychiatric Association), National Specialty Societies (e.g., American College of Gynecology), consensus panels, or other technology evaluating bodies (e.g., Hayes, Inc., Blue Cross and Blue Shield Association Medical Advisory Panel [MAP]).
- Government agencies such as the U.S. Food and Drug Administration, Centers for Medicare and Medicaid Services, Agency for Healthcare Research and Quality, Center for Disease Control, National Institutes of Health, and the New York State Department of Health.
- Opinions from qualified board-certified consultants in medicine and behavioral health that are supported by scientific evidence.
- Regulatory compliance
- CDPHP physician workgroups.
- Contract language.
- Pharmacists/doctors of pharmacy
- Industry standards (e.g., other payer policies)

The CDPHP technology assessment team determines the effectiveness of the technology based upon scientific evidence demonstrated in published clinical research. Prospective, randomized, and controlled clinical trials are the gold standard of scientific evidence. CDPHP recognizes that this level of evidence is not available to guide treatment decisions for all patients with serious disease. The CDPHP technology assessment team will determine when presented evidence meets generally accepted standards to show that a proposed health service is safe and effective.

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POLICY NAME: TECHNOLOGY ASSESSMENT & POLICY DEVELOPMENT

CDPHP Policy Development

CDPHP develops policies relating to health technologies, such as medical, behavioral health and surgical procedures, pharmaceuticals, diagnostic and screening tests, alternative therapies, and medical devices based upon several decision variables including, but not limited to, the following:

- Efficacy and safety
- Experimental status vs. standard of care
- High risk
- High volume
- Issues of controversy
- Medical appropriateness
- Regulatory requirements
- Consistent with CDPHP preventive health and clinical practice guidelines
- Cost effectiveness

The CDPHP medical technology assessment team is responsible for determining the need for an external resource coordination policy, while the Pharmacy and Therapeutics Team is responsible for determining the need for a pharmacy policy. Addition of new policies, deletion of outdated policies, and revision of current policies will be based upon input from enrollees, providers, and staff, as well as current trends in medical treatment and review of current peer reviewed literature. All draft policies are presented to and reviewed by the policy committee with the exception of pharmacy policies which will be presented to and reviewed by the Pharmacy and Therapeutics committee. In addition, draft policies developed to address a new technology or a controversial service, or revisions made to an existing policy, may be sent out to clinicians in the CDPHP network for their expert critique and review.

The policy committee is a multi-disciplinary team consisting of representation from configuration, finance, government programs, member and provider services, utilization management, appeals, behavioral health, healthcare network strategy, business development, self-funded and strategic accounts, commercial sales, claims operation and special investigation unit. It is supported by provider consultants in medicine and behavioral health, and workgroups as needed, to lend clinical expertise to the review activities. After approval by the policy committee, the formal draft is presented to the utilization management committee for review and approval. This committee consists of practicing community physicians appointed by the CDPHP board of directors, who represent a cross section of primary care physicians and specialties from the CDPHP network. Minutes from these respective committees are reported to the quality management committee and board of directors for final approval.

The policy category will be noted on the last page of the policy in order to show the status of the policy after its annual review, as well as the date approved by the utilization management committee or pharmacy and therapeutics committee:

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POLICY NAME: TECHNOLOGY ASSESSMENT & POLICY DEVELOPMENT

- New
- Revised - changes made to existing published policy
- Reviewed - no changes made to existing published policy

Resource coordination and pharmacy policies are re-evaluated and updated, as necessary, on an annual basis. Policies may be reviewed prior to their scheduled review date if new scientific evidence that would alter the policy criteria becomes available sooner.

Notification to updates made to resource coordination, behavioral health and pharmacy policies are distributed by mail every other month and are also made available through the CDPHP secure physician interface at www.cdphp.com. An individual policy mailing is performed upon member or provider request, including for those providers who do not have fax, email, or internet access.

- New and revised policies will become effective no less than 90 days from date of distribution.
- Selected policies may be implemented in less than 90 days when allowed for, or not in conflict with, state regulations. For example, 90 days prior notice is not required where the change is required by law or regulation, or required as a result of changes in fee schedules, reimbursement methodology or payment policies established by a government agency, or by a change to a CPT code.

POLICY CONSIDERATIONS

CDPHP reserves the right to change CPT or HCPCS codes in an existing published policy when applicable without 90 days' notice.

The CDPHP technology assessment team will consider technology evaluation requests made by practitioners, or non-participating practitioners who have provided consultation in accordance with the CDPHP Resource Coordination Policy: *Out of Network Care, 1370/20.000145.*

The CDPHP technology assessment team will present a review of current technology literature to the utilization management committee on an as needed basis.

The technology assessment team will maintain files of all reviewed literature.

Decisions are documented in writing at the technology assessment meetings, and minutes are taken at the policy committee, utilization management committee, pharmacy and therapeutics committee meetings to document the date policy issues are discussed.

When necessary, a technology-specific policy will be established through the appropriate committees. Recommended benefit structure changes will be forwarded to the product development team for consideration.

POLICY NAME: TECHNOLOGY ASSESSMENT & POLICY DEVELOPMENT

EXCLUSIONS

CDPHP excludes coverage for any medical or behavioral health care procedure, pharmaceutical, or device that have been determined to be investigational, experimental, unproven, or not medically necessary.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy to include the following: Clinical criteria contained in the CDPHP resource coordination policies is consistent with general Medicare coverage guidelines, national coverage decisions (NCD), and written local coverage determinations (LCD) of New York State Medicare contractors. Coverage of services includes those covered by original Medicare. Additional coverage may be provided to enrollees above what is offered by original Medicare at the discretion of CDPHP.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy to include the following: Coverage of services contained in a CDPHP policy is consistent with the policy and billing guidance outlined in Medicaid Updates and Medicaid Management information System (MMIS) provider manuals in accordance with New York State Department of Health. Additional coverage may be provided to enrollees above what is offered by the State at the discretion of CDPHP.

SOURCES

1. Aubrey MD, Wade: Revising the TEC Criteria, Technoligica, Aug. 1998
2. Greer N; An Evidence Grading System for Technology Assessment Reports, Annual Meeting of International Society of Technology Assessment in Health Care, 1999;15:150.

3. Managed Care Law
4. Member Contract Language
5. National Committee for Quality Assurance: HP Standards and Guidelines. Section UM 10: Evaluation of New Technology, 2020.
6. Other Payors
7. U.S. Preventive Services Task Force. Guide to Clinical Preventive Services, 2nd ed. Alexandria, Virginia: International Medical Publishing, 1996.
8. NYS Managed Care Reform Bill (S.5472-a/A.8402.a)

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POLICY APPROVAL DATES

New:	04/97
Revised:	06/98, 08/99, 01/00, 03/01, 06/02, 04/03, 02/04, 12/04, 10/05, 10/06, 09/07, 05/08, 11/09, 05/10, 05/11, 09/11, 05/13, 05/15, 05/17, 01/19, 5/20, 5/21, 11/25
Reviewed:	05/09, 05/12, 05/14, 05/16, 05/18, 05/19, 5/22, 5/23, 5/24, 5/25, 3/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
9/1/2021	Updated departments that are currently part of the policy committee team
9/1/2020	Added reference to Mandated Benefits for State Funded Programs payment policy. Added statement regarding Medicaid Updates and MMIS Manual in the Select Plan/HARP section.

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: TEMPOROMANDIBULAR JOINT DISORDERS

POLICY EFFECTIVE DATE:	10/1/2023
Policy Control #:	1370/20.000062
Next Annual Review:	September, 2027

DISCLAIMER

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PROCEDURE CODES

20605, 20606, 21010, 21050, 21060, 21070, 21073, 21116, 21240, 21242, 21243, 21480, 21485, 21490, 29800, 29804

DESCRIPTION

Temporomandibular joint disease (TMJ) is defined as any abnormality in joint function that impairs mandibular mobility. Temporomandibular disorders may include internal derangement of the joint and degenerative joint disease. Common symptoms include clicking, grinding, pain or stiffness in the jaw, jaw locking open or closed, muscle spasm, displacement of the joint, and/or difficulty in opening the jaw wide.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

- Orthognathic Surgery, 1370/20.000274
- Physical Therapy, 1370/20.000057

POSITION STATEMENT

CDPHP administers benefits to **confirm a diagnosis** of temporomandibular joint disorder as follows:

- Initial evaluation and radiological procedures

POLICY NAME: TEMPOROMANDIBULAR JOINT DISORDERS

CDPHP administers benefits for the **treatment** of medical related TMJ demonstrated by any of the following conditions:

- Intracapsular pathology caused by systemic illness, such as rheumatoid arthritis or;
- Intracapsular pathology due to internal derangement, such as displacement of temporomandibular joint disc or;
- Documented history of trauma (TMJ related cases involving trauma must have documentation of symptoms occurring within 12 months of the trauma).

CDPHP does not administer benefits for the treatment of dental related TMJ disorders.

POLICY CONSIDERATIONS

The management of medical TMJ disorders includes non-surgical and surgical services as described below.

Non-Surgical Management

Non-surgical management is almost always the initial treatment approach to reduce pain and improve function. Examples of such therapy include:

- Pain management with analgesics or anti-inflammatory medicine.
- Modification of diet and joint activity.
- Intra-oral appliances such as removable splints (all study models are considered global to the surgical splint).
- Improvement of joint mobility with muscle relaxants, physical therapy, and exercises.
- Therapeutic injections (intra-articular and trigger point injections may be used when the above non-invasive treatments do not provide adequate symptom relief).

Surgical Management

CDPHP may provide coverage for the surgical treatment of TMJ disorder when an initial course of covered non-surgical medical treatment has failed to reduce the patient's pain or improve function. Examples of such surgery include, but are not limited to, the following:

- Open or closed reduction of TMJ dislocation or fracture
- Arthocentesis, arthroscopy, arthroplasty, and arthrotomy

Cases of TMJ disease involving intracapsular pathology will be reviewed on an *individual case basis* utilizing medical records to obtain the following clinical information:

- Patient history and non-invasive diagnostic examination.

- TMJ radiographs (transcranial radiographs), MRI, and/or other imaging reports as appropriate.

Cases of TMJ involving displacement of temporomandibular joint disc to include documentation of clinical information as stated above, as well as all of the following criteria:

- Sudden onset of symptoms.
- Documentation of functional limitation of joint range of motion or significant pain unresolved after course of conservative therapy.
- No prior history of temporomandibular joint dysfunction relating to bruxism or malocclusion.

Physical therapy (PT) and durable medical equipment utilized in the treatment of TMJ disorders caused by a documented history of trauma or systemic disease are subject to all terms and conditions of the contracted benefit for the same.

EXCLUSIONS

Any services or supplies related to the treatment of TMJ when it is dental in nature.

Jaw motion rehabilitation systems, such as Therabite or Dynasplint for the treatment of mobility conditions associated with TMJ disorder (E1700, E1701, E1702).

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy.

SOURCES

1. American Society of Temporomandibular Joint Surgeons, Guidelines for Diagnosis and Management of Disorders involving the Temporomandibular Joint and Related Musculoskeletal Structures, www.astmjs.org/guidelines.html
2. Contract Clarification
3. Brooks, S; Brand, J; Gibbs, SJ; Hollender, L; Lurie, A; Omnell, KA; Westesson, PL; White, S: Oraland Maxilofacial Radiology: Imaging on the Temporomandibular Joint. Oral Surgery, Oral Medicine, Oral Pathology, Oral Radiology and Endodontics, Vol. 83, No. 5, May 1997, pp. 609-618.
4. Hayes, Incorporated Directory: Passive Rehabilitation Therapy for Mandibular Hypomobility,

September 12, 2002. Updated search on 1/7/07.
5. Hayes, Incorporated Search & Summary Report: Jaw Dynasplint System for Treatment of Mandibular Hypomobility, April 7, 2016.
6. National Institute of Dental and Craniofacial Research, Temporomandibular Disorders (TMD) www.nidcr.nih.gov
7. National Institute of Health Consensus Statement, Management of Temporomandibular Disorders, http://consensus.nih.gov/1996/1996TemporomandibularDisorders018html.htm
8. National Institute Of Dental and Craniofacial Research, TMD: Temporomandibular Disorders, http://www.nidcr.nih.gov/HealthInformation/DiseasesAndConditions/TMDTMJ/TMD.htm
9. Other Payers

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POLICY APPROVAL DATES

New:	04/89
Revised:	04/90, 07/92, 08/94, 01/98, 06/99, 03/00, 04/00, 01/01, 08/01, 05/03, 12/04, 11/05. 09/09, 09/11, 09/14, 09/16, 9/23
Reviewed:	12/91, 01/93, 08/95, 09/96, 09/02, 03/04, 11/06, 10/07, 09/08, 09/10, 09/12, 09/13, 09/15, 09/17, 09/18, 09/19, 09/20, 9/21, 9/22, 9/24, 9/25, 11/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
10/1/2023	Added code 20606 to Procedure Codes section.

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POLICY NAME: TEMPOROMANDIBULAR JOINT DISORDERS

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MEDICAL POLICY

Medical Policy Title	**Temporomandibular Joint Disorders (TMJD)**
Policy Number	**11.01.17**
Current Effective Date	**January 1, 2027**
Next Review Date	**January 2028**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

Services related to myofascial pain dysfunction (MPD) are not addressed in this policy as they are rendered by a dentist and considered a dental benefit, rather than a medical benefit.

POLICY STATEMENT(S)

I. Surgical intervention for the treatment of temporomandibular joint disorder is considered **medically appropriate** when **ALL** of the following criteria (P.S. A. B. C. and D.) are met:

A. **ONE (1)** of the following definitions of functional deficit is documented:

1. Presence of pain or other physical deficit that interferes with activities of daily living; or
2. Impaired physical activity (e.g., loss of range of motion);

AND

B. Documentation demonstrates that conservative treatments have been exhausted, with a minimum of six (6) weeks of failed therapy, including dates and duration for **TWO (2) or MORE** of the following*:

1. Medication (e.g., NSAIDS, muscle relaxants or antidepressants);
2. Corticosteroid Injection;
3. Dietary modifications such as a soft diet;
4. Behavioral therapy; or
5. Physical therapy;

*Conservative therapy documentation is not required in the setting of recent trauma, dislocation, severe malocclusion, dental infection or abscess.

AND

C. Documentation includes reports from Magnetic Resonance Imaging (MRI) or Computed Tomography (CT) of the TMJ;

AND

D. The specific documentation requirements for the requested surgery type are met:

1. Arthrocentesis, Arthroscopic Lysis and Lavage, or Operative Arthroscopy (CPT 20605, 20606, 29804)
    a. Imaging reports confirm **any** of the following:
        i. anterior disc displacement with or without reduction;
        ii. disc adhesions;
        iii. synovitis/capsulitis; **or**
        iv. degenerative osteoarthritis; **and**
    b. Physical exam findings are supportive of diagnosis;
2. Open Joint Surgeries (e.g., Arthroplasty or arthrotomy, disc repair procedures, discectomy with or without replacement, condylectomy, discoplasty/disc plication, discectomy/meniscectomy) (CPT 21010, 21050, 21060, 21070, 21240, 21242)
    a. Persistent pain despite previous arthroscopic surgery; **and**
    b. Imaging reports confirm **any** of the following:
        i. internal derangement;
        ii. degenerative joint disease;
        iii. rheumatoid arthritis;
        iv. infectious arthritis;
        v. mandibular dislocation;
        vi. neoplasia;
        vii. ankylosis;
        viii. condylar hyper-or hypoplasia;
        ix. condylar osteolysis; **or**
        x. fracture;
3. Temporomandibular Joint Replacement (CPT 21243):
    a. Imaging reports demonstrate an alteration and degeneration of joint structures at both the bone (e.g., osteophytes, geodes, subchondral cysts) and disc level;
    b. Reduced oral aperture (less than 35mm); **and**
    c. Prior surgeries (i.e., arthroscopy or open) have failed.

RELATED POLICIES

Corporate Medical Policy

1.01.02 Continuous Passive Motion Device in the Home Setting

1.01.07 Medical Management of Obstructive Sleep Apnea

1.01.55 Electrical Stimulation for Pain and Other Medical Conditions

7.01.41 Surgical Management of Sleep Disorders

7.01.101 Balloon Dilation of the Eustachian Tube (BDET)

8.01.10 Prolotherapy

8.01.24 Therapies (Speech, Physical and Occupational)

11.01.03 Experimental or Investigational Services

Pharmacy Policy

Botulinum Toxin (Botox, Daxxify, Dysport, Myobloc, Xeoman)- Pharmacy 77

Viscosupplementation with Hyaluronic Acid- Pharmacy 75

POLICY GUIDELINE(S)

I. Coverage for dental-related services is **not** generally provided under medical contracts.

II. Coverage for all TMJD-related services, devices or appliances related to TMJD is contract dependent.

DESCRIPTION

The temporomandibular joint (TMJ) connects the jawbone to the skull, acting like a sliding hinge on either side of the skull. There are more than 30 conditions that cause pain and dysfunction in the jaw joint and the associated muscles that allow for movement. TMJ disorders specifically are broken into three different classes: myofascial pain-dysfunction (MPD) syndrome, internal derangement, and degenerative joint disease (DJD); however, diagnostic criteria are based on subjective findings and patients can fall into more than one class. The U.S. National Institutes of Health acknowledged in 2017 that there are no widely accepted standard tests to correctly diagnosis TMJ disorders.

MPD is considered the most common cause of TMJ pain and is thought to be a psychophysiologic disease that primarily involves the muscles of mastication. Services to treat MPD are rendered by a dentist, and are therefore, not addressed within this policy.

Internal derangement is defined as an abnormal relationship of the articular disc to the mandibular condyle, fossa, and articular eminence. The muscle spasm seen in this condition is in response to the dysfunction; spasm is not the primary problem, as with MPD.

DJD (osteoarthritis) is the organic degeneration of the articular surfaces within the TMJ. It is secondary to micro/macro trauma, infection, and meniscal malalignment.

Diagnosis is typically one of exclusion and requires a combination of physical exam, patient interview, and a review of dental records. Generally, diagnostic testing or imaging are reserved for patients with severe or chronic symptoms.

Patients may experience some or even all of the following symptoms: headaches (over the eye, in

the temples, behind the eyes, and at the base of the skull); general facial pain, and more specific pain directly in front of the ears; ear symptoms, including ringing, buzzing, and congestion; neck and shoulder pain; clicking or grating noises of the joint with movement; locking of the jaw; and pain with function. In severe cases, there can be functional disability, malnutrition, or airway compromise.

The main goals of treatment of TMJ disorder are to reduce or eliminate pain or joint noises, or both, and to restore normal mandibular function. TMJ disorder is a complex disorder with treatment of dependent upon identification of contributing conditions and behaviors, with first-line treatments being conservative in nature due to their low risk of potential side effects.

Arthrocentesis, Arthroscopic Lysis and Lavage

Arthrocentesis is considered a simple, minimally invasive surgery, where the joint space is not viewed, but rather incorporates the use of needles and irrigation to remove inflammatory causes of joint pain and/or to increase the mobility of the mandible by hydraulically removing present adhesions.

Operative Arthroscopy

Arthroscopy of the TMJ is a minimally invasive surgery performed under local anesthesia with sedation or general anesthesia. The joint space is viewed via fiber-optic camera (arthroscope) to diagnose and treat joint problems. The incision is small, and repairs are conducted utilizing thin surgical instruments.

Open Joint Surgeries

Open joint surgery requires a cut to be made in front of the ear, sometimes extending into the hairline to fully expose the jaw joint. It is typically used when needing to alter the shape of the joint (arthroplasty), when minimally invasive surgery was ineffective or for more advanced disease. Open surgery has an increased risk of causing damage to facial nerves and issues with hearing given the proximity to the joint.

Replacement of the Temporomandibular Joint (TMJ)

When conservative therapies have failed, it may be necessary to improve the function of a damaged joint by replacing the bone with a prosthetic. Today's U.S. Food and Drug Administration (FDA) approved joint prosthetics can be stock or custom made. The lower jaw portion of the prosthetic are typically manufactured from metal such as titanium, while the upper jaw portion of the prosthetic is made with ultra-high molecular-weight polyethylene either with or without titanium. Replacement of the TMJ is an open surgery with incisions required in front of the ear, extending to the hairline as well as below the jaw. It is also not without risk, including heterotropic ossification, infection, and chronic post-operative pain.

SUPPORTIVE LITERATURE

Non-Surgical Treatments

Yao et al (2023) conducted a systematic review and meta-analysis of randomized trials in an attempt to provide evidence-based guidelines for adult patients living with moderate chronic pain (4-6cm on a

10cm pain scale for greater than or equal to three months duration) secondary to TMD. This evidence was summarized into a recommendation by Busse et al (2023). The recommendation notes the necessity of the review given the number of interventions available for treatment, that individuals may be exposed to simple, conservative, and inexpensive treatments while others with similar sets of symptoms will be exposed to potentially invasive, irreversible, and costly treatments. As a result of the review, and the limited available evidence, the panel was only able to state confidence regarding the benefits of cognitive behavioral therapy augmented with relaxation or biofeedback, therapist-assisted jaw mobilization, and manual trigger point therapy for reduction in chronic pain severity related to TMJD (GRADE moderate to high certainty of evidence).

Surgical Treatments

Arthrocentesis of the TMJ was introduced in 1991 by Nitzan et al and its use for pain control has been supported by multiple randomized controlled trials (RCTs), systematic reviews of RCTs, as well as observational studies. (e.g., Grossman (2012), Kaneyama et al (2004), Nitzan et al (2001), Emshoff (2005), Carvajal et al (2000), Alpaslan (2003), Frost et al (2012)).

Thorpe et al (2023) conducted a systematic review comparing arthrocentesis versus conservative treatments for TMJD by focusing on joint pain and mouth opening at six-months following the intervention. Studies included in the review were required to meet the following criteria: prospective randomized controlled trial conducted on humans, patients had a history of reduced mouth opening and pain, study included at least one group treated with arthrocentesis and one undergoing conservative therapies, and patients were assessed both preoperatively at recalls for maximum mouth opening and presence of pain with pain assessed via visual analogue scale and allocation being conducted on a per-patient basis. The initial search provided 879 records, with 12 articles selected for full-text analysis, with only seven meeting inclusion criteria. A total of 489 patients were represented in the studies, 448 of which were assessed at the 6-month recall mark. A bias analysis demonstrated that only one study was at low risk of bias. A random-effects model was used for the meta-analysis. Based upon the analysis, authors concluded a statistically significant superiority for arthrocentesis in the improvement of maximal mouth opening and borderline statistical superiority for pain improvement at six-months but note that the confidence interval for pain reduction crossed over zero and that the marginal differences are unlikely to be clinically relevant. Additionally, there was no conservative treatment to be found superior to another.

Tang and colleagues (2025) conducted a systematic review with meta-analysis and trial sequential to compare arthrocentesis to conservative treatments for symptomatic TMJ with short, intermediate, and long-term outcomes of objective measurements, including maximum mouth opening, joint blocks and noises, protrusive and lateral mandibular movements and cost, as well as subjective measurements of joint pain, mandibular function and quality of life (QOL). The intervention group included TMJ arthrocentesis via any technique, with or without concomitant therapies or injections. The control group only consisted of conservative treatments of any kind. The primary study outcome was pain using a numeric scale. Only RCTs, prospective non-randomized controlled trials and retrospective cohort studies with a control group were allowed for inclusion, which resulted in 21 records suitable for inclusion. Of those 21 records, 16 were included in the qualitative and meta-analyses and five were included for the qualitative analyses only. For the primary outcome, for pain

reduction, arthrocentesis was superior to conservative therapy in terms of pain reduction at both short (1-3 months) and intermediate (6-12 months) follow up. Only one RCT reported on pain reduction of long-term follow up (median 6.2 years), Tang et al (2023), which found arthrocentesis was more effective in pain reduction (-10.23 [95% CI -17.86;-2.60], p= 0.009) when compared to conservative treatments. For secondary outcomes, in regard to maximum mouth opening, 11 of 15 studies included in the quantitative analysis demonstrated improvement over time in both the arthrocentesis and conservative treatment groups, while five showed improvements in only the arthrocentesis group. One study demonstrated no statistically significant improvement over time in both groups, with two not adequately reporting differences between pre-and post-operative analysis. Studies assessing outcomes of joint pain at rest, mandibular function, joint bocks and noises, lateral and protrusive movements quality of life and cost were considered too heterogeneous to include in a meta-analysis, but authors concluded that there is a general trend of an equal or superior effect of arthrocentesis when compared to conservative therapies.

Almeida and colleagues (2025) conducted a systematic review to evaluate the long-term quality of life (QOL) outcomes after TMJ replacement, focusing on functional impairment, complication profiles, and differences between custom and stock prosthesis across both adult and pediatric populations. Eligibility criteria included patients undergoing TMJ replacement for end-stage disease (e.g., osteoarthritis, rheumatoid arthritis, juvenile idiopathic arthritis, trauma, ankylosis, condylar resorption, neoplasm). Authors included studies with or without comparator groups as well as any of the following: pre- versus postoperative outcomes, stock versus custom device, or replacement versus other surgical treatment options. Pain reduction (measured by VAS score), functional recovery (measured by maximum interincisal opening [MIO]) and QOL were primary outcomes. Complication rates and the use of advanced technologies were secondary outcomes. Included in the review were randomized controlled trials (RCTs), prospective and retrospective cohort studies and case series with more than five patients. Two reviewers independently conducted a search and out of 950 identified records, 64 were included for qualitative synthesis, representing anywhere from five to 1,262 patients. Follow up periods expanded across six months to over 20 years. Authors reported that TMJ replacement resulted in significant improvements in patient-reported QOL assessed via the SF-36 Health Survey; TMJ-specific patient reported outcome measures, narrative satisfaction reports or structured interviews, reduced pain and disability, improved chewing, speech and diet, enhanced social confidence, sleep quality, and emotional wellbeing. The mean gain of MIO was 26-36 mm, with studies reporting 75-85% reduction in VAS scores (which was consistent between stock and custom prosthesis groups). Regarding complications, an approximate 20% of individuals developed heterotrophic ossification but authors note that when autologous fat grafting was used the rate dropped to below 5%. Infections of the prosthetic were seen in 3-4.9% of cases, Mechanical failure or loosening in roughly 4-5%, chronic pain in 20-30% of cases (often due to central sensitization) and transient facial nerve injury in approximately 10% of cases. Permanent nerve injury occurred in 1-2% of cases. The use of custom prosthetics resulted in slightly higher MIO scores and fit for complex or revision cases while stock prostheses were comparable in pain reduction, QOL, and overall satisfaction in routine cases. Authors reviewed outcomes of pediatric TMJR reporting that there was no clear evidence of mandibular growth inhibition during 2-8 years of follow-up with significant gains in function, chewing, speech and psychosocial well-being identified. The authors

conclude that this systematic review demonstrates TMJ replacement as a highly effective, safe, and durable treatment for end-stage TMJ disorders, which has been noted to consistently provide pain relief, functional improvement, and improved quality of life across varied indications, and across varying populations.

In 2023, the National Institute of Dental and Craniofacial Research (NIDCR), a division of the U.S. National Institute of Health (NIH) called attention to the gaps that remain in understanding the underlying mechanisms of TMJ, and the impact on medical and dental professionals by issuing a notice of funding opportunity to develop a future interdisciplinary research initiative. The goal of the initiative was to improve the prevention, diagnosis, and treatment of temporomandibular disorders (TMD). Nine grants totaling $2.8 million were awarded to begin planning the creation of the TMD Collaborative for Improving Patient-Centered Translational Research (TMD IMPACT). Applications to join the collaboration by higher education institutions, for-profit organizations, non-profit organizations, local and federal governments were accepted through January 2025.

PROFESSIONAL GUIDELINE(S)

In 2018, the American Association of Oral and Maxillofacial Surgeons (AAOMS) published guidelines to evaluate the impairment of the oral and maxillofacial region, including assessment of the temporomandibular joint for permanent impairment using the measurement of the voluntary, non-painful interincisal opening between maxillary and mandibular central incisors to determine the interincisal range of motion, followed by measuring the lateral excursive distance of the mandible, using the dental midlines from maximum dental intercuspation. Adding the values for loss of impairment values of interincisal opening and lateral excursive distance provides the craniomandibular articulation impairment.

In 2024, AAOMS issued a statement about the management of selected clinical conditions and associated clinical procedures for temporomandibular disorders, which includes the diagnostic assessment of TMJ disorders. The statement identifies TMJ disorders being the result of internal derangement, degenerative joint disease, rheumatoid arthritis, infectious arthritis, mandibular dislocation, neoplasia, ankylosis, condylar hyper-or hypoplasia, condylar osteolysis and fractures. Patient historical and physical findings include; unilateral or bilateral pain with or without popping or crepitus, is usually continuous or intermittent and increases with function, is localized to the joint. The mandible can have hypo-or hypermobility. AAOMS includes imaging (e.g., plain, or tomographic TMJ radiographs, CT, MRI, three-dimensional imaging) and appropriate laboratory testing such as a rheumatoid panel. The guidelines suggest that non-surgical management includes "medication (e.g., NSAIDs), orthotic appliance, and physical therapy", while surgical treatments include "manipulation under anesthesia, arthrocentesis, non-arthroscopic lysis and lavage, arthroscopic surgery, open arthroplasty with or without autograft, open arthroplasty with alloplast, disc repair or removal (with or without replacement), coronoidectomy, condylectomy, mandibular condylotomy, myotomy, orthognathic surgery, partial or total reconstruction". The therapeutic outcomes include "a level of pain that is of little or no concern to the patient, improved jaw function, improved ability to masticate food, functional and stable occlusion, limited period of disability, acceptable clinical appearance, absence of recurrent jaw locking or dislocation, limited progression of the disease, and in growing children, continued symmetrical growth of the mandible in proper relationship to the midface."

The American Society of Temporomandibular Surgeons (ASTMJS) is a non-profit organization comprised of maxillofacial, orthopedic, plastic/reconstructive, and oral surgical specialists. The ASTMJS website (2025) includes parameters and guidelines for treatment, stating the following "In the United States, the NIH has estimated that 10 million Americans have painful TMJ dysfunction, the majority of which are self-limiting or respond to non-surgical treatment. As in orthopedic management of other joint systems of the body, anti-inflammatory medication, physical therapy, orthotics or splints, and rest are usually sufficient initial treatment modalities. However, the time given to initial treatment must be finite when such treatment proves to be ineffective, or the clinical condition deteriorates. Surgical procedures are indicated when pre-surgical imaging studies confirm pathologic and structural changes of the joint that creates significant pain dysfunction and impairment."

For more information, refer to the ASTMJS website, available from: https://astmjs.org/tmd-general-information/ [accessed 2025 Oct 14].

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates temporomandibular joint prosthetics as medical devices. All TMJ prosthetics require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Oct 14]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2025 Oct 14]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
20605	Arthrocentesis, aspiration and/or injection, intermediate joint or burse (e.g., temporomandibular, acromioclavicular, wrist, elbow, or ankle, olecranon bursa); without ultrasound guidance
20606	with ultrasound guidance, with permanent recording and reporting
21010	Arthrotomy, temporomandibular joint
21050	Condylectomy, temporomandibular joint (separate procedure)

Code	Description
21060	Meniscectomy, partial or complete, temporomandibular joint
21070	Coronoidectomy (separate procedure)
21073	Manipulation of the temporomandibular joint(s) (TMJ), therapeutic, requiring an anesthesia service (i.e., general or monitored anesthesia care)
21240	Arthroplasty, temporomandibular joint, with or without autograft (includes obtaining graft)
21242	Arthroplasty, temporomandibular joint, with allograft
21243	Arthroplasty, temporomandibular joint, with prosthetic joint replacement
21480	Closed treatment of temporomandibular dislocation; initial or subsequent
21485	complicated (e.g., recurrent requiring intermaxillary fixation or splinting), initial or subsequent
21490	Open treatment of temporomandibular dislocation
29800	Arthroscopy, temporomandibular joint, diagnostic, with or without synovial biopsy (separate procedure)
29804	Arthroscopy, temporomandibular joint, surgical

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HCPCS Codes

Code	Description
Not Applicable	

CDT Codes

Code	Description
D0320	Temporomandibular joint arthrogram, including injection
D0321	Other temporomandibular joint radiographic images, by report
D7810-D7880	Reduction of dislocation and management of other temporomandibular joint dysfunctions (code range)

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ICD10 Codes

Code	Description
M26.60-M26.69	Disorders of temporomandibular joint (code range)

REFERENCES

Almeida L, et al. Quality of life outcomes following total temporomandibular joint replacement: a systematic review of long-term efficacy, functional improvements, and complication rates across prosthesis types. 2025 July 09;14:1-12.

American Association of Oral and Maxillofacial Surgeons (AAOMS) [Internet]. Clinical Paper: temporomandibular disorders. 2024 [accessed 2025 Oct 09]. Available from: https://aaoms.org/wp-content/uploads/2024/07/tmd_disorders.pdf

American Association of Oral and Maxillofacial Surgeons (AAOMS) [Internet]. Position Paper: The contemporary management of temporomandibular joint intra-articular pain and dysfunction.

American Society of TMJ Surgeons (ASTMJS) [Internet]. Surgical management of TMJ disorders. No Publication Date [accessed 2025 Oct 09]. Available from: https://astmjs.org/surgical-management-of-tmj-disorders-2/

Armijo-Olivo S, et al. Effectiveness of manual therapy and therapeutic exercise for temporomandibular disorders: systematic review and meta-analysis. Phys Ther. 2016 Jan;96(1):9-25.

British Association of Oral and Maxillofacial Surgeons (BAOMS) [Internet]. Open surgery to temporomandibular joint-information for patients. 2023 [accessed 2025 Oct 14]. Available from: https://www.baoms.org.uk/patients/procedures/34/open_jaw_joint_surgery

British Association of Oral and Maxillofacial Surgeons (BAOMS) [Internet]. Temporomandibular Joint Replacement Surgery. 2025 Sep [accessed 2025 Oct 14]. Available from: https://www.baoms.org.uk/patients/procedures/45/temporomandibular_joint_replacement_surgery

Calixtre LB, et al. Manual therapy for the management of pain and limited range of motion in subjects with signs and symptoms of temporomandibular disorder: a systematic review of randomised controlled trials. J Oral Rehabil. 2015 Nov;42(11):847-61.

de Freitas RF, et al. Counseling and self-management therapies for temporomandibular disorders: a systematic review. J Oral Rehabil. 2013 Nov;40(11):864-74.

de Souza RF, et al. Interventions for the management of temporomandibular joint osteoarthritis. Cochrane Database Systematic Reviews. 2012; Issue 4. Art. No.: CD007261.

Keenan JR. Unclear results for the use of botulinum toxin therapy for TMD pain. Evid Based Dent. 2015 Dec;16(4):122.

Li C, et al. Osteoarthritic changes after superior and inferior joint space injection of hyaluronic acid for the treatment of temporomandibular joint osteoarthritis with anterior disc displacement without reduction: a cone-beam computed tomographic evaluation. J Oral Maxillofac Surg. 2015

Feb;73(2):232-44.

National Institute of Dental and Craniofacial Research (NIDCR) [Internet]. Overview: temporomandibular disorders. 2025 Jul [accessed 2025 Oct 17]. Available from: https://www.nidcr.nih.gov/health-info/tmd

National Institutes of Health, National Institute of Dental and Craniofacial Research [Internet]. TMJ (Temporomandibular Joint and Muscle Disorders). Updated 2025 Aug [accessed 2025 Oct 14]. Available from: http://www.nidcr.nih.gov/OralHealth/Topics/TMJ/

Schiffman E, et al; International RDC/TMD Consortium Network, International Association for Dental Research; Orofacial Pain Special Interest Group, International Association for the Study of Pain. Diagnostic criteria for temporomandibular disorders (dc/tmd) for clinical and research applications: recommendations of the International RDC/TMD Consortium Network and Orofacial Pain Special Interest Group. J Oral Facial Pain Headache 2014 Winter;28(1):6-27. Update J Am Dent Assoc. Jun 2016;147(6):438-445.

Tang YH, et al. Arthrocentesis versus non-surgical intervention as initial treatment for temporomandibular joint arthralgia: a randomized controlled trial with long-term follow- up. Int J Oral Maxillofac Surg. 2023;52:595-603.

Tang YH, et al. Arthrocentesis versus conservative treatments for temporomandibular joint disorders: A systematic review with meta-analysis and trial sequential analyses. Journal of Cranio-Maxillo-Facial Surgery. 2025;53:250-261.

Thorpe ARDS, et al. A systematic review and meta-analysis of randomized controlled trials comparing arthrocentesis with conservative management for painful temporomandibular joint disorder. Int J Oral Maxillofac Surg 2023;52:889-896.

SEARCH TERMS

TMJ, TMJD, temporomandibular joint disorder, degenerative joint disease (DJD), myofascial pain dysfunction (MPD)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Temporomandibular joint dysfunction is not addressed in National or Regional Medicare coverage determinations or policies. However, treatment of TMJ syndrome is addressed in the chapter addressing Covered Medical and Other Health Services, Section 150.1, in the Medicare Benefit Policy Manual. Please refer to the following website for Medicare members:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf [accessed 2025 Oct 22].

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a

specific service, medical policy criteria apply to the benefit.

- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

MEDICAL POLICY

Medical Policy Title	**Temporomandibular Joint Disorders (TMJD)**
Policy Number	**11.01.17**
Current Effective Date	**February 15, 2027**
Next Review Date	**October 2027**

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(Link to Product Disclaimer)

Services related to myofascial pain dysfunction (MPD) are not addressed in this policy as they are rendered by a dentist and considered a dental benefit, rather than a medical benefit.

POLICY STATEMENT(S)

I. Non-surgical intervention (e.g. oral appliances) for the treatment of temporomandibular joint disorder is considered **medically appropriate** when **ALL** of the following criteria (P.S. A. B. C. and D.) are met:

A. **ONE (1)** of the following definitions of functional deficit is documented:

1. Presence of pain or other physical deficit that interferes with activities of daily living; or
2. Impaired physical activity (e.g., loss of range of motion);

AND

B. Documentation demonstrates that conservative treatments have been exhausted, with a minimum of six (6) weeks of failed therapy, including dates and duration for **TWO (2) or MORE** of the following*:

1. Medication (e.g., NSAIDS, muscle relaxants or antidepressants);
2. Corticosteroid Injection;
3. Dietary modifications such as a soft diet;
4. Behavioral therapy; or
5. Physical therapy;

*Conservative therapy documentation is not required in the setting of recent trauma, dislocation, severe malocclusion, dental infection or abscess.

AND

C. Documentation includes reports from Magnetic Resonance Imaging (MRI) or Computed Tomography (CT) of the TMJ;

AND

D. The specific documentation requirements for the requested non-surgical treatment are met:
   1. Imaging reports confirm **any** of the following:
      a. anterior disc displacement with or without reduction;
      b. disc adhesions;
      c. synovitis/capsulitis;
      d. degenerative osteoarthritis;
      e. internal derangement;
      f. degenerative joint disease;
      g. rheumatoid arthritis;
      h. infectious arthritis;
      i. mandibular dislocation;
      j. neoplasia;
      k. ankylosis;
      l. condylar hyper-or hypoplasia; **or**
      m. condylar osteolysis

II. Surgical intervention for the treatment of temporomandibular joint disorder is considered **medically appropriate** when **ALL** of the following criteria (P.S. A. B. C. and D.) are met:

A. **ONE (1)** of the following definitions of functional deficit is documented:
   1. Presence of pain or other physical deficit that interferes with activities of daily living; or
   2. Impaired physical activity (e.g., loss of range of motion);

AND

B. Documentation demonstrates that conservative treatments have been exhausted, with a minimum of six (6) weeks of failed therapy, including dates and duration for **TWO (2) or MORE** of the following*:
   1. Medication (e.g., NSAIDS, muscle relaxants or antidepressants);
   2. Corticosteroid Injection;
   3. Dietary modifications such as a soft diet;
   4. Behavioral therapy; or
   5. Physical therapy;

*Conservative therapy documentation is not required in the setting of recent trauma, dislocation, severe malocclusion, dental infection or abscess.

AND

C. Documentation includes reports from Magnetic Resonance Imaging (MRI) or Computed Tomography (CT) of the TMJ;

AND

D. The specific documentation requirements for the requested surgery type are met:

1. Arthrocentesis, Arthroscopic Lysis and Lavage, or Operative Arthroscopy (CPT 20605, 20606, 29804)
    a. Imaging reports confirm **any** of the following:
        i. anterior disc displacement with or without reduction;
        ii. disc adhesions;
        iii. synovitis/capsulitis; **or**
        iv. degenerative osteoarthritis; **and**
    b. Physical exam findings are supportive of diagnosis;
2. Open Joint Surgeries (e.g., Arthroplasty or arthrotomy, disc repair procedures, discectomy with or without replacement, condylectomy, discoplasty/disc plication, discectomy/meniscectomy) (CPT 21010, 21050, 21060, 21070, 21240, 21242)
    a. Persistent pain despite previous arthroscopic surgery; **and**
    b. Imaging reports confirm **any** of the following:
        i. internal derangement;
        ii. degenerative joint disease;
        iii. rheumatoid arthritis;
        iv. infectious arthritis;
        v. mandibular dislocation;
        vi. neoplasia;
        vii. ankylosis;
        viii. condylar hyper-or hypoplasia;
        ix. condylar osteolysis; **or**
        x. fracture;
3. Temporomandibular Joint Replacement (CPT 21243):
    a. Imaging reports demonstrate an alteration and degeneration of joint structures at both the bone (e.g., osteophytes, geodes, subchondral cysts) and disc level;

b. Reduced oral aperture (less than 35mm); **and**

c. Prior surgeries (i.e., arthroscopy or open) have failed.

Device Repair

III. Repair of a medically necessary [device] or components not under warranty will be considered **medically appropriate** when the following criteria are met:

A. Physician documentation includes **ALL** of the following:

1. date of device implantation/initiation;
2. manufacturer warranty information, if applicable;
3. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device;

B. The device is no longer functioning adequately; and **BOTH** of the following criteria are met:

1. inadequate function interferes with activities of daily living; **and**
2. repair is expected to make the equipment fully functional (as defined by manufacturer).

IV. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

Device Replacement

V. Replacement of a medically necessary [device] or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:

A. The device is no longer functioning adequately and has been determined to be non-repairable, or the cost of the repair is in excess of the replacement cost;

B. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

VI. The replacement of a properly functioning [device], its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing;

VII. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

VIII. Accessories or components for [device] that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

1.01.02 Continuous Passive Motion Device in the Home Setting

1.01.07 Medical Management of Obstructive Sleep Apnea

1.01.61 Non-Invasive Surface Electrical Stimulation for Pain and Rehabilitation

7.01.41 Surgical Management of Sleep Disorders

7.01.101 Balloon Dilation of the Eustachian Tube (BDET)

8.01.10 Prolotherapy

8.01.24 Therapies (Speech, Physical and Occupational)

11.01.03 Experimental or Investigational Services

Pharmacy Policy

Botulinum Toxin (Botox, Daxxify, Dysport, Myobloc, Xeoman)- Pharmacy 77

Viscosupplementation with Hyaluronic Acid- Pharmacy 75

POLICY GUIDELINE(S)

I. Coverage for dental-related services is **not** generally provided under medical contracts.

II. Coverage for all TMJD-related services, devices or appliances related to TMJD is contract dependent.

DESCRIPTION

The temporomandibular joint (TMJ) connects the jawbone to the skull, acting like a sliding hinge on either side of the skull. There are more than 30 conditions that cause pain and dysfunction in the jaw joint and the associated muscles that allow for movement. TMJ disorders specifically are broken into three different classes: myofascial pain-dysfunction (MPD) syndrome, internal derangement, and degenerative joint disease (DJD); however, diagnostic criteria are based on subjective findings and patients can fall into more than one class. The U.S. National Institutes of Health acknowledged in 2017 that there are no widely accepted standard tests to correctly diagnosis TMJ disorders.

MPD is considered the most common cause of TMJ pain and is thought to be a psychophysiologic disease that primarily involves the muscles of mastication. Services to treat MPD are rendered by a dentist, and are therefore not addressed within this policy.

Internal derangement is defined as an abnormal relationship of the articular disc to the mandibular condyle, fossa, and articular eminence. The muscle spasm seen in this condition is in response to the dysfunction; spasm is not the primary problem, as with MPD.

DJD (osteoarthritis) is the organic degeneration of the articular surfaces within the TMJ. It is secondary to micro/macro trauma, infection, and meniscal malalignment.

Diagnosis is typically one of exclusion and requires a combination of physical exam, patient interview, and a review of dental records. Generally, diagnostic testing or imaging are reserved for patients with severe or chronic symptoms.

Patients may experience some or even all of the following symptoms: headaches (over the eye, in the temples, behind the eyes, and at the base of the skull); general facial pain, and more specific pain directly in front of the ears; ear symptoms, including ringing, buzzing, and congestion; neck and shoulder pain; clicking or grating noises of the joint with movement; locking of the jaw; and pain with function. In severe cases, there can be functional disability, malnutrition, or airway compromise.

The main goals of treatment of TMJ disorder are to reduce or eliminate pain or joint noises, or both, and to restore normal mandibular function. TMJ disorder is a complex disorder with treatment of dependent upon identification of contributing conditions and behaviors, with first-line treatments being conservative in nature due to their low risk of potential side effects.

Arthrocentesis, Arthroscopic Lysis and Lavage

Arthrocentesis is considered a simple, minimally invasive surgery, where the joint space is not viewed, but rather incorporates the use of needles and irrigation to remove inflammatory causes of joint pain and/or to increase the mobility of the mandible by hydraulically removing present adhesions.

Operative Arthroscopy

Arthroscopy of the TMJ is a minimally invasive surgery performed under local anesthesia with sedation or general anesthesia. The joint space is viewed via fiber-optic camera (arthroscope) to diagnose and treat joint problems. The incision is small, and repairs are conducted utilizing thin surgical instruments.

Open Joint Surgeries

Open joint surgery requires a cut to be made in front of the ear, sometimes extending into the hairline to fully expose the jaw joint. It is typically used when needing to alter the shape of the joint (arthroplasty), when minimally invasive surgery was ineffective or for more advanced disease. Open surgery has an increased risk of causing damage to facial nerves and issues with hearing given the proximity to the joint.

Replacement of the Temporomandibular Joint (TMJ)

When conservative therapies have failed, it may be necessary to improve the function of a damaged joint by replacing the bone with a prosthetic. Today's U.S. Food and Drug Administration (FDA) approved joint prosthetics can be stock or custom made. The lower jaw portion of the prosthetic are typically manufactured from metal such as titanium, while the upper jaw portion of the prosthetic is made with ultra-high molecular-weight polyethylene either with or without titanium. Replacement of the TMJ is an open surgery with incisions required in front of the ear, extending to the hairline as well as below the jaw. It is also not without risk, including heterotropic ossification, infection, and chronic post-operative pain.

SUPPORTIVE LITERATURE

Non-Surgical Treatments

Yao et al (2023) conducted a systematic review and meta-analysis of randomized trials in an attempt to provide evidence-based guidelines for adult patients living with moderate chronic pain (4-6cm on a 10cm pain scale for greater than or equal to three months duration) secondary to TMD. This evidence was summarized into a recommendation by Busse et al (2023). The recommendation notes the necessity of the review given the number of interventions available for treatment, that individuals may be exposed to simple, conservative, and inexpensive treatments while others with similar sets of symptoms will be exposed to potentially invasive, irreversible, and costly treatments. As a result of the review, and the limited available evidence, the panel was only able to state confidence regarding the benefits of cognitive behavioral therapy augmented with relaxation or biofeedback, therapist-assisted jaw mobilization, and manual trigger point therapy for reduction in chronic pain severity related to TMJD (GRADE moderate to high certainty of evidence).

Surgical Treatments

Arthrocentesis of the TMJ was introduced in 1991 by Nitzan et al and its use for pain control has been supported by multiple randomized controlled trials (RCTs), systematic reviews of RCTs, as well as observational studies. (e.g., Grossman (2012), Kaneyama et al (2004), Nitzan et al (2001), Emshoff (2005), Carvajal et al (2000), Alpaslan (2003), Frost et al (2012)).

Thorpe et al (2023) conducted a systematic review comparing arthrocentesis versus conservative treatments for TMJD by focusing on joint pain and mouth opening at six months following the intervention. Studies included in the review were required to meet the following criteria: prospective randomized controlled trial conducted on humans, patients had a history of reduced mouth opening and pain, study included at least one group treated with arthrocentesis and one undergoing conservative therapies, and patients were assessed both preoperatively at recalls for maximum mouth opening and presence of pain with pain assessed via visual analogue scale and allocation being conducted on a per-patient basis. The initial search provided 879 records, with 12 articles selected for full-text analysis, with only seven meeting inclusion criteria. A total of 489 patients were represented in the studies, 448 of which were assessed at the 6-month recall mark. A bias analysis demonstrated that only one study was at low risk of bias. A random-effects model was used for the meta-analysis. Based upon the analysis, authors concluded a statistically significant superiority for arthrocentesis in the improvement of maximal mouth opening and borderline statistical superiority for pain improvement at six-months but note that the confidence interval for pain reduction crossed over zero and that the marginal differences are unlikely to be clinically relevant. Additionally, there was no conservative treatment to be found superior to another.

Tang and colleagues (2025) conducted a systematic review with meta-analysis and trial sequential to compare arthrocentesis to conservative treatments for symptomatic TMJ with short, intermediate, and long-term outcomes of objective measurements, including maximum mouth opening, joint blocks and noises, protrusive and lateral mandibular movements and cost, as well as subjective measurements of joint pain, mandibular function and quality of life (QOL). The intervention group

included TMJ arthrocentesis via any technique, with or without concomitant therapies or injections. The control group only consisted of conservative treatments of any kind. The primary study outcome was pain using a numeric scale. Only RCTs, prospective non-randomized controlled trials and retrospective cohort studies with a control group were allowed for inclusion, which resulted in 21 records suitable for inclusion. Of those 21 records, 16 were included in the qualitative and meta-analyses and five were included for the qualitative analyses only. For the primary outcome, for pain reduction, arthrocentesis was superior to conservative therapy in terms of pain reduction at both short (1-3 months) and intermediate (6-12 months) follow up. Only one RCT reported on pain reduction of long-term follow up (median 6.2 years), Tang et al (2023), which found arthrocentesis was more effective in pain reduction (-10.23 [95% CI -17.86;-2.60], p= 0.009) when compared to conservative treatments. For secondary outcomes, in regard to maximum mouth opening, 11 of 15 studies included in the quantitative analysis demonstrated improvement over time in both the arthrocentesis and conservative treatment groups, while five showed improvements in only the arthrocentesis group. One study demonstrated no statistically significant improvement over time in both groups, with two not adequately reporting differences between pre-and post-operative analysis. Studies assessing outcomes of joint pain at rest, mandibular function, joint bocks and noises, lateral and protrusive movements quality of life and cost were considered too heterogeneous to include in a meta-analysis, but authors concluded that there is a general trend of an equal or superior effect of arthrocentesis when compared to conservative therapies.

Almeida and colleagues (2025) conducted a systematic review to evaluate the long-term quality of life (QOL) outcomes after TMJ replacement, focusing on functional impairment, complication profiles, and differences between custom and stock prosthesis across both adult and pediatric populations. Eligibility criteria included patients undergoing TMJ replacement for end-stage disease (e.g., osteoarthritis, rheumatoid arthritis, juvenile idiopathic arthritis, trauma, ankylosis, condylar resorption, neoplasm). Authors included studies with or without comparator groups as well as any of the following: pre- versus postoperative outcomes, stock versus custom device, or replacement versus other surgical treatment options. Pain reduction (measured by VAS score), functional recovery (measured by maximum interincisal opening [MIO]) and QOL were primary outcomes. Complication rates and the use of advanced technologies were secondary outcomes. Included in the review were randomized controlled trials (RCTs), prospective and retrospective cohort studies and case series with more than five patients. Two reviewers independently conducted a search and out of 950 identified records, 64 were included for qualitative synthesis, representing anywhere from five to 1,262 patients. Follow-up periods expanded across six months to over 20 years. Authors reported that TMJ replacement resulted in significant improvements in patient-reported QOL assessed via the SF-36 Health Survey; TMJ-specific patient reported outcome measures, narrative satisfaction reports or structured interviews, reduced pain and disability, improved chewing, speech and diet, enhanced social confidence, sleep quality, and emotional wellbeing. The mean gain of MIO was 26-36 mm, with studies reporting 75-85% reduction in VAS scores (which was consistent between stock and custom prosthesis groups). Regarding complications, an approximate 20% of individuals developed heterotrophic ossification but authors note that when autologous fat grafting was used the rate dropped to below 5%. Infections of the prosthetic were seen in 3-4.9% of cases, Mechanical failure or loosening in roughly 4-5%, chronic pain in 20-30% of cases (often due to central sensitization)

and transient facial nerve injury in approximately 10% of cases. Permanent nerve injury occurred in 1-2% of cases. The use of custom prosthetics resulted in slightly higher MIO scores and fit for complex or revision cases while stock prostheses were comparable in pain reduction, QOL, and overall satisfaction in routine cases. Authors reviewed outcomes of pediatric TMJR reporting that there was no clear evidence of mandibular growth inhibition during 2-8 years of follow-up with significant gains in function, chewing, speech and psychosocial well-being identified. The authors conclude that this systematic review demonstrates TMJ replacement as a highly effective, safe, and durable treatment for end-stage TMJ disorders, which has been noted to consistently provide pain relief, functional improvement, and improved quality of life across varied indications, and across varying populations.

In 2023, the National Institute of Dental and Craniofacial Research (NIDCR), a division of the U.S. National Institute of Health (NIH) called attention to the gaps that remain in understanding the underlying mechanisms of TMJ, and the impact on medical and dental professionals by issuing a notice of funding opportunity to develop a future interdisciplinary research initiative. The goal of the initiative was to improve the prevention, diagnosis, and treatment of temporomandibular disorders (TMD). Nine grants totaling $2.8 million were awarded to begin planning the creation of the TMD Collaborative for Improving Patient-Centered Translational Research (TMD IMPACT). Applications to join the collaboration by higher education institutions, for-profit organizations, non-profit organizations, local and federal governments were accepted through January 2025.

PROFESSIONAL GUIDELINE(S)

In 2018, the American Association of Oral and Maxillofacial Surgeons (AAOMS) published guidelines to evaluate the impairment of the oral and maxillofacial region, including assessment of the temporomandibular joint for permanent impairment using the measurement of the voluntary, non-painful interincisal opening between maxillary and mandibular central incisors to determine the interincisal range of motion, followed by measuring the lateral excursive distance of the mandible, using the dental midlines from maximum dental intercuspation. Adding the values for loss of impairment values of interincisal opening and lateral excursive distance provides the craniomandibular articulation impairment.

In 2024, AAOMS issued a statement about the management of selected clinical conditions and associated clinical procedures for temporomandibular disorders, which includes the diagnostic assessment of TMJ disorders. The statement identifies TMJ disorders being the result of internal derangement, degenerative joint disease, rheumatoid arthritis, infectious arthritis, mandibular dislocation, neoplasia, ankylosis, condylar hyper-or hypoplasia, condylar osteolysis and fractures. Patient historical and physical findings include; unilateral or bilateral pain with or without popping or crepitus, is usually continuous or intermittent and increases with function, is localized to the joint. The mandible can have hypo-or hypermobility. AAOMS includes a history, screening and physical, imaging (e.g., plain, or tomographic TMJ radiographs, CT, MRI, three-dimensional imaging), appropriate laboratory testing such as a rheumatoid panel and initiating the least invasive therapy for treatment. The guidelines suggest that non-surgical management includes "medication (e.g., NSAIDs), orthotic appliance, and physical therapy", while surgical treatments include "manipulation

under anesthesia, arthrocentesis, non-arthroscopic lysis and lavage, arthroscopic surgery, open arthroplasty with or without autograft, open arthroplasty with alloplast, disc repair or removal (with or without replacement), coronoidectomy, condylectomy, mandibular condylotomy, myotomy, orthognathic surgery, partial or total reconstruction". The therapeutic outcomes include "a level of pain that is of little or no concern to the patient, improved jaw function, improved ability to masticate food, functional and stable occlusion, limited period of disability, acceptable clinical appearance, absence of recurrent jaw locking or dislocation, limited progression of the disease, and in growing children, continued symmetrical growth of the mandible in proper relationship to the midface."

The American Society of Temporomandibular Surgeons (ASTMJS) is a non-profit organization comprised of maxillofacial, orthopedic, plastic/reconstructive, and oral surgical specialists. The ASTMJS website (2025) includes parameters and guidelines for treatment, stating the following "In the United States, the NIH has estimated that 10 million Americans have painful TMJ dysfunction, the majority of which are self-limiting or respond to non-surgical treatment. As in orthopedic management of other joint systems of the body, anti-inflammatory medication, physical therapy, orthotics or splints, and rest are usually sufficient initial treatment modalities. However, the time given to initial treatment must be finite when such treatment proves to be ineffective, or the clinical condition deteriorates. Surgical procedures are indicated when pre-surgical imaging studies confirm pathologic and structural changes of the joint that creates significant pain dysfunction and impairment."

For more information, refer to the ASTMJS website, available from: https://astmjs.org/tmd-general-information/ [accessed 2026 Jul 26].

REGULATORY STATUS

The United States Food and Drug Administration (FDA) regulates temporomandibular joint prosthetics as medical devices. All TMJ prosthetics require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Jul 27]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Jul 27]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
20605	Arthrocentesis, aspiration and/or injection, intermediate joint or burse (e.g., temporomandibular, acromioclavicular, wrist, elbow, or ankle, olecranon bursa); without ultrasound guidance
20606	with ultrasound guidance, with permanent recording and reporting
21010	Arthrotomy, temporomandibular joint
21050	Condylectomy, temporomandibular joint (separate procedure)
21060	Meniscectomy, partial or complete, temporomandibular joint
21070	Coronoidectomy (separate procedure)
21073	Manipulation of the temporomandibular joint(s) (TMJ), therapeutic, requiring an anesthesia service (i.e., general or monitored anesthesia care)
21240	Arthroplasty, temporomandibular joint, with or without autograft (includes obtaining graft)
21242	Arthroplasty, temporomandibular joint, with allograft
21243	Arthroplasty, temporomandibular joint, with prosthetic joint replacement
21299	Unlisted craniofacial and maxillofacial procedure
21480	Closed treatment of temporomandibular dislocation; initial or subsequent
21485	complicated (e.g., recurrent requiring intermaxillary fixation or splinting), initial or subsequent
21490	Open treatment of temporomandibular dislocation
29800	Arthroscopy, temporomandibular joint, diagnostic, with or without synovial biopsy (separate procedure)
29804	Arthroscopy, temporomandibular joint, surgical

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HCPCS Codes

Code	Description
Not Applicable	

CDT Codes

Code	Description
D0320	Temporomandibular joint arthrogram, including injection
D0321	Other temporomandibular joint radiographic images, by report
D7810-D7880	Reduction of dislocation and management of other temporomandibular joint dysfunctions (code range)

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ICD10 Codes

Code	Description
M26.60-M26.69	Disorders of temporomandibular joint (code range)

REFERENCES

Almeida L, et al. Quality of life outcomes following total temporomandibular joint replacement: a systematic review of long-term efficacy, functional improvements, and complication rates across prosthesis types. 2025 July 09;14:1-12.

American Association of Oral and Maxillofacial Surgeons (AAOMS) [Internet]. Clinical Paper: temporomandibular disorders. 2024 [accessed 2026 Jul 27]. Available from: https://aaoms.org/wp-content/uploads/2024/07/tmd_disorders.pdf

American Association of Oral and Maxillofacial Surgeons (AAOMS) [Internet]. Position Paper: The contemporary management of temporomandibular joint intra-articular pain and dysfunction. 2024 [accessed 2026 Jul 31]. Available from: https://aaoms.org/wp-content/uploads/2024/08/tmj-contemporary-mgmt-position-paper.pdf

American Society of TMJ Surgeons (ASTMJS) [Internet]. Surgical management of TMJ disorders. No Publication Date [accessed 2026 Jul 27]. Available from: https://astmjs.org/surgical-management-of-tmj-disorders-2/

Armijo-Olivo S, et al. Effectiveness of manual therapy and therapeutic exercise for temporomandibular disorders: systematic review and meta-analysis. Phys Ther. 2016 Jan;96(1):9-25.

British Association of Oral and Maxillofacial Surgeons (BAOMS) [Internet]. Open surgery to temporomandibular joint-information for patients. 2023 [accessed 2026 Jul 27]. Available from: https://www.baoms.org.uk/patients/procedures/34/open_jaw_joint_surgery

British Association of Oral and Maxillofacial Surgeons (BAOMS) [Internet]. Temporomandibular Joint Replacement Surgery. 2025 Sep [accessed 2026 Jul 27]. Available from: https://www.baoms.org.uk/patients/procedures/45/temporomandibular_joint_replacement_surgery

Calixtre LB, et al. Manual therapy for the management of pain and limited range of motion in subjects with signs and symptoms of temporomandibular disorder: a systematic review of randomised controlled trials. J Oral Rehabil. 2015 Nov;42(11):847-61.

de Freitas RF, et al. Counseling and self-management therapies for temporomandibular disorders: a systematic review. J Oral Rehabil. 2013 Nov;40(11):864-74.

de Souza RF, et al. Interventions for the management of temporomandibular joint osteoarthritis. Cochrane Database Systematic Reviews. 2012; Issue 4. Art. No.: CD007261.

Keenan JR. Unclear results for the use of botulinum toxin therapy for TMD pain. Evid Based Dent. 2015 Dec;16(4):122.

Li C, et al. Osteoarthritic changes after superior and inferior joint space injection of hyaluronic acid for the treatment of temporomandibular joint osteoarthritis with anterior disc displacement without reduction: a cone-beam computed tomographic evaluation. J Oral Maxillofac Surg. 2015 Feb;73(2):232-44.

National Institute of Dental and Craniofacial Research (NIDCR) [Internet]. Overview: temporomandibular disorders. 2025 Jul [accessed 2026 Jul 27]. Available from: https://www.nidcr.nih.gov/health-info/tmd

National Institutes of Health, National Institute of Dental and Craniofacial Research [Internet]. TMJ (Temporomandibular Joint and Muscle Disorders). Updated 2025 Aug [accessed 2026 Jul 27]. Available from: http://www.nidcr.nih.gov/OralHealth/Topics/TMJ/

Schiffman E, et al; International RDC/TMD Consortium Network, International Association for Dental Research; Orofacial Pain Special Interest Group, International Association for the Study of Pain. Diagnostic criteria for temporomandibular disorders (dc/tmd) for clinical and research applications: recommendations of the International RDC/TMD Consortium Network and Orofacial Pain Special Interest Group. J Oral Facial Pain Headache 2014 Winter;28(1):6-27. Update J Am Dent Assoc. Jun 2016;147(6):438-445.

Tang YH, et al. Arthrocentesis versus non-surgical intervention as initial treatment for temporomandibular joint arthralgia: a randomized controlled trial with long-term follow- up. Int J Oral Maxillofac Surg. 2023;52:595-603.

Tang YH, et al. Arthrocentesis versus conservative treatments for temporomandibular joint disorders: A systematic review with meta-analysis and trial sequential analyses. Journal of Cranio-Maxillo-Facial Surgery. 2025;53:250-261.

Thorpe ARDS, et al. A systematic review and meta-analysis of randomized controlled trials comparing arthrocentesis with conservative management for painful temporomandibular joint disorder. Int J Oral Maxillofac Surg 2023;52:889-896.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Temporomandibular joint dysfunction is not addressed in National or Regional Medicare coverage determinations or policies. However, treatment of TMJ syndrome is addressed in the chapter addressing Covered Medical and Other Health Services, Section 150.1, in the Medicare Benefit Policy Manual. Please refer to the following website for Medicare members:

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf [accessed 2026 Jul 27].

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

Policy/Procedure Name: Tepezza (teprotumumab-trbw) and Lumvoa (veligrotug) **Control Number: 1350/20.000383**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care for enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Tepezza (teprotumumab-trbw) is an insulin-like growth-factor-1 receptor inhibitor indicated for the treatment of thyroid eye disease (TED). Tepezza is a fully human IgG1 monoclonal antibody, with a mechanism of action that is not fully characterized, though its binding blocks activation of the IGF-1R and subsequent signaling. This is the first FDA-approved drug for the treatment of TED (also referred to as Graves' orbitopathy). Graves' disease affects approximately one to two percent of the U.S. population. Approximately 20–25 percent of those with the condition also have TED, and among them about five percent have moderate to severe TED disease.

TED is an autoimmune condition of the retroorbital tissues. The result is inflammation and tissue expansion behind the eye, leading to proptosis (bulging eye), which is accompanied by pain and diplopia (swelling/stiffness of the muscles that move the eye, progressing so that the eyes can no longer move in line with each other), and in the most severe cases, blindness. The condition of TED occurs very often alongside Graves' disease. In the vast majority of cases that are considered mild, the symptoms appear as mild to moderate eyelid swelling, proptosis < 3 mm above the upper limit of normal for race, with no or intermittent diplopia and corneal exposure responsive to lubricants. Moderate to severe symptoms include inflamed eyes with increasing diplopia or proptosis ≥ 3 mm above the upper limit of normal for race, and a spectrum of mild corneal irritation to ulceration from overexposure.

The approach to treatment of TED should be reversal of hyperthyroidism (and resultant hypothyroidism as a consequence of hyperthyroidism therapy), if present. Additional treatment approaches include smoking cessation, local measures to reduce ocular surface irritation, and therapy to reduce inflammation/swelling in the periorbital tissues. In mild cases, local measures often provide sufficient relief of symptoms, and even selenium or non-steroidal anti-inflammatory drugs may be considered. Moderate to severe cases should first be treated with systemic glucocorticoids (GCs). If a contraindication, intolerance, or lack of response exists to GCs, other options include alternative medical therapies (teprotumumab included), external orbital radiation, or orbital decompression surgery. The 2016 European Thyroid Association/European Group on Graves' Orbitopathy Guidelines for the Management of Graves' Orbitopathy advises that for moderate-to-severe cases of TED, high-dose GCs, preferably via the intravenous route, are the first line for treatment with optional cumulative doses of 4.5-5 g of methylprednisolone, but higher doses (up to 8 g) can be used for more severe forms. Second-line therapy options include a second round of GCs as they are efficacious; however, partial or inadequate responses or recurrences are not uncommon, and this should be done only if the cumulative dose of 8 g of methylprednisolone has not been reached.

Tepezza was evaluated in two randomized, placebo-controlled trials.[6,7] The Phase 3 OPTIC trial was similar in design and endpoints to the Phase 2 predecessor. OPTIC enrolled 83 patients with moderate to severe active TED every three weeks for a total of eight doses, with a final evaluation at 24 weeks. The baseline mean proptosis measurement for the teprotumumab arm was 22.62 mm, and 23.2 mm in the placebo group. The primary outcome was a reduction in proptosis of ≥ 2 mm at week 24.[7] Several secondary outcomes were measured, and included an overall response (reduction ≥ 2 points in clinical activity score [CAS] plus reduction in proptosis of ≥ 2 mm), mean change in proptosis, a clinical activity score of 0 or 1 (no or minimal inflammation), and results of the Graves' ophthalmopathy-specific quality-of-life questionnaire (GO-QOL).[6,7] At week 24, the proptosis response was higher in the active-treatment arm compared to placebo (83% [n-34] versus 10% [n-4], P < 0.001) with a number needed to treat of 1.36.[7] Secondary outcomes all statistically significantly favored therapy over placebo, including an overall response of 78% (n-32) versus 7% (n-3), mean change in proptosis (-2.82 mm versus 0.54 mm), and CAS of 0-1 (59% versus 21%). Lastly, the mean change in GO-QOL was improved in the treatment arm over placebo (13.79 points versus 4.43 points, P ≤ 0.001).[7] Adverse effects were noted, and occurred in less than 5% of the studied population. Adverse effects of interest include development of hyperglycemia (n-2), transient hearing impairment and hearing loss, and weight loss of at least 5 kilograms.[7] Two serious adverse effects were described: pneumothorax (determined to be unrelated), and an infusion reaction that led to withdrawal from the trial.

Lumvoa, an insulin-like growth factor-1 receptor (IGF-1R) inhibitor, is indicated for the treatment of thyroid eye disease regardless of thyroid eye disease activity or duration. The efficacy of Lumvoa was evaluated in two randomized, double-blind, placebo-controlled, Phase III pivotal studies (THRIVE and THRIVE-2). Both studies enrolled patients ≥ 18 years of age with moderate to severe thyroid eye disease. THRIVE enrolled patients with active disease (clinical activity score [CAS] ≥ 3) and disease onset < 15 months of screening. THRIVE-2 enrolled patients with any CAS (range 0 to 7) and disease onset > 15 months. Selected patients with prior orbital decompression surgery were allowed to participate but patients with hearing impairment were excluded from both studies. Key efficacy endpoints were the same for both trials and were the proptosis responder rate (defined as the proportion of patients with ≥ 2 mm reduction in proptosis in the study eye from baseline without deterioration in proptosis [≥ 2 mm increase] in the non-study eye) at Week 15 and the mean change in proptosis

from baseline to Week 15. In both studies, the proptosis responder rate at Week 15 and the mean change in proptosis from baseline to Week 15 were significantly greater in the Lumvoa group vs. placebo.

Summary	
Effective date of policy:	8/28/2026
Indications	Thyroid eye disease
Availability	Tepezza: 500 mg/10.5 ml (47.6 mg/mL) Lumvoa: 500 mg/10 mL single-dose vials
HCPCS	Tepezza: J3241 Lumvoa: No specific code

Required Criteria for Approval

All of the following conditions for the requested indication must be met in order to approve Tepezza therapy:

Drug	Criteria
Tepezza (teprotumumab)	1. Member must be at least 18 years old AND 2. Must be prescribed by an endocrinologist or ophthalmologist AND 3. Must have a diagnosis of thyroid eye disease (TED) AND 4. Must have moderate-to-severe TED defined as one of the following (a, b, c, or d): a. Lid retraction ≥ 2 mm b. Moderate to severe soft tissue involvement c. Proptosis > 3 mm above normal for race and sex (see Appendix) d. Diplopia AND 5. Documentation within the past 12 months must be provided to indicate one of the following (a or b): a. Patient is euthyroid prior to starting treatment OR b. Patient has mild hypo- or hyperthyroidism defined as a free thyroxine (T4) or free triiodothyronine (T3) levels less than 50% above or below the normal limits AND patient is currently receiving treatment to correct thyroid levels AND 6. Must not have been previously treated with an IGF-1 receptor inhibitor (e.g., Lumvoa (veligrotug), Tepezza (teprotumumab)) 7. Retreatment is considered not medically necessary and will not be covered based on currently available literature 8. FDA approved dosing is 10 mg/kg for the first infusion, followed by 20 mg/kg every 3 weeks for 7 additional infusions. a. If the prescriber agrees to dose rounding, then the approved dose may be rounded down to the nearest 500 mg vial if the resulting reduction is less than or equal to 10% of the calculated FDA-approved weight-based dose. This applies to all lines of business for new starts only. 9. Approval will be for 7 months to allow for 8 infusions total.
Lumvoa (veligrotug)	1. Must be 18 years of age or older 2. Must be prescribed by an endocrinologist or ophthalmologist **AND** 3. Must have a diagnosis of thyroid eye disease (TED) **AND** 4. Must have documentation of moderate-to-severe TED defined as **<u>one</u>** of the following (a, b, c, or d): a. Lid retraction <u>≥</u> 2 mm b. Moderate to severe soft tissue involvement c. Proptosis <u>≥</u> 3 mm above normal for race and sex (see Considerations) d. Diplopia **AND** **5.** Documentation within the past 12 months must be provided to indicate one of the following (a or b): **a.** Patient is euthyroid prior to starting treatment **OR** **b.** Patient has mild hypo- or hyperthyroidism defined as a free thyroxine (T4) or free triiodothyronine (T3) levels less than 50% above or below the normal limits **AND** patient is currently receiving treatment to correct thyroid levels **AND** 6. Must not have been previously treated with an IGF-1 receptor inhibitor (e.g., Lumvoa (veligrotug), Tepezza (teprotumumab)) 7. Retreatment is considered experimental/investigational 8. FDA approved dosing is 10 mg/kg every three weeks for a total of 5 infusions

a. If the prescriber agrees to dose rounding, then the approved dose may be rounded down to the nearest 500 mg vial if the resulting reduction is less than or equal to 10% of the calculated FDA-approved weight-based dose. This applies to all lines of business for new starts only.

9. Approval will be for 6 months to allow for 5 infusions total given every 3 weeks

Considerations

Prior authorization is obtained through the CDPHP pharmacy department.

Proptosis upper limit of normal by race and sex		
	Female	Male
White	19 mm	21 mm
African American	23 mm	24 mm
Chinese	18 mm	19 mm
Thai	16 mm	17 mm

References

		Updated	Accessed
1	Tepezza [prescribing information]. Horizon Therapeutics USA, Inc., Lake Forest, IL 60045	11/2025	8/2026
2	Davies T, et al. Clinical features and diagnosis of Graves' Orbitopathy (Ophthalmopathy). Ross D, ed. UpToDate. https://www.uptodate.com. Accessed March 16, 2020.	12/24	1/25
3	Davies T, et al. Treatment of Graves' Orbitopathy (Ophthalmopathy). Ross D, ed. UpToDate. https://www.uptodate.com. Accessed March 16, 2020.	12/24	1/25
4	Bartalena L, Baldeschi L, Boboridis K, et al. The 2016 European Thyroid Association/European Group on Graves' Orbitopathy Guidelines for the Management of Graves' Orbitopathy. Eur Thyroid J 2016; 5:9.	2016	1/25
5	Ross DS, Burch HB, Cooper DS, et al. 2016 American Thyroid Association Guidelines for Diagnosis and Management of Hyperthyroidism and Other Causes of Thyrotoxicosis. Thyroid 2016; 26:1343.	2016	1/25
6	Smith TJ, Kahaly GJ, Ezra DG, et al. Teprotumumab for Thyroid-Associated Ophthalmopathy. N Engl J Med 2017;376:1748-61.	2017	1/25
7	Douglas RS, Kahaly GJ, Patel A, et al. Teprotumumab for the Treatment of Active Thyroid Eye Disease. N Engl J Med 2020; 382:341-352.	1/20	1/25
8	Migliori ME, et al. Determination of the Normal Range of Exophthalmometric Values for Black and White Adults. Am J Ophth 1984:438-442.	1984	1/25
9	Schaffer, R. Smokers, women experience proptosis reduction with teprotumumab in thyroid eye disease. Endocrinetoday. April 2, 2020. Available at: https://www.healio.com/news/endocrinology/20200402/smokers-women-experience-proptosis-reduction-with-teprotumumab-in-thyroid-eye-disease	4/20	1/25
10	Bartalena L, Kahaly GJ, Baldeschi L, et al. The 2021 European Group on Graves' orbitopathy (EUGOGO) clinical practice guidelines for the medical management of Graves' orbitopathy. European Journal of Endocrinology 2021; 185:G43-G67.	2021	1/25
11	Lumvoa [prescribing information]. Viridian Therapeutics, Inc. Waltham, MA 02453.	6/2026	8/2026

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 8/28/2026

New: 4/2020

Revised	Reviewed
9/2021, 4/2022, 4/2025, 9/2025	4/2021, 4/2023, 4/2024

Revision Date	Changes Made
9/2021	Removed requirement for prior corticosteroid therapy, removed exclusion of prior surgical treatment or orbital irradiation for TED
4/2022	Changed Inclusion Criteria from "Enrollee does not smoke" to: If enrollee is currently smoking, enrollee has been counseled by requesting provider of the importance of smoking cessation, as smoking is known to worsen Graves hyperthyroidism/TED Changed Exclusion Criteria from "Enrollee has received previous treatment with Rituximab or Tocilizumab" to state Enrollee is not currently utilizing another biologic immunomodulator
4/2025	Removed requirement for smoking cessation counseling, removed exclusion criteria, removed additional documentation for confirming diagnosis of TED (now just require a CAS score $\geq$ 4)
9/2025	Thyroid status (euthyroid or mild hyper/hypothyroidism) updated to require documentation within the past 12 months
8/2026	Added Lumvoa Revised Tepezza criteria to align closer with Lumvoa

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MEDICAL POLICY

Medical Policy Title	**Testing for the Use of Biologic Therapeutics for the Treatment of Inflammatory Disorders**
Policy Number	**2.02.47**
Current Effective Date	**November 1, 2026**
Next Review Date	**November 2027**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Measurement of serum and/or antibody levels for biologic therapies (e.g., Infliximab, Adalimumab, Vedolizumab, Ustekinumab) pre- or post-treatment in patients with inflammatory disorders, are considered **investigational**, and include but are not limited to **ANY** of the following tests:

   A. Procise ADL;

   B. Procise IFX;

   C. PredictrPK IFX;

   D. ADALX (Adalimumab Quantitative with Reflex to Antibody, Serum) test;

   E. Anser ADA test;

   F. Anser IFX test;

   G. Anser UST test;

   H. Anser VDZ test.

II. Testing used to predict the likelihood of response or non-response to biologic therapies (e.g., PrismRA), either alone or as a combination test are considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Biological therapeutics are defined by the World Health Organization (WHO) as a class of medicines that are grown and then purified from large scale cell cultures of bacteria or yeast, plant, or animal cells. They are used in vaccines, growth factors, immune modulators, or monoclonal antibodies.

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- Examples of biological therapeutics are infliximab (Remicade) (IFX), adalimumab (Humira)(ADA), vedolizumab (Entyvio) (VDZ), and ustekinumab (Stelara) (UST), etanercept (Enbrel), certolizumab (Cimzia).
- Infliximab, adalimumab, etanercept, certolizumab are anti-tumor necrosis factor-α (anti-TNF-α) therapies. These therapies are effective when there is insufficient control of disease with conventional treatment in patients with inflammatory disorders, such bowel disease (IBD), ulcerative colitis, Crohn's disease, rheumatoid arthritis (RA), psoriatic arthritis, and ankylosing spondylitis.

Up to 30% of patients may not initially respond to anti-TNF-α therapy, and among those who do, up to 60% may lose responsiveness over time. This diminished or absent response is thought to be linked to the development of antibodies against anti-TNF agents, particularly Infliximab. These antibodies, known as Anti-Infliximab Antibodies (ATI) or human antichimeric antibodies (HACAs), can form as early as after the first dose and persist for years, potentially reducing drug concentration and efficacy due to accelerated clearance. Their presence is also associated with adverse reactions, including acute infusion and delayed hypersensitivity responses. To manage nonresponse, clinicians may adjust the dose or interval, switch to another anti-TNF drug, or opt for a different class of medication. Because loss of response can lead to relapse, reduced quality of life, and increased healthcare costs, monitoring serum drug and antibody levels has been suggested as part of anti-TNF therapy regimens.

Detection of drug and antidrug antibodies is commonly performed using ELISA, radioimmunoassay (RIA), and homogenous mobility shift assay (HMSA), each with its own limitations. ELISA is restricted to measuring antidrug antibodies only when drug levels are undetectable, while RIA involves complex procedures, extended incubation times, and safety concerns due to radioactive materials. HMSA offers the advantage of detecting antibodies even in the presence of the drug in serum. However, technical inconsistencies across these methods hinder reliable interstudy comparisons, and standardized threshold values for Infliximab or adalimumab antibodies have yet to be established for each assay type.

Prometheus Laboratories Inc. offers non-radiolabeled, fluid-phase homogenous mobility shift assay (HMSA) tests called Anser IFX for infliximab, Anser ADA for adalimumab, Anser VDZ for vedolizumab, and Anser UST for ustekinumab. The four tests are not enzyme-linked immunosorbent assay (ELISA)-based; however, each can measure anti-drug antibodies in the presence of detectable drug levels, improving on a major limitation of the ELISA method. The tests measure serum drug concentrations and anti-drug antibodies.

The PrismRA (Scipher Medicine laboratory) test predicts the likelihood of non-response to TNFi therapies. The test analyzes 23 biological features, including RNA expression data, demographic variables, and disease-associated clinical metrics, which are discriminatory between the molecular signatures of those who respond or do not respond adequately to TNFi therapies.

SUPPORTIVE LITERATURE

Bronsky et al (2025) conducted a prospective single-center observational study that evaluated the usefulness of therapeutic drug monitoring (TDM) for ustekinumab (USTE) and vedolizumab (VEDO) in pediatric inflammatory bowel disease (pIBD) patients. This study involved 87 children with Crohn's disease, ulcerative colitis, or unclassified IBD, analyzing 641 drug observations. The primary goal was to assess the relationship between serum trough levels (TLs) and disease activity, measured by fecal calprotectin (F-CPT). The study found that USTE trough levels were not significantly associated with disease activity, as measured by F-CPT, suggesting limited value of TDM for USTE in pediatric IBD. In contrast, VEDO trough levels showed a negative association with F-CPT levels, indicating a potential role for TDM in guiding VEDO therapy. However, the ability of VEDO trough levels to predict remission (F-CPT < 250 µg/g) was poor, with an optimal threshold of 15.1 µg/mL yielding high sensitivity (0.82) but low specificity (0.32), and an area under the curve (AUC) of only 0.56. Other factors such as treatment phase, drug intensification, undetectable TLs, and IBD type were not significantly linked to disease activity. Mild anti-drug antibodies were found in a few cases (5 USTE, 16 VEDO) but had no clinical impact. Overall, TDM may be helpful for VEDO but not for USTE, and clinically useful dosing thresholds remain difficult to establish.

Nguyen et al (2022) conducted a systematic review and metanalysis of RCTs comparing TDM with conventional management in patients with IBD. Proactive TDM has been proposed to improve outcomes in patients with IBD being treated with TNFα antagonists. The study identified RCTs in patients with IBD treated with TNFα antagonists comparing proactive TDM through routine assessments of trough concentration, regardless of trough concentrations, with conventional management where dose adjustments were driven by clinical assessments. In the nine RCTs that were used for the metanalysis, it was found that there was no significant difference in the failing to maintain clinical remission in patients who underwent proactive TDM. The proactive TDM arm was more likely to undergo dose escalation, however there was no difference found in the risk of developing antidrug antibodies or other serious adverse events. In conclusion it was found that in patients with IBD treated with TNFα antagonists, regardless of disease activity, routine TDM to target biologic concentration to specific thresholds did not show clinical benefit. The RCTs focused on adults and optimization of TNFα antagonist during the maintenance phase, further studies would be needed to assess induction phase of drug use, or if individuals with more severe phenotype may benefit from routine proactive TDM.

Syversen et al (2021) conducted a randomized, parallel-group, open-label clinical trial for 411 adults with rheumatoid arthritis, spondyloarthritis, psoriatic arthritis, ulcerative colitis, Crohn's disease, or psoriasis initiating infliximab therapy. The researchers aimed to assess whether TDM during initiation of infliximab therapy improves the efficiency of treatment compared to the standard without TDM. Participants were randomized 1:1 (198 in the TDM group and 200 in the standard therapy group) Clinical readmission at 30 weeks was achieved in 50.5% for TDM and 53% in the standard groups. Adverse events were reported in 68% in TDM and 70% in standard groups. The finding reported do not support routine use of TDM during infliximab induction for improving disease remission rates. It was suggested that further studies should be completed to determine if TDM is associated with fewer infusion reactions. Limitations included lack of double blinding, open label, and discrepancies

amongst assays for infliximab and antidrug antibodies, and individual patient responses to treatment.

Steenholdt et al (2014) published a post hoc comparison of different ATI assays. Blood samples were collected from 66 of 69 patients enrolled in an RCT (discussed next) that assessed algorithmic treatment for CD relapse during infliximab therapy. Samples were analyzed by three binding assays: RIA, ELISA, and HMSA; and by a reporter gene assay, a functional cell-based technique. ATI were detected in 18 patients (27%) by radioimmunoassay, six patients (9%) by ELISA, and 22 patients (33%) by HMSA. The reporter gene assay reported anti-infliximab activity, most likely due to ATI, in seven patients (11%). As observed by the authors, this suggests that ATI detected by RIA and HMSA are not necessarily functionally active. Five patients (8%) were ATI-positive, and 43 patients (65%) were ATI-negative by all four assays. Correlations were statistically significant ($p<0.001$) in all pairwise comparisons (Pearson *r*, 0.77-0.96). However, statistical agreement between assays could not be estimated accurately (e.g., using the intraclass correlation coefficient) because different assays reported values on different arbitrary scales. Regardless of assay used, most patients (74%-88%) had therapeutic serum infliximab levels and undetectable ATI, suggesting nonpharmacologic reasons for relapse or for symptoms mimicking relapse.

Wang et al (2013) developed and validated a non-radiolabeled HMSA to measure antibodies-to-adalimumab (ATA) and adalimumab levels in serum samples. Analytic validation of performance characteristics (calibration standards, assay limits, intra- and inter-assay precision, linearity of dilution, substance interference) was performed for both the ATA- and adalimumab HMSA. Because the elimination half-life of adalimumab (10-20 days) overlaps the dosing interval (every two weeks), ATA-positive sera to provide calibration standards were difficult to collect from human patients. (The drug-free interval for antibody formation is small.) Therefore, anti-sera from rabbits immunized with adalimumab were pooled to form calibration standards. Serial dilutions of these ATA calibration standards then generated a standard curve against which test samples were compared. Over the course of 29 experimental runs, intra-assay precision and accuracy for the adalimumab-HMSA (as indicated by the CV) was < 20% and < 3%, respectively; inter-assay (run-to-run, analyst-to-analyst, and instrument-to-instrument) precision and accuracy were less than 12% and less than 22%, respectively. For the ATA HMSA, CVs for intra-assay precision and accuracy were less than 3% and less than 13%, respectively; CVs for inter-assay precision and accuracy were less than 9% and less than 18%, respectively. ELISA could not be used as a standard comparator, due to competition from the circulating drug. Analysis of 100 serum samples from patients who were losing response to adalimumab showed that 44% were above the cut point for ATA (0.55 U/mL), and 26% were below the cut point for serum adalimumab level. In samples below the adalimumab cut point (0.68 µg/mL), 68% were ATA-positive; in samples with adalimumab levels greater than 20 µg/mL, 18% were ATA-positive.

Lee et al (2012) conducted a meta-analysis of patients with IBD receiving infliximab to determine the prevalence of ATI, the effect of ATI on the prevalence of infusion reactions, and the effect of ATI on disease remission rates. Databases were searched through October 2011, and 18 studies involving 326 patients were included. The studies included nine randomized, controlled trials (RCTs), five cohort studies, and four retrospective cohort studies. The prevalence of ATI was 45.8% when

episodic infusions of infliximab were given and 12.4% when maintenance infliximab was given. The rates of infusion reactions were significantly higher in patients with ATI (relative risk [RR], 2.07; 95% confidence interval [CI], 1.61 to 2.67). Immunosuppressants resulted in a 50% reduction in the risk of developing ATI ($p<0.001$). Patients with ATI were less likely to be in clinical remission, but this was not statistically significant (RR=0.90; 95% CI, 0.79 to 1.02; p=0.10). The meta-analysis concluded that patients who test positive for ATI are at an increased risk of infusion reactions but have similar rates of remission compared with patients who test negative for ATI.

The clinical utility of vedolizumab trough levels (VTLs) in IBD is not well-defined. The data to support the routine use of therapeutic drug-monitoring during maintenance therapy are lacking. Further studies to determine the role of therapeutic drug-monitoring of vedolizumab are needed.

PROFESSIONAL GUIDELINE(S)

American College of Gastroenterology 2019 Clinical Guidelines for Ulcerative Colitis (UC) in Adults, states:

- "In patients with moderately to severely active UC who are responders to anti-TNF therapy and now losing response, we suggest measuring serum drug levels and antibodies (if there is not a therapeutic level) to assess the reason for loss of response (conditional recommendation, very low quality of evidence)".

National Institute for the Health and Care Excellence (NICE) 2022 Guidelines for ProciseDx Point-of-Care Platform for Inflammatory Bowel Disease states:

- "Further research needs to evaluate the use of ProciseDx in clinical care for diagnosing and monitoring IBD, including its effect on clinical decision making and dosing resource use and patient outcomes."

REGULATORY STATUS

ProciseDx has been U.S. Food and Drug Administration cleared for therapeutic Drug Monitoring (TDM) for Infliximab and Adalimumab.

Anser tests by Prometheus Laboratories have not been cleared or approved by the US FDA.

Infliximab, adalimumab, vedolizumab, and ustekinumab are biologic therapeutics that have received approval by the U.S. Food and Drug Administration (FDA).

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
80145 (E/I)	Adalimumab (Therapeutic level testing)
80230 (E/I)	Infliximab (Therapeutic level testing)
80280 (E/I)	Vedolizumab (Therapeutic level testing)
84999	Unlisted chemistry procedure
0514U (E/I)	Gastroenterology (irritable bowel disease [IBD]), immunoassay for quantitative determination of adalimumab (ADL) levels in venous serum in patients undergoing adalimumab therapy, results reported as a numerical value as micrograms per milliliter (mcg/mL) (Procise ADL, ProciseDx Inc.)
0515U (E/I)	Gastroenterology (irritable bowel disease [IBD]), immunoassay for quantitative determination of infliximab (IFX) levels in venous serum in patients undergoing infliximab therapy, results reported as a numerical value as micrograms per milliliter (mcg/mL) (Procise IFX, ProciseDx Inc.)

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HCPCS Codes

Code	Description
J0135	Injection, adalimumab, 20 mg
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J3357	Ustekinumab, for subcutaneous injection, 1 mg
J3358	Ustekinumab, for intravenous injection, 1 mg
J3380	Injection, vedolizumab, 1 mg

ICD10 Codes

Code	Description
K50.00-K50.919	Crohn's disease (code range)
K51.00-K51.919	Ulcerative (chronic) pancolitis (code range)

Code	Description
L40.50-L40.59	Arthropathic psoriasis (code range)
M05.40 – M05.479	Rheumatoid myopathy with rheumatoid arthritis (code range)
M06.4	Inflammatory polyarthropathy
M08.00-M08.09	Juvenile rheumatoid arthritis (code range)
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M08.40-M08.48	Pauciarticular juvenile rheumatoid arthritis (code range)
M12.00-M12.09	Chronic postrheumatic arthropathy [Jaccoud] (code range)
M45.0-M45.9	Ankylosing spondylitis of the spine (code range)

REFERENCES

Afif W, et al. Clinical utility of measuring infliximab and human anti-chimeric antibody concentrations in patients with inflammatory bowel disease. Am J Gastroenterol. 2010 May;105(5):1133-39.

Bartelds GM, et al. Development of antidrug antibodies against adalimumab and association with disease activity and treatment failure during long-term follow-up. JAMA. 2011 Apr 13;(305(14):1460-8.

Benucci M, et al. Antidrug antibodies against TNF-blocking agents; correlations between disease activity, hypersensitivity reactions, and different classes of immunoglobulins. Biologics. 2015 Feb 17;9:7-12.

Bergman MJ, et al. Clinical utility and cost savings in predicting inadequate response to anti-TNF therapies in rheumatoid arthritis. Rheumatol Ther. 2020 Dec;7(4):775-792.

Bodini G, et al. Adalimumab trough serum levels and anti-adalimumab antibodies in the long-term clinical outcomes of patients with Crohn's disease. Scand J Gastroenterol. 2016 Sept;51(9):1081-6.

Bouden S, et al. No correlation between anti-drug antibodies and therapeutic response in Tunisian patients with chronic inflammatory diseases treated by TNF blockers. Curr Rheumatol Rev. 2024;20(4):435-443.

Bronsky J, et al. Association of serum levels of ustekinumab, vedolizumab, and faecal calprotectin in paediatric patients with inflammatory bowel diseases: a prospective observational study. Paediatr

Drugs. 2025 Sep;27(5):629-640.

Cheifetz AS, et al. A comprehensive literature review and expert consensus statement on therapeutic drug monitoring of biologics in inflammatory bowel disease. Am J Gastroenterol. 2021 Oct 1;116(10):2014-2025.

Cludt I, et al. Anti-therapeutic antibodies and their clinical impact in patients treated with the TNF antagonist adalimumab. Cytokine. Aug 2017;96:16-23.

Finckh A, et al. Influence of anti-infliximab antibodies and residual infliximab concentrations on the occurrence of acquired drug resistance to infliximab in rheumatoid arthritis patients. Joint Bone Spine. 2010 Jul;77(4):313-8.

Frederiksen MT, et al. Antibodies against infliximab are associated with de novo development of antibodies to adalimumab and therapeutic failure in infliximab-to adalimumab switchers with IBD. Inflamm Bowel Dis. 2014 Oct;20(10):1714-21.

Garces S, et al. The immunogenicity of anti-TNF therapy in immune-mediated inflammatory disease: a systematic review of the literature with a meta-analysis. Ann Rheum Dis. 2013;72(12)1947-55.

Jairath V, et al. ENTERPRET: A randomized controlled trial of vedolizumab dose optimization in patients with ulcerative colitis who have early nonresponse. Clin Gastroenterol Hepatol. 2024 May;22(5):1077-1086.e13.

Lee LY, et al. Anti-Infliximab antibodies in inflammatory bowel disease: prevalence, infusion reactions, immunosuppression and response, a meta-analysis. Eur J Gastroenterol Hepatol. 2012 May 27;24(9):1078-85.

Nencini F, et al. The kinetics and antidrug antibodies, drug levels, and clinical outcomes in infliximab-exposed patients with immune-mediated disorders. J Allergy Clin Immunol Pract. 2018 Nov-Dec;6(6):2065-2072.

Nguyen NH, et al. Proactive therapeutic drug monitoring versus conventional management for inflammatory bowel diseases: a systematic review and meta-analysis. Gastroenterology. 2022 Oct;163(4):937-949.e2.

Pecoraro V, et al. The impact of immunogenicity of TNFα inhibitors in autoimmune inflammatory disease. A systematic review and meta-analysis. Autoimmun Rev. 2017 Jun;16(6):564-575.

Rubin DT, et al. ACG clinical guideline: ulcerative colitis in adults. Am J Gastroenterol. 2019 Mar;114(3):384-413.

Steenholdt C, et al. Clinical implications of measuring drug and anti-drug antibodies by different assays when optimizing infliximab treatment failure in Crohn's disease: post hoc analysis of a randomized controlled trial. Am J Gastroenterol. 2014 Jul;109(7):1055-64.

Steenholdt C, et al. Individualized therapy is more cost-effective than dose intensification in patients with Crohn's disease who lose response to anti-TNF treatment: a randomized, controlled trial. Gut. 2014 Jun;63(6):919-27.

Stein R, et al. Serum infliximab, antidrug antibodies, and tumor necrosis factor predict sustained response in pediatric Crohn's disease. Inflamm Bowel Dis. 2016 Jun;2296):1370-7.

Syversen SW, et al. Effect of therapeutic drug monitoring vs standard therapy during infliximab induction on disease remission in patients with chronic immune-mediated inflammatory diseases: a randomized clinical trial. JAMA. 2021 May 4;325(17):1744-1754.

Vande Casteele N, et al. Pharmacokinetics of anti-TNF monoclonal antibodies in inflammatory bowel disease: adding value to current practice. J Clin Pharmacol. 2015 Mar;55(Suppl3):S39-50.

Vande Casteele N, et al. The relationship between infliximab concentrations, antibodies to infliximab and disease activity in Crohn's disease. Gut. 2015 Oct;64(10):1539-45.

Wang SL, et al. Monitoring of adalimumab and antibodies-to-adalimumab levels in patient serum by the homogeneous mobility shift assay. J Pharm Biomed Anal. 2013 May 5;78-79:39-44.

World Health Organization. Biologicals [Internet]. [Accessed 2025 August 19] Available from: https://www.who.int/health-topics/biologicals#tab=tab_1

Xiang D, et al. Development and validation of enzyme-linked immunosorbent assays for the measurement of infliximab and anti-drug antibody levels. Heliyon. 2023 Nov 4;9(11):e21858.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

There is currently no National Coverage Determination (NCD) or Local Coverage Determination (LCD) for Measurement of Serum Antibodies to Infliximab and Adalimumab.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 7/26
Revised:
Reviewed:

Date	Summary of Changes
11/1/2026	• New

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

The Centers for Disease Control and Prevention (CDC) estimates that 25 million Americans, including five million children, have asthma. Patients with severe asthma represent fewer than five to ten percent of all individuals with asthma. In addition to being treated with inhaled corticosteroids (ICS) and long-acting beta agonist (LABA) therapy, these patients are often treated with oral corticosteroids (OCS).

Tezspire (tezepelumab) is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2λ), indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. TSLP is believed to play important roles in type 2 immunity but, also in other inflammatory pathways.

The Global Initiative for Asthma (GINA) guidelines recommend treatment by a specialist when asthma cannot be controlled by standard inhaler treatment with confirmed adherence and proper inhaler technique. With a confirmed diagnosis of severe asthma, patients should be evaluated for type 2 inflammation. Patients without type 2 inflammation may be appropriate for biologic therapy including Tezspire. Of note, the GINA guidelines do specifically call out that there is insufficient evidence for the use of Tezspire in patients on maintenance oral corticosteroids. In patients with type 2 inflammation, Tezspire is noted in guidelines to be appropriate for patients with exacerbations in the last year. Patients with higher blood eosinophils and higher FeNO are predicted to have better outcomes with Tezspire. It is recommended that type 2 targeted biologics are trialed for a 4-month time period. If within these 4 months the patient does not demonstrate a response, they should be switched to a different agent.

Summary

Effective Date of Policy:	6/15/2026
Indications	Add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma
ICD10 Diagnosis Codes	J45 (subcodes), J32 and 33 subcodes
HCPCS	J2356
Availability	*210 mg/1.91 mL (110 mg/mL) solution in a single-dose glass vial* *210 mg/1.91 mL (110 mg/mL) solution in a single-dose pre-filled syringe*
Duration	Initial: six months Continuation: two years

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy:

Specific Indication	Criteria
Indication **Add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma** (FDA approval) ICD10: J45	1. Therapy is being requested by a pulmonologist or allergist/immunologist **AND** 2. The member is at least 12 years of age or older **AND** 3. The member must have severe asthma **AND** 4. The member must be a non-smoker defined as someone who has not smoked in the preceding six months **AND** 5. The member must have well-documented use of high-dose inhaled corticosteroids (ICS) (see Tables 1-3 in considerations section) for at least 3 months, be compliant with existing therapy, and have followed GINA guidelines for asthma treatment including an adequate trial of a high-dose inhaled steroid in combination with a long-acting beta agonist a. Compliance will be assessed based on pharmacy refill history. If the patient does not have pharmacy benefits through this health plan, a recent pharmacy profile will be requested. Progress notes documenting usage of sample medication may also be requested. b. If there is a contraindication to use of a long-acting beta agonist, then an alternative controller drug may be used in combination with a high-dose inhaled steroid such as a leukotriene inhibitor or long-acting muscarinic antagonist.

	c. Patient must have documentation of inadequate control despite optimal therapy (above) for a period of at least 3 months **AND** 6. Tezspire must be used in combination with existing asthma therapy (as defined above). a. Monotherapy will not be authorized as this agent is only FDA-approved as add-on maintenance treatment **AND** 7. The patient must have eosinophils < 150 cells per microliter (the measurement must have been taken within the last 6 weeks) AND the patient must NOT be oral corticosteroid dependent (OCS; OCS-dependence is defined as reliance on daily, maintenance oral prednisone, methylprednisolone, etc. [OCS-dependence should be supported by clinical progress notes and/or pharmacy claims]) **AND** 8. The member must have experienced 2 or more asthma exacerbations despite therapy, within the preceding 12 months that required medical attention (defined as non-routine doctor visits, urgent care, emergency room visits or documented need for acute systemic steroids). 9. Initial approval will be for 6 months. Subsequent recertifications will be for 2 years and will require an objective assessment of response from the provider (reductions in hospitalizations, ER visits, and rescue medication use) as well as compliance history with the inhaled corticosteroid and controller medication. Recertification will not be granted if the patient starts or re-starts smoking. See recertification statement and additional approval time-period table for medical benefit in policy guidelines section of this policy. 10. Dosing: 210 mg subcutaneously once every 4 weeks
Chronic Rhinosinusitis with Nasal Polyps (FDA approval) ICD10: J32 and J33	1. Must be prescribed by or in consultation by an Allergist/Immunologist, or Otolaryngologist **AND** 2. Must have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) a. Chronic is defined as having lasted for at least 12 weeks **AND** b. Must currently have nasal polyposis, confirmed by evidence (such as direct examination, nasal endoscopy, imaging studies such as a sinus CT scan) 3. Must be ≥ 12 years of age **AND** 4. Must have had either: **a.** Prior nasal surgery **OR** **b.** Prior treatment with a course of systemic corticosteroids 5. Step therapy applies – Step therapy (a **AND** b) applies to New Starts for all lines of business, **including** Medicare Part B: a. Must have documented inadequate response despite at least 3 months of compliant use of mometasone nasal spray at a dose of 2 sprays in each nostril twice daily (compliance will be verified through pharmacy claims history. Note: each inhaler =17g = 120 sprays, therefore claims should reflect **34 g/30 days** for the required dosing) **AND** b. Must have documented inadequate response despite at least 3 months of compliant use of Xhance nasal spray at a dose of 2 sprays in each nostril twice daily (compliance will be verified through pharmacy claims history. Note: each inhaler =16ml = 120 sprays, therefore claims should reflect **32 ml/30 days** for the required dosing) **AND** 6. Must have had serious side effects or drug failure of Dupixent unless there is a medical reason why Dupixent cannot be used 7. Must be used in combination with an intranasal corticosteroid a. Tezspire as monotherapy for this indication will not be authorized as both agents are only FDA approved as an add-on maintenance treatment 8. Approved dosing: Tezspire 210mg once every 4 weeks 9. Initial approval will be granted for **6** months. All recertifications will be for 2 years and will require documentation of continued use of an intranasal corticosteroid and clinical benefit from Tezspire use (e.g., reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal symptoms, improved sense of smell) 10. Tezspire will not be approved for use in combination with Dupixent, Nucala or Xolair for Chronic Rhinosinusitis with Nasal Polyps

Exclusion Criteria

- Tezspire will not be approved as monotherapy for asthma
- Tezspire will not be approved to be used in combination with other biologic therapies for the treatment of asthma or nasal polyps.

- For any diagnosis, if Tezspire therapy is initiated with samples and the member does not meet our criteria for coverage (as outlined above) before the start of Tezspire therapy, upon completion of the samples, coverage of Tezspire will not be granted.

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.

Table 1:

Estimated comparative daily doses for inhaled glucocorticoids in adolescents ≥12 years and adults

Drug	Low dose (total daily dose)	Medium dose (total daily dose)	High dose (total daily dose)*
Beclomethasone HFA (Qvar RediHaler product available in United States) Administer as 2 divided doses	80 to 160 mcg	>160 to 320 mcg	>320 to 640 mcg
40 mcg per actuation	2 or 4 inhalations	¶	¶
80 mcg per actuation	2 inhalations	4 inhalations	6 or 8 inhalations
Beclomethasone HFAΔ (Qvar product available in Canada, Europe, and elsewhere) Administer as 2 divided doses	100 to 200 mcg	>200 to 400 mcg	>400 to 800 mcg
50 mcg per actuation	2 to 4 inhalations	¶	¶
100 mcg per actuation	2 inhalations	4 inhalations	6 or 8 inhalations
Budesonide DPI (Pulmicort Flexhaler product available in United States) Administer as 2 divided doses	180 to 360 mcg	>360 to 720 mcg	>720 to 1440 mcg
90 mcg per actuation	2 or 4 inhalations	¶	¶
180 mcg per actuation	2 inhalations	4 inhalations	6 or 8 inhalations
Budesonide DPIΔ (Pulmicort Turbuhaler or Turbohaler product available in Canada, Europe, and elsewhere) Administer low doses (ie, ≤400 mcg/day) once daily; administer higher doses (ie, >400 mcg/day) as 2 to 4 divided doses	200 to 400 mcg	>400 to 800 mcg	>800 to 2400 mcg
100 mcg per actuation	2 to 4 inhalations	¶	¶
200 mcg per actuation	1 to 2 inhalations	3 to 4 inhalations	¶
400 mcg per actuation	1 inhalation	2 inhalations	3 to 6 inhalations
Ciclesonide HFA (Alvesco product available in United States, Europe, and elsewhere) United States: Administer as 2 divided doses Australia, Europe, and elsewhere: Administer lower doses (ie, 160 to 320 mcg/day) once daily; administer 640 mcg dose as 2 divided doses	160 mcg	320 mcg	640 mcg
80 mcg per actuation	2 inhalations	4 inhalations	¶
160 mcg per actuation	◇	2 inhalations	4 inhalations
Ciclesonide HFAΔ (Alvesco product available in Canada) Administer lower doses (eg, 100 to 400 mcg) once daily; administer 800 mcg dose as 2 divided doses	100 to 200 mcg	>200 to 400 mcg	>400 to 800 mcg
100 mcg per actuation	1 to 2 inhalations	3 to 4 inhalations	¶
200 mcg per acutation	1 inhalation	2 inhalations	3 to 4 inhalations

Fluticasone propionate HFA (Flovent HFA product available in United States) Administer as 2 divided doses	176 to 220 mcg	>220 to 440 mcg	>440 to 1760 mcg
44 mcg per actuation	4 inhalations	¶	¶
110 mcg per actuation	2 inhalations	4 inhalations	¶
220 mcg per actuation	◇	2 inhalations	4 to 8 inhalations
Fluticasone propionate HFAΔ (Flovent HFA product available in Canada; Flixotide Evohaler product available in Europe and elsewhere) Administer as 2 divided doses	100 to 250 mcg	>250 to 500 mcg	>500 to 2000 mcg
50 mcg per actuation	2 to 4 inhalations	¶	¶
125 mcg per actuation	2 inhalations	4 inhalations	¶
250 mcg per actuation	◇	2 inhalations	4 to 8 inhalations
Fluticasone propionate DPI (Flovent Diskus product available in United States and Canada; Flixotide Accuhaler product available in Europe and elsewhere) Administer as 2 divided doses	100 to 250 mcg	>250 to 500 mcg	>500 to 2000 mcg
50 mcg per actuation	2 to 4 inhalations	¶	¶
100 mcg per actuation	2 inhalations	4 inhalations	¶
250 mcg per actuation	◇	2 inhalations	4 to 8 inhalations
500 mcg per actuation (strength not available in United States)	◇	◇	2 or 4 inhalations
Fluticasone propionate DPI (Armonair Digihaler product available in United States; Aermony Respiclick product available in Canada) Administer as 2 divided doses	110 mcg	226 mcg	464 mcg
55 mcg per actuation	2 inhalations	¶	¶
113 mcg per actuation	◇	2 inhalations	¶
232 mcg per actuation	◇	◇	2 inhalations
Fluticasone furoate DPI (Arnuity Ellipta product available in United States, Canada, Australia, and elsewhere, but not available in Europe or UK) Administer once daily **NOTE:** Inhaled fluticasone furoate has a greater anti-inflammatory potency per microgram than fluticasone propionate inhalers. Thus, fluticasone furoate is administered at a lower daily dose and used only once daily.	50 mcg (by use of pediatric DPI, which is off-label in adolescents and adults)	100 mcg	200 mcg
50 mcg per actuation	1 inhalation	¶	¶
100 mcg per actuation	◇	1 inhalation	2 inhalations
200 mcg per actuation	◇	◇	1 inhalation
Mometasone DPI (Asmanex Twisthaler product available in United States) May administer lower doses (ie, 220 to 440 mcg/day) once daily; administer 880 mcg dose as 2 divided doses	220 mcg	>220 to 440 mcg	>440 to 880 mcg
110 mcg per actuation	2 inhalations	¶	¶
220 mcg per actuation	1 inhalation	2 inhalations	4 inhalations

Mometasone DPI (Asmanex Twisthaler product available in United States) May administer lower doses (ie, 220 to 440 mcg/day) once daily; administer 880 mcg dose as 2 divided doses	220 mcg	>220 to 440 mcg	>440 to 880 mcg
110 mcg per actuation	2 inhalations	¶	¶
220 mcg per actuation	1 inhalation	2 inhalations	4 inhalations
Mometasone HFA (Asmanex HFA product available in United States) Administer as 2 divided doses	200 mcg	>200 to 400 mcg	>400 to 800 mcg
100 mcg per actuation	2 inhalations	4 inhalations	¶
200 mcg per actuation	◇	2 inhalations	4 inhalations
Mometasone DPIΔ (Asmanex Twisthaler product available in Canada, Europe, and elsewhere) May administer lower doses (ie, 200 to 400 mcg/day) once daily; administer 800 mcg dose as 2 divided doses	200 mcg	>200 to 400 mcg	>400 to 800 mcg
200 mcg per actuation	1 inhalation	2 inhalations	¶
400 mcg per actuation	◇	1 inhalation	2 inhalations

- **The most important determinant of appropriate dosing is the clinician's judgment of the patient's response to therapy.** The clinician must monitor the patient's response on several clinical parameters and adjust the dose accordingly. The stepwise approach to therapy emphasizes that once control of asthma is achieved, the dose of medication should be carefully titrated to the minimum dose required to maintain control, thus reducing the potential for adverse effects.
- Suggested total daily doses for low, medium, and high dose inhaled glucocorticoid regimens are based on daily doses recommended by Global Initiative for Asthma (GINA), National Asthma Education and Prevention Program (NAEPP), and/or product labeling[1-5]. This is not a table of equivalence.
- Depending on the specific product, total daily doses are administered once or divided and given twice daily. Refer to local product information or a clinical drug reference (eg Lexicomp).
- Some doses are outside the approved product information recommendations.

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant metered dose inhaler.

* Evidence for additional improvement with dose increases >1000 mcg/day is limited.

¶ Select alternate preparation with higher mcg/actuation to improve convenience.

Δ Products shaded in light gray color are not available in the United States but are available widely elsewhere.

◇ Select preparation with fewer mcg/actuation.

Table 2:

Usual doses of combined inhaled glucocorticoids and bronchodilators

Medication	Low dose	Medium dose	High dose
ICS-SABA combination			
Budesonide-albuterol HFA (Brand name: Airsupra)*			
NOTE: Not used for maintenance therapy.			
Acute symptom relief: Budesonide-albuterol (80 mcg/90 mcg) 2 inhalations as needed (usual maximum: 12 inhalations/day).			
ICS-LABA combinations			
Beclomethasone [beclometasone]-formoterol DPI or HFA (Not available in United States or Canada, but available elsewhere [sample brand names: Formodual, Fostair, Foster])¶Δ			
100 mcg/6 mcg	1 inhalation twice a day	2 inhalations twice a day	
200 mcg/6 mcg			2 inhalations twice a day
Budesonide-formoterol HFA (Brand name: Symbicort)¶			
80 mcg/4.5 mcg	2 inhalations twice a day		
160 mcg/4.5 mcg		2 inhalations twice a day	
Fluticasone furoate-vilanterol DPI (Brand name: Breo Ellipta)Δ			
NOTE: Inhaled fluticasone furoate has a greater anti-inflammatory potency per microgram than fluticasone propionate inhalers. Thus, fluticasone furoate is administered at a lower daily dose and used only **once** daily.			
50 mcg/25 mcg◇	1 inhalation once daily		
100 mcg/25 mcg		1 inhalation once daily	
200 mcg/25 mcg			1 inhalation once daily
Fluticasone propionate-formoterol MDI (Not available in United States or Canada, but available elsewhere [sample brand name: Flutiform])			
50 mcg/5 mcg	2 inhalations twice daily		
125 mcg/5 mcg		2 inhalations twice daily	
250 mcg/10 mcg			2 inhalations twice daily
Fluticasone propionate-salmeterol DPI (Brand names: Advair Diskus, Wixela Inhub)Δ			
100 mcg/50 mcg	1 inhalation twice a day		
250 mcg/50 mcg		1 inhalation twice a day	
500 mcg/50 mcg			1 inhalation twice a day
Fluticasone propionate-salmeterol HFA (Brand name: Advair HFA)			
45 mcg/21 mcg	2 inhalations twice a day		
115 mcg/21 mcg		2 inhalations twice a day	
230 mcg/21 mcg			2 inhalations twice a day
Fluticasone propionate-salmeterol DPI (Brand names: AirDuo RespiClick, AirDuo Digihaler)Δ§			
55 mcg/14 mcg	1 inhalation twice a day		
113 mcg/14 mcg	1 inhalation twice a day	1 inhalation twice a day	
232 mcg/14 mcg			1 inhalation twice a day
Mometasone-formoterol HFA (Brand name: Dulera)			
100 mcg/5 mcg		2 inhalations twice a day	
200 mcg/5 mcg			2 inhalations twice a day
Mometasone-indacaterol DPI (Brand name: Atectura Breezhaler; available in Canada)Δ			
80 mcg/150 mcg	1 inhalation (capsule) once a day		
160 mcg/150 mcg		1 inhalation (capsule) once a day	
320 mcg/150 mcg			1 inhalation (capsule) once a day
ICS-LAMA-LABA combinations¥			
Fluticasone furoate-umeclidinium-vilanterol DPI (Brand name: Trelegy Ellipta)Δ			
100 mcg/62.5 mcg/25 mcg		1 inhalation once daily	
200 mcg/62.5 mcg/25 mcg			1 inhalation once daily
Mometasone-glycopyrrolate (glycopyrronium)-indacaterol DPI (Brand name: Enerzair Breezhaler; available in Canada)*Δ			
160 mcg/50 mcg/150 mcg			1 inhalation (capsule) once a day

Do not exceed the maximum number of inhalations/puffs per day listed in the table due to the risk of toxicity from an excess dose of long-acting beta-agonist (ie, salmeterol, formoterol, or vilanterol). Brand names and dose per puff or per inhalation of commercially available fixed dose combinations are according to United States prescribing information, unless otherwise noted. Consult local product information before use.

ICS: inhaled glucocorticoid (inhaled corticosteroid); SABA: short-acting beta-agonist; LABA: long-acting beta-agonist; LAMA: long-acting muscarinic antagonist; HFA: metered dose inhaler with hydrofluoroalkane propellant; DPI: dry powder inhaler; SMI: soft mist inhaler.

* Not approved for use in patients <18 years old.

¶ When using ICS-formoterol as reliever, use one to two inhalations as needed. Maximum daily dose of maintenance and rescue is 12 inhalations.

Δ DPI contains lactose which may have small amounts of milk protein.

◇ Fluticasone furoate-vilanterol 50 mcg/25 mcg DPI is approved for use in patients 5 to 11 years old; use in adolescents and adults is off-label.

§ In AirDuo inhalers, the daily dose of salmeterol is approximately one-fourth of the dose in Advair, and the daily dose of fluticasone is approximately one-half that of the comparable low-, medium-, and high-dose strengths of Advair.

¥ Alternatively, tiotropium SMI (Brand name: Spiriva Respimat) can be used with an ICS or ICS-LABA inhaler. The dose in asthma is two inhalations (1.25 mcg/inhalation) once daily.

Reference: Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. https://ginasthma.org/wp-content/uploads/2023/05/GINA-2023-Full-Report-2023-WMS.pdf. Updated 2023 (Accessed on June 13, 2023).

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Table 3:

Estimated comparative daily doses for inhaled glucocorticoids in children

Drug	Low daily dose		Medium daily dose		High daily dose	
	Child 0 to 4	Child 5 to 11	Child 0 to 4	Child 5 to 11	Child 0 to 4	Child 5 to 11
Beclomethasone HFA 40 or 80 mcg/puff	NA	40 mcg/puff - 1 to 2 puffs twice per day	NA	40 mcg/puff - 2 to 4 puffs twice per day 80 mcg/puff - 1 to 2 puffs twice per day	NA	80 mcg/puff - 3 to 4 puffs twice per day
Budesonide DPI* (breath activated) 90 or 180 mcg/inhalation	NA	90 mcg/inhalation - 1 to 2 inhalations twice per day	NA	180 mcg/inhalation - 1 to 2 inhalations twice per day	NA	180 mcg/inhalation - 3 to 4 inhalations twice per day
Budesonide nebulization suspension¶ 0.25 mg/2 mL, 0.5 mg/2 mL, or 1 mg/2 mL	0.25 to 0.5 mg once daily or as 2 divided doses	0.5 mg once daily or as 2 divided doses	0.75 to 1 mg once daily or as 2 or 3 divided doses	1 mg once daily or as 2 divided doses	1.25 to 2 mg once daily or as 2 divided doses	2 mg once daily or as 2 divided doses
Ciclesonide HFAΔ 80 or 160 mcg/puff	NA	80 mcg/puff - 1 to 2 puffs once daily	NA	80 mcg/puff - 3 to 4 puffs once daily	NA	80 mcg/puff - 5 to 6 puffs once daily or as 2 divided doses 160 mcg/puff - 3 puffs once daily or as 2 divided doses
Fluticasone HFA◇ 44, 110, or 220 mcg/puff	44 mcg/puff - 2 puffs twice per day◇	44 mcg/puff - 1 to 2 puffs twice per day	44 mcg/puff - 2 to 4 puffs twice per day 110 mcg/puff - 1 puff in AM and 2 puffs in PM	44 mcg/puff - 2 to 4 puffs twice per day 110 mcg/puff - 1 puff in AM and 2 puffs in PM	110 mcg/puff - 2 puffs twice per day 220 mcg/puff - 1 puff twice per day	110 mcg/puff - 2 puffs twice per day 220 mcg/puff - 1 puff twice per day
Fluticasone DPI (breath activated)§ 50, 100, or 250 mcg/inhalation	NA	50 mcg/inhalation - 1 to 2 inhalations twice per day	NA	50 mcg/inhalation - 3 to 4 inhalations twice per day 100 mcg/inhalation - 1 inhalation in AM and 2 inhalations in PM to 2 inhalations twice per day	NA	100 mcg/inhalation - 2 inhalations in AM and 3 inhalations in PM 250 mcg/inhalation - 1 inhalation twice per day
Mometasone aerosol DPI (breath activated)* 110 or 220 mcg/inhalation	NA	110 mcg/inhalation - 1 inhalation once daily	NA	110 mcg/inhalation - 2 to 3 inhalations once daily	NA	110 mcg/inhalation - 4 inhalations once daily or 2 inhalations twice per day 220 mcg/inhalation - 2 inhalations once daily or 1 inhalation twice per day
Mometasone HFA MDI 50, 100, or 200 mcg/puff	NA	50 mcg/puff - 1 puff once or twice per day	NA	50 mcg/puff - 2 to 3 puffs twice per day 100 mcg/puff - 1 puff twice per day	NA	100 mcg/puff - 2 puffs twice per day 200 mcg/puff - 1 inhalation twice per day

Some doses may be outside approved package labeling, especially in the high-dose range. Doses shown and strengths (ie, mcg per puff or inhalation) are based upon product descriptions approved in the United States, which may differ from how strengths are described for products available in other countries. Consult local product information before use.

HFA: hydrofluoroalkane; NA: not approved and no data available for this age group; DPI: dry-powder inhaler; AM: in morning; PM: in evening; US FDA: US Food and Drug Administration; MDI: metered-dose inhaler.

* Contains milk protein.

¶ Budesonide suspension is compatible with albuterol, ipratropium, and levalbuterol nebulizer solutions in the same nebulizer. Use only jet nebulizers as ultrasonic nebulizers are ineffective for suspensions.

Δ Ciclesonide is not approved by the US FDA for use in children under 12. It is approved for use in children 6 years of age and older in Canada, some European countries, and elsewhere.

◇ For fluticasone HFA, the low dose for children <4 years is higher than for children 5 to 11 years of age due to lower dose delivered with facemask and data on efficacy in young children.

§ Contains lactose.

Data from:

1. National Heart, Blood, and Lung Institute Expert Panel Report 3 (EPR 3): Guidelines for the Diagnosis and Management of Asthma. NIH Publication no. 08-4051, 2007.
2. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. Updated 2012. Available at www.ginasthma.org.

References

		Accessed
1	ICER. Tezepelumab for Severe Asthma. Evidence Report. 2021 Nov 4.	3/2022
2	ICER. Tezepelumab for Severe Asthma: Final Policy Recommendations. 2021 Dec 16. Available at: https://icer.org/news-insights/press-releases/icer-publishes-final-evidence-report-and-policy-recommendations-on-tezepelumab-for-severe-asthma/	1/2023
3	Tezspire (tezepelumab) Clinical Trial (NCT03347279). Available at: https://clinicaltrials.gov/ct2/show/NCT03347279?cond=tezepelumab&draw=3&rank=13	1/2023
4	Tezspire [package insert]. Thousand Oaks, CA: Amgen Inc.; 2023 May.	10/2025
5	Menzies A, Corren J, Bourdin A, et al. Tezepelumab in adults and adolescents with severe, uncontrolled asthma. 2021 May 13. New England Journal of Medicine. Available at: https://www.nejm.org/doi/full/10.1056/NEJMoa2034975	1/2024
6	Global Initiative for Asthma. Global strategy for asthma management and prevention, 2023. Updated July 2023. Available from: www.ginasthma.org	1/2024

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE CHOICES:	Subject to all terms and conditions noted in above application if administered under the medical benefit
SELECT/HARP PLAN:	Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program

CDPHP Pharmacy Services 6/15/2026

New: 4/2022

Date	Notes
4/2023	Reviewed with no changes
4/2024	Revised: • Background updated to reflect current guidelines • Removed exclusion criteria of eosinophilic or allergic asthma diagnosis • Changed the criteria related to smoking status from "The enrollee must not use tobacco products or have had a greater than 10 pack-year past history of smoking" to "The enrollee must be a non-smoker defined as someone who has not smoked in the preceding 6 months"
4/2025	Revised. Added allergist/immunologist as acceptable prescribers
6/2025	Removed requirement that the member must have a specific eosinophil count
12/2025	Added indication for Chronic Rhinosinusitis with Nasal Polyps
6/2026	Added corticosteroid tables to considerations section Updated asthma criteria wording

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MEDICAL POLICY

Medical Policy Title	**Therapies (Speech, Physical, and Occupational)**
Policy Number	**8.01.24**
Current Effective Date	**January 1, 2027**
Next Review Date	**November 2027**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

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Individualized Education Program (IEP)

Initial Therapy Requests

I. Restorative or habilitative physical therapy (PT), occupational therapy (OT) or speech therapy (ST) are considered **medically appropriate** with **ANY** of the following indications when determined by standardized assessments:
   A. Functional physical impairment due to disease;
   B. Trauma/injury;
   C. Previous therapeutic processes (e.g., traumatic brain injury, cardiovascular accident/stroke);
   D. Prior therapeutic intervention(s);
   E. Children exhibiting at least a moderate to severe delay or disability as determined by standardized assessments, resulting from disease, trauma, congenital anomaly, or developmental delay;
      1. A moderate to severe deficit is generally defined as (Refer to Policy Guideline):
         a. A score at least 1.5 standard deviations below the mean (i.e., a standard score of 77 or below for most standardized tests that have an average score of 100 with a

standard deviation of 15). (Standardized Speech Tests)

2. Cross-disciplinary and age equivalency scores may be considered, as well as percentage scores, and standard deviation when determining the severity of the impairment.

II. In determining the **medical appropriateness** of PT, OT or ST services, consideration will be given to individuals based on **BOTH** of the following criteria:

A. The degree of limitation/deficit the impairment imposes on the individual; **and**

B. Deficit(s) are expected to improve over a short period of time (generally up to two (2) months) with treatment.

Continuation of Services

III. Continuation of PT, OT, or ST services beyond the initial evaluation and approved therapy sessions will be considered **medically appropriate** if **ALL** of the following criteria have been met:

A. Maintenance service level has not been achieved (Refer to Policy Guidelines);

B. Significant improvement must be demonstrated in objective measures including but not limited to **ANY** of the following:

1. Standardized assessments;
2. Non-imaging assessment; **or**
3. Speech specific testing (e.g., Repeat barium swallow; Fiberoptic endoscopic examination of swallowing (FEES), Weight gain);

C. Documentation of **ALL** of the following:

1. Showing continued improvement within the past treatment period;
2. An updated treatment plan; **and**
3. That the member is actively participating in therapy sessions.

Speech Therapy

IV. Speech Therapy services are considered **not medically necessary** for **ANY** the following indications:

A. Vocal cord polyps, as the usual recommended treatment is excision of the polyps;

B. Untreated conductive hearing loss, as diagnosis of and treatment for the hearing loss should first be provided;

C. Individual is receiving maintenance services (Refer to Policy Descriptions);

D. Oral myofunctional disorders (e.g., tongue thrust, deviant swallow, reverse swallow, visceral swallow);

E. Pragmatic language disorders/impairments.

Dysphagia and Feeding Difficulties

*For continuation of ST service (Refer to Policy Statement III).

V. Dysphagia in children with the potential functional ability to feed by mouth in need of ST is considered **medically appropriate** for and **EITHER** of the following indications:
   A. Evaluation of and diagnosis of aspiration or laryngeal penetration by a physician with expertise in the diagnosis and treatment of dysphagia;
   B. The child has a history of or is at high risk for recurrent aspiration or choking or has clinical signs/symptoms of aspiration.

VI. Feeding difficulties in children in need of ST is considered **medically appropriate** when **ANY** of the following criteria are met:
   A. Food refusal creating a risk of malnutrition, leading to the required use of enteral feeding or nutritional supplements; (Refer to Policy Guidelines)
   B. Nutritional status deficiencies that risk diet related diseases (e.g., rickets, scurvy).

Vocal Cord Dysfunction and Voice Therapy

* For continuation of ST service (Refer to Policy Statement III).

VII. Vocal Cord Dysfunction (VCD) treatment using ST is considered **medically appropriate**. (Treatment of VCD is not the same as voice therapy).

VIII. Voice therapy (Voice therapy is not the same as treatment of Vocal Cord Dysfunction) is considered **medically appropriate** for voice disorders when **ALL** of the following criteria has been met:
   A. When a pathological process has been identified (e.g., anatomic laryngeal/vocal cord abnormality);
   B. Other methods of treatment have been documented as ineffective.

IX. Voice therapy is considered **not medically necessary** for **ANY** of the following:
   A. Intensive behavioral therapy with or without the use of a computerized software program including but not limited to:
      1. Lee Silverman Voice Therapy, LSVT LOUD;
      2. SPEAK OUT!

Physical and Occupational Therapy

X. Non-skilled therapy services that do not require the expertise of an OT or PT therapist are considered **not medically necessary** and include but are not limited to **ANY** of the following:
   A. Passive range of motion (PROM) treatment that is not related to restoration of a specific loss of function;
   B. Treatments, given to an individual who presents without complications, including but not

limited to **ANY** of the following:

1. Infrared heat;
2. Whirlpool, paraffin or contrast baths;
3. Hubbard tank;
4. Cold, ice or heat packs;
5. Aquatic exercises;
6. Transcutaneous Electrical Nerve Stimulation (TENS);

C. Services that maintain function by using routine, repetitive procedures, exercise, conditioning or gym programs (land- or water-based), for stable, chronic conditions (lasting longer than three months since initial onset), such as fibromyalgia or chronic pain syndrome (chronic low-back pain);

D. Vasopneumatic compression, when used alone and without the need for skilled monitoring of potential adverse signs and symptoms;

E. Crutch training.

XI. The following PT or OT services are considered **not medically necessary** for **ANY** of the following:

A. Gait analysis;

B. Sensory integration therapy (SIT);

C. Hippotherapy, equine movement therapy, horseback riding;

D. Isokinetic testing with an isokinetic dynamometer (e.g., Biodex, Cybex II, Omnikinetic, Lido Active) in the assessment of muscle strength;

E. Programs solely for sports and/or recreational purposes (e.g., conditioning, strength training, and aquatic exercise programs such as water aerobics and water walking);

F. Maintenance programs (Refer to Policy Descriptions);

G. Work-related or workers' compensation programs (Refer to Policy Description, including but not limited to:

1. Work evaluation;
2. Work reconditioning, or work hardening programs;
3. Sheltered work programs; **or**
4. Vocational training.

XII. The following PT or OT Services are considered **investigational** for all indications, including but not limited to:

A. Dry needling;

B. Constraint-induced movement therapy (CIMT), as a sole measure of therapy.

RELATED POLICIES

Corporate Medical Policy

1.01.03 Augmentative and Alternative Communication Systems (e.g., Speech Generating Devices)

7.01.84 Gender Reassignment and Treatments for Commercial and Medicare Members

2.01.13 Computerized Motion Diagnostic Imaging (CMDI)/Gait Analysis

7.01.11 Cosmetic and Reconstructive Procedures, which includes iontophoresis

10.01.02 Chiropractic Care

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. OT, PT and ST services should be provided by the appropriate licensed therapist operating within their scope of practice. The therapist should address the functional needs of patients with physical impairments resulting from various causes, including disease, trauma, congenital anomalies, or prior therapeutic interventions. Treatment goals should be tailored to the patient's specific diagnosis, with an expectation of measurable improvement within a reasonable and predictable timeframe. The therapy provided should be specific, effective, and appropriate for the patient's diagnosis and physical condition.

II. Documentation for therapy services must contain a written plan of care, which should include:

A. Diagnosis, including severity level of diagnosis;

B. Specific statements of long- and short-term functional-based goals;

C. Measurable objectives based on standardized outcome measures defined in evaluation and reassessed during follow-up sessions;

D. A reasonable estimate of when the goals will be reached;

E. The specific treatment techniques and/or activities to be used in treatment (skilled intervention);

F. The frequency and duration of treatment; and

G. Prior level of function (PLOF), prior treatment, and current level of function (CLOF).

III. Classification of Impairments According to Severity

A. Mild Impairment:

1. Less than one (1) standard deviation from normal,

2. Appropriate for PT one (1) time per week.

B. Moderate Impairment:
   1. One (1)-to-two (2) standard deviations from normal,
   2. Appropriate for PT two (2) times per week.

C. Severe Impairment:
   1. More than two standard deviations from normal,
   2. Appropriate for PT three (3) times per week.

Individualized Education Program (IEP)

I. New York State Department of Health Early Intervention Program defines a developmental delay that has been measured by qualified personnel using clinical opinion, appropriate diagnostic procedures and/or instruments as documented as **ANY** of the following:
   A. A 12-month delay in one functional area;
   B. A 33% delay in one functional area or a 25% delay in each of two (2) areas;
   C. If appropriate standardized instruments are individually administered in the evaluation process, a score of at least 2.0 standard deviations below the mean in one functional area or a score of at least 1.5 standard deviations below the mean in each of two functional areas.

II. If outpatient therapies requested are in addition to the early intervention services, or school-based services noted in the IEP, or the provider does not feel that the child's needs are being met by the school-based services noted in the IEP, or when there is no IEP provided but it is documented that the child receives school-based services, or documentation must include rationale supporting the medical necessity of the additional outpatient services beyond what the child is already receiving at school as noted in the IEP.

III. Coverage is not available for services provided by school districts, as stipulated in a child's (preschool, ages 3-5 years, and school, ages 5-21 years) IEP, as the services are generally considered free care or a government program.
   A. When applicable, an IEP should be completed through the school district before a request for coverage is submitted to the Health Plan. If an IEP is not submitted, the request for speech therapy will be reviewed by the Health Plan for medical necessity in accordance with member's subscriber contract.
   B. Speech therapy services denied by the school district, including summer services, and not covered in a child's IEP will be reviewed by the Health Plan for medical necessity in accordance with member's subscriber contract.
   C. If a child is home-schooled, an assessment by the school district should be completed prior to submitting a request to the Health Plan for coverage. Requests for home-schooled children outside NYS will be decided in accordance with NYS laws; however, if an appeal is requested and another state's law is provided or cited, the case should be forwarded for legal review, to determine whether the other state's law should be applied.

D. Interim summer programs are provided by school districts for children whose handicapping conditions are severe enough to warrant a structured learning environment of 12 months' duration in order to maintain developmental levels. For preschool children, summer instruction must be available for those whose disabilities are severe enough to exhibit the need for a structured learning environment of 12 months duration to prevent substantial regression.

Speech Therapy Guidelines

IV. A maintenance program may be established when the response to treatment has plateaued, or restorative potential is judged insignificant after a reasonable period of time. In these situations, coverage is limited to the initial evaluation and the design of an appropriate maintenance program.

Tools for Assessment of Malnutrition:

- The World Health Organization (WHO) provides tools to assess malnutrition https://www.who.int/health-topics/malnutrition#tab=tab_1
- Based ideal weight for children on National Center for Health Statistics (NCHS) growth charts. Https://www.cdc.gov/growthcharts/
- The 2015 Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition consensus statement for indicators recommended for the identification and documentation of pediatric malnutrition (undernutrition) listed testing that should be used to assess malnutrition:
  - Food/Nutritional Intake;
  - Assessment of Energy and Protein Needs;
  - Growth Parameters;
  - Mid-Upper Arm Circumference;
  - Weight Gain Velocity;
  - Handgrip Strength; and
  - Documentation of Tanner Stages.

Standardized Tests for Evaluation of Speech Disorders (list is not all inclusive)

V. A common standard score scale has a mean (average) of 100 and a standard deviation of 15.
   A. Goldman Fristoe Test of Articulation (GFTA)
   B. Arizona Articulation Proficiency Scale (AAPS)
   C. Preschool Language Scale (PLS)
   D. Clinical Evaluation of Language Fundamentals (CELF)
   E. Clinical Assessment of Articulation and Phonology (CAAP)

F. Stuttering Severity Index (SSI)

G. Recessive Expressive Emergent Language (REEL)

H. Test of Language Development (TOLD-P)

Feeding Difficulties in Children

VI. Feeding difficulties in children are dependent on the child's specific diagnosis. Typically, up to four (4) visits are allowed for feeding difficulties in neurotypical children. However, additional speech therapy visits may be medically appropriate for neuroatypical children or significant aerodigestive abnormalities with feeding difficulties (e.g., autism).

DESCRIPTION

Maintenance Program

Maintenance program is defined as a program that consists of activities that preserve the patient's present level of function and prevent regression of that function. Maintenance begins when the therapeutic goals of a treatment plan have been achieved or when no additional functional progress is apparent or expected to occur.

Work-Related or Workers' Compensation Programs

- Work-related or workers' compensation are for conditioning primarily for return to work and not treatment of a medical condition.
- When PT or OT services are needed to treat a medical or surgical condition in order for a patient to return to work, services are covered by the New York State Vocational and Educational Services for Individuals with Disabilities (VESID) Program.

Speech Therapy

Speech therapy services are those necessary for the diagnosis and treatment of speech and language impairments/disorders that result in communication disabilities, as well as for the diagnosis and treatment of swallowing disorders, or dysphagia.

Speech disorders refer to those affecting the articulation of speech sounds, the fluency with which speech is produced, or quality.

Speech Disorders

- Articulation disorders are also called phonological disorders and include:
    - Motor speech disorders resulting from damage to the central or peripheral nervous system (e.g., cerebral vascular accident, traumatic brain injury, or neurogenic disorders such as Parkinson's disease, Huntington disease, amyotrophic lateral sclerosis, and perinatal conditions); and
    - Functional articulation disorders, which have no known cause or result from causes other than known neurological insults or physical abnormalities. Functional articulation disorders account for the majority of articulation disorders in children.

- Fluency disorders are also referred to as stuttering, involve the interruption in the flow of speaking manifested as an atypical rate, rhythm, repetitions in sounds, syllables, words, and phrases; or some combination of these.
- Voice disorders are characterized by abnormal pitch, loudness, resonance, quality, or duration of voice, or by an inability to use voice, or some combination of these, result from overuse or misuse of vocal cords, medical condition or psychological disorder impacting the ability to communicate effectively.
- Language disorders are disorders of impaired comprehension and/or use of spoken, written, and/or other symbol systems used for communication (e.g., aphasia secondary to cerebral vascular accident, dementia, hearing impairment).
- Pragmatics is the system of combining the form (phonology, morphology, and syntax) and content (semantics) of language into functional and socially appropriate communication. A person with a pragmatic language disorder/impairment may say inappropriate or unrelated things during a conversation, tell stories in a disorganized way, or have little variety in the use of language.

Other Common Speech Terms

- Aphasia is defined as the absence or impairment of the ability to communicate through speech, writing, or signs because of brain dysfunction.
- Aphonia is defined as a loss of speech sounds from the larynx.
- Apraxia is defined as the inability to form words or speak, despite the ability to use oral and facial muscles to make sounds.
- Dysarthria is defined as impairments or clumsiness in the uttering of words due to diseases that affect the oral, lingual, or pharyngeal muscles.
- Dysphonia is defined as any impairment of the voice or speaking ability.
- Neurosensory Hearing Loss is defined as a decreased ability to perceive sounds as compared to normal.

Voice Therapy

Vocal cord dysfunction (VCD), also known as paradoxical vocal fold movement- is a respiratory disorder characterized by paradoxical closure of the vocal cords during the respiratory cycle that leads to airway obstruction. Symptoms can range from wheezing to stridor. VCD can be mistaken for asthma and is distinguished from asthma by the performance of a pulmonary function test and laryngoscopy. VCD is often treated with speech therapy, relaxation techniques, or psychotherapy.

Lee Silverman Voice Therapy, LSVT LOUD has been proposed as an intensive behavioral voice therapy program for individuals with Parkinson disease and other neurological disorders and is aimed at improving the vocal loudness of these patients. The LSVT Companion System may be used as a technical adjunct to the program, to complement person-to-person voice therapy. The sound produced by a patient's voice is received by a calibrated microphone and converted to a visual display

that consists of different visual and auditory feedback. The patient is given a target range of both vocal intensity (loudness) and fundamental frequency (pitch) and instructed to maintain a given loudness and or pitch for a given duration.

SPEAK OUT! is a program designed for individuals with Parkinson's disease to improve speech (speaking with intent) and swallowing. The exercises used target vocal function and speech clarity and moving it from an automatic function to an intentional task.

Dysphagia

Dysphagia is defined as difficulty swallowing. It is a frequently occurring impairment for children with disabilities because many disabling conditions are associated with oropharyngeal or esophageal dysfunction. The workup for dysphagia usually includes an evaluation by a speech therapist and may also include a video fluoroscopic barium study (often referred to as a cookie swallow) or a fiber-optic endoscopic evaluation of swallow. Speech and occupational therapists often collaborate in feeding therapy for children with poor oral motor and swallowing skills on the basis of the child's needs and the expertise of the providers involved.

Nutritional status deficiency refers to an imbalance in the intake of essential nutrients required by the body.

Physical Therapy

PT is the treatment of disease or injury by the use of therapeutic exercise and other interventions that focus on improving posture, locomotion, strength, endurance, balance, coordination, joint mobility, flexibility, and the ability to perform the functional activities of daily living, as well as the relief of pain. PT is a short-term therapy that is expected to result in significant, measurable improvements.

Baseline objective measurement(s) is/are essential to determine clinical effectiveness of all PT interventions. Clinical assessment of the patient's strength, prior to the initiation of PT, is essential to determining the therapeutic effectiveness of PT. Assessment data is obtained through a variety of standardized tests (e.g., measurement, functional performance, and manual or isokinetic muscle evaluation).

Hippotherapy (Equine-Assisted Therapy) is a treatment strategy that uses the movement of horses to engage sensory, neuromotor, and cognitive systems to achieve functional outcomes. It has been proposed as a therapy for individuals with impaired walking or balance.

Isokinetic exercise involves muscle use in an action that results in a movement without changing angular velocity. It involves the accommodation of resistance throughout the range of motion, to closely resemble normal action of muscle. Dynamometers are pieces of equipment that use hydraulics to maintain constant velocity and are controlled by a computer and associated software to measure joint flexion and extension via torque, typically of the knee, but can be adapted for other joints.

Dry needling refers to a procedure whereby a fine needle is inserted into the trigger point, to induce a twitch response and relieve pain. Research suggests that dry needling may improve pain control and reduce muscle tension in neck and/or shoulder pain, plantar heel pain, temporomandibular myofascial pain, and other conditions. Dry needling can be deep or superficial. Deep dry needling is

believed to inactivate trigger points by eliciting contraction and subsequent relaxation of the muscle via a spinal cord reflex. Superficial needing is believed to activate mechanoreceptors and have an indirect effect on pain by inhibiting C-fiber pain impulses.

Sensory integration therapy (SIT) is a form of PT that has been investigated as a method of treatment for developmental disorders in patients with established sensory processing dysfunction, as in autism spectrum disorder (ASD). Sensory integration therapy is aimed at improving the way the brain processes and organizes sensations, as opposed to teaching higher-order skills. Therapy usually involves activities that provide vestibular, proprioceptive, and tactile stimuli, which are selected to match specific sensory processing deficits of the child. For example, swings are commonly used to incorporate vestibular input, while trapeze bars and large foam pillows or mats may be used to stimulate somatosensory pathways of proprioception and deep touch. Tactile reception may be addressed through a variety of activities and surface textures involving light touch.

Occupational Therapy (OT)

Occupational Therapy (OT) is a short-term form of rehabilitation therapy involving the treatment of individuals of all ages with functional deficits resulting from injury, disease, or birth. Occupational therapists assess all components of function (strength, range of motion, sensation, coordination, cognition, perception, vision, memory, judgment, safety, etc.) and work with the individual through the use of goal-directed, graded activity and exercise to improve skills.

Sensory Integration Therapy (SIT) is a form of OT that has been investigated as a method of treatment for autism, intellectually disable, or learning disabilities. Sensory integration therapy is aimed at improving the way the brain processes and organizes sensations, as opposed to teaching higher-order skills.

Constraint-Induced Movement Therapy (CIMT) is proposed as a method of therapy to help patients with neurological disorders (e.g., cerebral palsy, congenital hemiplegia, stroke) regain the use of dysfunctional limb(s). CIMT involves restraint of the unaffected limb and intensively engaging the affected limb in repetitive exercises, which results in the new neural pathways being generated in the brain.

SUPPORTIVE LITERATURE

Speech Therapy

Sackley et al (2024) conducted a multicenter, three arm, unblinded, randomized controlled trial involving 388 people with Parkinson's and dysarthria to assess the clinical effectiveness of two speech and language therapy approaches versus no speech and language therapy. Participants were randomly assigned to one of three groups: Lee Silverman Voice Treatment (LSVT LOUD, n=130), NHS speech and language therapy (n=129), or no therapy (n=129). The primary outcome was self-reported Voice Handicap Index (VHI) at three months. Participants receiving LSVT LOUD reported lower VHI scores at three months than those who did not receive speech and language therapy (−8.0 points; 99% CI −13.3 to −2.6). NHS therapy showed no significant difference from no therapy (1.7 points; CI−3.8 to 7.1). Patients in the LSVT LOUD group also reported LVH index scores than did those randomized to NHS speech and language therapy (−9.6 points; CI−14.9 to −4.4). Adverse

events, mainly vocal strain, were reported in 93 LSVT LOUD participants and 46 NHS therapy participants; none were serious. LSVT LOUD was more effective than both NHS therapy and no therapy in reducing voice-related disability. NHS therapy showed no clear benefit over no treatment.

Namasivayam et al (2021) conducted a two-arm randomized control trial studying the effectiveness of Prompts for Restructuring Oral Muscular Phonetic Targets (PROMPT) in children with severe speech motor delays (SMD). The study was comprised of 49 children with SMD. The intervention group received 45 min of PROMPT intervention two times a week for 10 weeks or were waitlisted for the same duration and received only home training instructions. Outcome measures for speech motor control, articulation, speech intelligibility, and functional communication were assessed at baseline and at 10 weeks. PROMPT interventions were found to be clinically effective intervention for children with SMD.

Behrman et al (2020) conducted a prospective study on 40 individuals with idiopathic Parkinson's disease (PD) to assess the outcome of the SPEAK OUT! and the LOUD Crowd therapy programs. Of the 40 individuals, 12 received 40-minute sessions, 3 times per week of SPEAK OUT!, for 4 weeks. Assessments were conducted at baseline, within one week and 6 weeks after completion of the SPEAK OUT! sessions, while also participating in LOUD Crowd. Twenty-five (25) adults without communication disorders were assessed at the same schedule as the SPEAK-OUT! recipients. In the PD group reading and monologue intensity increased significantly. The mean values of intensity for the PD group were lower than those of the control group at baseline, but posttherapy values for the two groups were equivalent. Posttherapy, it was determined that there is evidence of effectiveness of this program on hypokinetic dysarthria secondary to PD.

Hippotherapy

The literature regarding hippotherapy consists of systematic reviews, randomized trials, and case series involving individuals with cerebral palsy, multiple sclerosis, stroke or gait and balance disorders. The randomized trials are generally small, can be described as having significant methodologic problems, and have not demonstrated that hippotherapy is superior to alternative therapies. Therefore, the evidence is insufficient to determine that it results in an improvement in the net health outcome.

Isokinetic Testing

Several isokinetic dynamometers have received FDA approval. Published literature suggests that due to the large variations in testing methods, isokinetic dynamometry has not been medically proven to improve net health outcomes or to be more effective than established methods of assessment of muscle strength. The effectiveness of isokinetic dynamometry has not been demonstrated outside the investigational setting.

Dry Needling

Dry needling has been investigated in randomized controlled trials (RCTs) and systematic reviews. Reviewers have summarized that studies have not associated dry needling with reductions in shoulder or neck pain compared to other modalities.

Young et al (2024) conducted a randomized, single blinded, multicenter, parallel group trial

comparing the effects of adding thrust spinal manipulations and electrical dry needling to conventional physical therapy in patients with lumbar spinal stenosis (LSS). Over 34 months, 128 patients from 12 outpatient clinics in eight states were assessed using Numeric Pain Rating Scale (NPRS) and the Oswestry Disability Index (ODI) (primary outcomes) and the Roland Morris Disability Index (RMDI), Global Rating of Change (GROC), and medication intake (secondary outcome) at 2 and 6 weeks and 3 months. At 3 months, the MEDNCPT group experienced greater reductions in overall pain and related disability compared to the conventional physical therapy (CPT) group. At 3 months, significantly more patients in the MEDNCPT group reported a successful outcome (GROC≥+5) than the CPT group. No significant differences were observed at earlier follow-ups. Limitations included the lack of sham-needling comparison group, the MEDNCPT group received additional treatments compared to the CPT group, the use of separate region-specific pain scores.

Sensory Integration Therapy (SIT)

There is insufficient evidence to permit conclusions regarding the effectiveness of SIT or whether SIT improves the net health outcome in children with autism and developmental impairments. Only one study was published for SIT in autistic children, and three studies were published for SIT in developmentally delayed children; the validity of all four studies is questionable. The evidence indicates that SIT does not improve the net health outcome in learning-disabled children when compared to alternative treatments or no treatment at all.

Occupational Therapy

García-Pérez et al (2024) conducted a prospective, randomized controlled clinical trial in 60 adults who have suffered a stroke and were discharged home and what the effectiveness of an early OT intervention programs (EOTIPS). Participants were assigned to the experimental group (n=30) were included in EOTIPS and were compared to a control group (n=30). Evaluations assessed quality of life (Stroke and Aphasia Quality of Life Scale [SAQOL-39]), functional independence (Modified Rankin Scale [mRS]), perceptual-cognitive skills (Montreal Cognitive Assessment [MoCA]), upper limb function (Fugl Meyer Assessment [FMA]), mobility (Berg Balance Scale [BBS] and Timed Up & Go [TUG]), communication skills (Communicative Activity Log [CAL]) and mood disorders (Beck Depression Inventory–II [BDI-II]); completed within two weeks post-stroke and at three month follow-up. Intent-to-treat analysis, considering all participants (dropouts as failures), and efficacy analysis, considering only end-of-treatment participants. Participants in the intervention group showed a significant better evolution in the main outcome measure of quality of life (SAQOL-39 p = .029), as well as for independence (mRSp = .004), perceptual-cognitive skills (MoCA p = .012) and symptoms of depression (BDI-II p = .011) compared to the control group. The study supports EOTIPS as effective in improving post-stroke recovery. Limitations included lack of therapist blinding, inclusion of only mild-to-moderate stroke cases, variability in rehab sessions, and inconsistent caregiver support.

Sensory Integration Therapy (SIT)

There is insufficient evidence to permit conclusions regarding the effectiveness of SIT or whether SIT improves the net health outcome in children with autism and developmental impairments. Only one study was published for SIT in autistic children, and three studies were published for SIT in

intellectually disabled children; the validity of all four studies is questionable. The evidence indicates that SIT does not improve the net health outcome in learning-disabled children when compared to alternative treatments or no treatment at all.

Randall et al (2024) conducted a two-arm RCT to assess the clinical and cost-effectiveness of manualized Sensory Integration Therapy (SIT) for autistic children with sensory processing difficulties. They recruited 138 children and carers (92% of those screened), with retention rates of 77.5% at 6 months and 69.9% at 12 months. Intervention fidelity was high, with 78.3% receiving a sufficient dose, though session attendance varied. Descriptive statistics covered recruitment, demographics, adherence, and adverse effects—none were reported. Qualitative interviews with carers and therapists found the intervention generally acceptable, despite logistical barriers like scheduling, travel, and COVID-19. The process evaluation highlighted contextual factors affecting effectiveness and emphasized the importance of caregiver involvement and individualized outcomes in future research.

Constraint-Induced Movement Therapy (CIMT)

There is insufficient evidence to permit conclusions regarding the effectiveness of CIMT for any indication. The majority of studies address the utilization of CIMT in either cerebral palsy, congenital hemiplegia, or stroke rehabilitation. Several studies, systematic reviews and meta-analyses have recently been published. They conclude that further rigorous, well-designed, randomized, controlled studies addressing CIMT are needed, to determine the efficacy of its use.

Reddy et al (2022) conducted a systematic review and meta-analysis aiming to delineate the effect of various lower extremity CIMT (LECIMT) protocols on gait speed, balance, and cardiovascular outcomes. For this study, clinical trials involving stroke populations in different stages of recovery, greater than 18 years old, and treated with LECIMT were considered, only ten studies were included. CIMT, when compared to controlled interventions, showed superior or similar effects. The effect of LECIMT on gait speed and balance were non-significant, with mean differences (SMDs) of 0.13 and 4.94 and at 95% confidence intervals (Cis) of (-0.18–0.44) and (-2.48–12.37), respectively. In this meta-analysis, the authors observed that despite the fact that several trials claimed the efficacy of LECIMT in improving lower-extremity functions, gait speed and balance did not demonstrate a significant effect size favoring LECIMT. Therefore, CIMT treatment protocols should consider the patient's functional requirements, cardinal principles of CIMT, and cardiorespiratory parameters.

PROFESSIONAL GUIDELINE(S)

In the American Speech-Language-Hearing Association (ASHA) 2015 Speech-Language Pathology Medical Review Guidelines they state that "eligibility for services or evaluation is indicated if one or more of the following factors are present:

- When a referral is made from a teacher, family member, or a professional in hearing, speech and language.
- Failure to pass a screening assessment for function of communication and/or swallowing.
- Individual is unable to communicate functionally or optimally across environments.

- Individual is unable to swallow to maintain adequate nutrition or hydration.
- Evaluation by ASHA-certified speech-language pathologist shows the presence of a speech or swallowing disorder.
- Individual's communications skills are not comparable to others of the same age, gender, ethnicity, or cultural and linguistic background.
- Communication skills are negatively affecting health, safety, social, emotional, educational or vocational status.
- Swallowing skills negatively affect his or her nutritional health or safety.
- Family or guardian want to achieve and/or maintain optimal communication and/or swallowing skills.
- Individual or family is looking for services to enhance communications skills."

The 2016 Guidelines for Adults Stoke Rehabilitation and Recovery by the American Heart Association (AHA) and American Stroke Association (ASA) (Winstein et al 2016), which were accepted by the ASHA state:

- "Speech and language therapy is recommended for individuals with aphasia. (class I, level of evidence A)
- Computerized treatment may be considered to supplement treatment provided by a speech language pathologist." (class IIb, level of evidence A)

In June 2012, the American Academy of Pediatrics (AAP) issued a policy statement indicating that treatment "with the use of sensory-based therapies may be acceptable as one of the components of a comprehensive treatment plan. However, parents should be informed that the amount of research regarding the effectiveness of sensory integration therapy is limited and inconclusive."

Becker et al (2015) presented The Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition consensus statement for indicators recommended for the identification and documentation of pediatric malnutrition (undernutrition). The recommendations are as follows:

- "Food/Nutritional Intake- Completed by history and/or direct observation for food and/or nutrients consumed.
- Assessment of Energy and Protein Needs- measured by indirect calorimetry (most precise) or estimated through the use of standard equations.
- Growth Parameters-Growth should be monitored at regular intervals and are typically expressed and reported in comparison with population data (normally in percentiles). Standard deviation comparisons are recommended for tracking and assessing nutritional status:
    - In children less than 36 months of age- measures of growth include length-for-age, weight-for-age, head circumference-for-age, and weight-for-length.

  - In children ages 2–20 years, standing height-for-age, weight-for-age, and body mass index (BMI)-for-age.
- Weight Gain Velocity- defined as the rate of change in weight or length/height over time.
- Mid-Upper Arm Circumference- has been correlated to BMI in children and adults. It is important measurement in individuals whose weight may be affected by fluid retention (edema, ascites or steroids).
- Handgrip Strength- using a handheld dynamometer, it measures the maximum strength of the hand and the forearm muscles.
- Documentation of Tanner Stages-Because of the variability in genetic determinants for the onset of puberty, using the Tanner staging is limited (Becker 2015)."

REGULATORY STATUS

As of January 1, 2014, the Patient Protection and Affordable Care Act (PPACA) required all health insurers to provide coverage for essential health benefits, including habilitative services. Under PPACA, habilitative services are health care services that help a person keep, learn or improve skills and functioning for daily living and include the management of limitations and disabilities, including services or programs that help maintain or prevent deterioration in physical, cognitive, or behavioral function.

Under federal law, all health insurers must provide essential health benefits in the individual and small group markets, including habilitative services. The law defines habilitative services as health care services that help a person keep, learn or improve skills and functioning for daily living and include the management of limitations and disabilities, including services or programs that help maintain or prevent deterioration in physical, cognitive, or behavioral function.

Certain contracts only cover short-term therapy services for a limited number of visits per condition, per lifetime, or per contract year. These limits generally apply to all therapies combined (PT, OT and ST). The visit limits do not apply when PT, OT or ST are for the treatment of a Mental Disorder (including autism spectrum disorder). Mental Disorder is defined in the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders.

New York State Laws

Under New York State law, all insured contracts providing physician services, or providing medical, major medical, or similar comprehensive-type coverage, must provide coverage for the screening, diagnosis, and treatment of autism spectrum disorders when prescribed or ordered by a licensed physician or a licensed psychologist for medically necessary services. Treatment includes services provided by a licensed or certified speech therapist, occupational therapist, physical therapist, and social worker, when the policy generally provides such coverage. Therapeutic treatment must include care that is deemed habilitative or non-restorative.

New York State law restricts the practice of PT to licensed physical therapists or certified physical therapist assistants. Individuals who are not licensed or certified may not provide PT services. Athletic trainers are not licensed or otherwise authorized in New York State to practice PT.

The New York State Vocational and Educational Services for Individuals with Disabilities (VESID) Program covers PT or OT services that are needed to treat a medical or surgical condition for a patient to return to work.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
20560 (E/I)	Needle insertion(s) without injection(s); 1 or 2 muscle(s)
20561 (E/I)	Needle insertion(s) without injection(s); 3 or more muscle(s)
92507	Treatment of speech, language, voice, communication, and/ or auditory processing disorder; individual
92508	Treatment of speech, language, voice, communication, and/ or auditory processing disorder; group, Two (2) or more individuals
92521	Evaluation of speech fluency (e.g., stuttering, cluttering)
92522	Evaluation of speech sound production (e.g., articulation, phonological process, apraxia, dysarthria)
92523	Evaluation of speech sound production (e.g., articulation, phonological process, apraxia, dysarthria); with evaluation of language comprehension and expression (e.g., receptive and expressive language)
92524	Behavioral and qualitative analysis of voice and resonance
92526	Treatment of swallowing dysfunction and/or oral function for feeding
92610	Evaluation of oral and pharyngeal swallowing function
96105	Assessment of aphasia (includes assessment of expressive and receptive speech and language function, language comprehension, speech production ability, reading, spelling, writing, e.g., by Boston Diagnostic Aphasia Examination) with interpretation and report, per hour

Code	Description
97010	Application of a modality to 1 or more areas; hot or cold packs
97012	traction, mechanical
97014	electrical stimulation (unattended)
97016	vasopneumatic devices (NMN when used without skilled monitoring)
97018	paraffin bath
97022	whirlpool
97024	diathermy (e.g., microwave)
97026	infrared
97028	ultraviolet
97032	electrical stimulation (manual), each 15 minutes
97033	iontophoresis, each 15 minutes
97034	contrast baths, each 15 minutes
97035	ultrasound, each 15 minutes
97036	Hubbard tank, each 15 minutes
97110	Therapeutic procedure, 1 or more areas, each 15 minutes; therapeutic exercises to develop strength and endurance, range of motion and flexibility
97112	neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and/or proprioception for sitting and/or standing activities
97113	aquatic therapy with therapeutic exercises
97116	gait training (includes stair climbing)
97140	Manual therapy techniques (e.g., mobilization/ manipulation, manual lymphatic drainage, manual traction), 1 or more regions, each 15 minutes
97150	Therapeutic procedure(s), group (2 or more individuals)

Code	Description
97161	Physical therapy evaluation: low complexity
97162	Physical therapy evaluation: moderate complexity
97163	Physical therapy evaluation: high complexity
97164	Re-evaluation of physical therapy established plan of care
97168	Re-evaluation of occupational therapy established plan of care, requiring these components: An assessment of changes in patient functional or medical status with revised plan of care; An update to the initial occupational profile to reflect changes in condition or environment that affect future interventions and/or goals; and A revised plan of care. A formal reevaluation is performed when there is a documented change in functional status or a significant change to the plan of care is required. Typically, 30 minutes are spent face-to-face with the patient and/or family.
97530	Therapeutic activities, direct (one-on-one) patient contact (use of dynamic activities to improve functional performance), each 15 minutes
97533 (NMN)	Sensory integrative techniques to enhance sensory processing and promote adaptive responses to environmental demands, direct (one-on-one) patient contact, each 15 minutes
97535	Self-care/home management training (e.g., activities of daily living (ADL) and compensatory training, meal preparation, safety procedures and instructions in use of assistive technology devices/adaptive equipment) direct one-on-one contact, each 15 minutes
97537 (NMN)	Community/work reintegration training (e.g., shopping, transportation, money management, avocational activities and/or work environment/modification analysis, work task analysis), direct one-on-one contact, each 15 minutes
97542	Wheelchair management (e.g., assessment, fitting, training), each 15 minutes
97545 (NMN)	Work hardening/conditioning; initial two hours
97546 (NMN)	each additional hour

Code	Description
97750	Physical performance test or measurement (e.g., musculoskeletal, functional capacity), with written report, each 15 minutes Note: Considered NMN when used for isokinetic testing or vibromyography.
97760	Orthotic(s) management and training (including assessment and fitting when not otherwise reported), upper extremity (ies), lower extremity(ies) and/or trunk, initial orthotic(s) encounter, each 15 minutes
97761	Prosthetic(s) training, upper and/or lower extremity(ies), initial prosthetic(s) encounter, each 15 minutes
97763	Orthotic(s)/prosthetic(s) management and/or training, upper extremity(ies), and/or trunk, subsequent orthotic(s)/prosthetic(s) encounter, each 15 minutes

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Modifier Code

Code	Description
96	Habilitative Services
97	Rehabilitative Services

HCPCS Codes

Code	Description
S9128	Speech therapy; in the home, per diem (This policy does not address home care services, please refer to InterQual for review.)
S9152	Speech therapy, re-evaluation
G0129	Occupational therapy requiring the skills of a qualified occupational therapist, furnished as a component of a partial hospitalization treatment program, per session (45 minutes or more)

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

Speech Therapy

American Speech-Language-Hearing Association [Internet]. Speech-Language Pathology Medical Review Guidelines 2015. [accessed 2025 Oct 09]. Available from: http://www.asha.org/siteassets/uploadedfiles/slp-medical-review-guidelines.pdf

American Speech-Language Hearing Association [Internet]. Feeding and swallowing disorders in children. [accessed 2025 Oct 09]. Available from: https://www.asha.org/public/speech/swallowing/feeding-and-swallowing-disorders-in-children/

American Speech-Language Hearing Association [Internet]. Pediatric feeding and swallowing. [accessed 2025 Oct 09]. Available from: https://www.asha.org/practice-portal/clinical-topics/pediatric-feeding-and-swallowing/

Antonetti AEDS, et al. Efficacy of a semi-occluded vocal tract exercises-therapeutic program in behavioral dysphonia: A randomized and blinded clinical trial. J Voice. 2023 Mar;37(2):215-225.

Barsties V, et al. The efficacy of different voice treatments for vocal fold polyps: a systematic review and meta-analysis. J Clin Med. 2023 May 13;12(10):3451.

Becker P, et al. Academy of Nutrition and Dietetics; American Society for Parenteral and Enteral Nutrition. Consensus statement of the Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition: indicators recommended for the identification and documentation of pediatric malnutrition (undernutrition). Nutr Clin Pract. 2015 Feb;30(1):147-61.

Behrman A, et al. The Effect of SPEAK OUT! and The LOUD Crowd on Dysarthria Due to Parkinson's Disease. Am J Speech Lang Pathol. 2020 Aug 4;29(3):1448-1465.

Bothe AK, et al. Stuttering treatment research 1970-2005: I. Systematic review incorporating trial quality assessment of behavioral, cognitive, and related approaches. Am J Speech Lang Pathol. 2006 Nov;15(4):321-41.

Brady MC, et al. Speech and language therapy for aphasia following stroke. Cochrane Database Syst Rev. 2016 Jun 1;(6):CD000425.

Duncan DR, et al. Feeding interventions are associated with improved outcomes in children with laryngeal penetration. J Pediatr Gastroenterol Nutr. 2019 Feb;68(2):218-224.

Galeoto G, et al. Evaluation of physiotherapy and speech therapy treatment in patients with apraxia: a systematic review and meta-analysis. Clin Ter. 2020 Sep-Oct;171(5):e454-e465.

Halpern AE, et al. Innovative technology for the assisted delivery of intensive voice treatment (LSVT LOUD) for Parkinson disease. Am J Speech Lang Pathol. 2012 Nov;21(4):354-67.

Houtrow A, et al. Prescribing physical, occupational, and speech therapy services for children with disabilities. Pediatrics 2019 Apr;143(4):e20190285.

Kalinowski J and Saltuklaroglu T. The road to efficient and effective stuttering management:

information for physicians. Curr Med Res Opin. 2004 Apr;20(4):509-15.

Morgan AT, et al. Intervention for childhood apraxia of speech. Cochrane Database Syst Rev. 2018 May 30;(5):CD006278.

Namasivayam AK, et al. PROMPT intervention for children with severe speech motor delay: a randomized control trial. Pediatr Res. 2021 Feb;89(3):613-621.

National Institute on Deafness and Other Communication Disorders [Internet]. Glossary [updated 2025 Mar 3; accessed 2025 Oct 09]. Available from: http://www.nidcd.nih.gov/health/glossary/pages/glossary.aspx

National Institute on Deafness and Other Communication Disorders. Stuttering [Internet]. NIH Pub. No. 97-4232. 2016 Feb [updated 2017 Mar 6; accessed 2025 Oct 09]. Available from: https://www.nidcd.nih.gov/health/stuttering

New York State Education Law. EDN Article 89, Sections 4401 (2) (k), 4402 (2) (a) and Article 65 Section 3204 (4-a).

New York State Education Department. Regulations of the Commissioner of Education [Internet]. Part 200 – Students with disabilities. Updated 2016 Oct [accessed 2025 Oct 09]. Available from: https://www.nysed.gov/special-education/new-york-state-laws-and-regulations-related-special-education-and-students

Ohlsson AC, et al. Voice therapy outcome-a randomized clinical trial comparing individual voice therapy, therapy in group, and controls without therapy. J Voice. 2020 Mar;34(2):303.e17-303.e26.

Pennington L, et al. Speech therapy for children with dysarthria acquired before three years of age. Cochrane Database of Syst Rev. 2016 Jul 18;(7):CD006937.

Patient Protection and Affordable Care Act (PPACA) SEC. 1302 [42 U.S.C.28022] Essential Health Benefits Requirements (b) (1) (G) Rehabilitative and habilitative services and devices. June 9, 2010

Rangarathnam B, et al. A randomized controlled trial of the effects of flow phonation voice treatment for primary muscle tension dysphonia. J Commun Disord. 2023 Jan-Feb;101:106290.

Sackley CM, et al. Lee Silverman voice treatment versus NHS speech and language therapy versus control for dysarthria in people with Parkinson's disease (PD COMM): pragmatic, UK based, multicentre, three arm, parallel group, unblinded, randomised controlled trial. BMJ. 2024 Jul 10;386:e078341.

Saltuklaroglu T and Kalinowski J. How effective is therapy for childhood stuttering? Dissecting and reinterpreting the evidence in light of spontaneous recovery rates. Int J Lang Commun Disord. 2005 Jul-Sep;40(3):359-74.

Slinger C, et al. Speech and language therapy for management of chronic cough. Cochrane Database Syst Rev. 2019 Jul 23;7:CD013067.

United States Department of Education. Individuals with Disabilities Education Act (IDEA) [Internet]. Public Law 94-142 and Public Law 114-95 [accessed 2025 Oct 09] Available from: https://sites.ed.gov/idea/

Winstein CJ, et al. American Heart Association Stroke Council, Council on Cardiovascular and Stroke Nursing, Council on Clinical Cardiology, and Council on Quality of Care and Outcomes Research. guidelines for adult stroke rehabilitation and recovery: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2016 Jun;47(6):e98-e169.

Zumbansen A, et al. Differential effects of speech and language therapy and rTMS in chronic versus subacute post-stroke aphasia: results of the NORTHSTAR-CA Trial. Neurorehabil Neural Repair. 2022 Apr;36(4-5):306-316.

Physical and Occupational Therapy

American Academy of Pediatrics [Internet]. Sensory integration therapies for children with developmental and behavioral disorders. Policy statement. Pediatrics. 2012 Jun 1;129(6):1186-9. [accessed 2025 Oct 09]. Available from: http://pediatrics.aappublications.org/content/129/6/1186

Bartels EM, et al. Aquatic exercise for the treatment of knee and hip osteoarthritis. Cochrane Database Syst Rev 2016 Mar 23;(3):CD005523.

Bunketorp-Käll L, et al. Effects of horse-riding therapy and rhythm and music-based therapy on functional mobility in late phase after stroke. NeuroRehabilitation. 2019 Dec 18;45(4):483-492.

Chamudot R, et al. Effectiveness of modified constraint-induced movement therapy compared with bimanual therapy home programs for infants with hemiplegia: a randomized controlled trial. Am J Occup Ther. 2018 Nov/Dec;72(6):7206205010p1-7206205010p9.

Charles D, et al. A systematic review of manual therapy techniques, dry cupping and dry needling in the reduction of myofascial pain and myofascial trigger points. J Bodyw Mov Ther. 2019 Jul;23(3):539-546.

Childs JD, et al. Neck pain: Clinical practice guidelines linked to the International Classification of Functioning, Disability, and Health from the Orthopedic Section of the American Physical Therapy Association. J Orthop Sports Phys Ther. 2008 Sep;38(9):A1-A34.

Cole JP, et al. Vibromyographic quantification of voluntary isometric contractile force in the brachioradialis. Conf Proc IEEE Eng Med Biol Soc. 2006;1:1708-10.

Hoare, et al. Constraint-induced movement therapy for upper extremities in people with stroke. Cochrane Database Syst Rev. 2018 Dec 12;(4):CD004149.

Durand E, et al. At-home and in-group delivery of constraint-induced movement therapy in children with hemiparesis: A systematic review. Ann Phys Rehabil Med. 2018 Jul;61(4):245-261.

Ernst M, et al. Physical exercise for people with Parkinson's disease: a systematic review and network meta-analysis (Review) Cochrane Database Syst Rev 2023 Jan;1(1):CD013856.

Flood MW, et al. Quantitative clinical assessment of motor function during and following LSVT-BIG® therapy. J Neuroeng Rehabil. 2020 Jul 13;17(1):92.

García-Pérez P, et al. Early Occupational Therapy Intervention post-stroke (EOTIPS): A randomized controlled trial. PLoS One. 2024 Aug 19;19(8):e0308800.

Ghaderi F, et al. Pelvic floor rehabilitation in the treatment of women with dyspareunia: a randomized

controlled clinical trial. Int Urogynecol J. 2019 Nov;30(11):1849-1855.

Gildir S, et al. A randomized trial of trigger point dry needling versus sham needling for chronic tension-type headache. Medicine (Baltimore). 2019 Feb;98(8):e14520.

Gibson E, et al. Occupational therapy for cognitive impairment in stroke patients. Cochrane Library database of Systematic Reviews. 2022 Mar;3(3):1-236.

Gordon NF, et al. Physical activity and exercise recommendations for stroke survivors: an American Heart Association scientific statement from the Council on Clinical Cardiology, Subcommittee on Exercise, Cardiac Rehabilitation, and Prevention; the Council on Cardiovascular Nursing; the Council on Nutrition, Physical Activity, and Metabolism; and the Stroke Council. Circ. 2004 Apr 27;109(16):2031-41.

Handoll HH and Elliott J. Rehabilitation for distal radial fractures in adults. Cochrane Database Syst Rev. 2015 Sep 25;(9):CD003324.

Hansen A, et al. Effectiveness of physical therapy- and occupational therapy-based rehabilitation in people who have glioma and are undergoing active anticancer treatment: single-blind, randomized controlled trial. Phys Ther. 2020 Mar 10;100(3):564-574.

Hoare BJ, et al. Constraint-induced movement therapy in children with unilateral cerebral palsy. Cochrane Database Syst Rev. 2019 Apr 1;(4):CD004149.

Hoffmann T, et al. Occupational therapy for cognitive impairment in stroke patients. Cochrane Database Syst Rev. 2010 Sep 8;(9):CD006430.

Iliescu AM, et al. Evaluating the effectiveness of aquatic therapy on mobility, balance, and level of functional independence in stroke rehabilitation: a systematic review and meta-analysis. Clin Rehabil. 2020 Jan;34(1):56-68.

Landesman Ramey S, et al. Constraint-induced movement therapy for cerebral palsy: a randomized trial. Pediatrics. 2021 Nov;148(5):e2020033878.

Legg LA, et al. Occupational therapy for patients with problems in activities of daily living after stroke. Cochrane Database Syst Rev. 2017 Jul;(7):CD003585.

Liu L, et al. Evidence for dry needling in the management of myofascial trigger points associated with low back pain: a systematic review and meta-analysis. Arch Phys Med Rehabil. 2018 Jan;99(1):144-152.e2.

McClinton SM, et al. Effectiveness of physical therapy treatment in addition to usual podiatry management of plantar heel pain: a randomized clinical trial. BMC Musculoskelet Disord. 2019 Dec 28;20(1):630.

Myers SM, et al. Management of children with autism spectrum disorders. Pediatrics. 2007 Nov;120(5):1162-82.

Nasb M, et al. Constraint-induced movement therapy combined with botulinum toxin for post-stroke spasticity: a systematic review and meta-analysis. Cureus. 2021 Sep 1;13(9):e17645.

Navarro-Santana MJ, et al. Effects of trigger point dry needling on lateral epicondylalgia of

musculoskeletal origin: a systematic review and meta-analysis. Clin Rehabil. 2020 Jun 23;269215520937468.

Navarro-Lozano F, et al. Effects of non-immersive virtual reality and video games on walking speed in parkinson disease: a systematic review and meta-analysis. Journal of Clinical Medicine. 2022 Nov;11(22):6610.

New York State Education Department. Regulations of the Commissioner of Education [Internet]. Part 200 – Students with disabilities. [accessed 2025 Oct 09]. Available from: https://www.nysed.gov/special-education/new-york-state-laws-and-regulations-related-special-education-and-students

Rahou-El-Bachiri Y, et al. Effects of trigger point dry needling for the management of knee pain syndromes: a systematic review and meta-analysis. J Clin Med. 2020 Jun 29;9(7):2044.

Randell E, et al. Exploring critical intervention features and trial processes in the evaluation of sensory integration therapy for autistic children. Trials. 2024 Feb 17;25(1):131.

Reddy RS, et al. Impact of Constraint-Induced Movement Therapy (CIMT) on functional ambulation in stroke patients-a systematic review and meta-analysis. Int J Environ Res Public Health. 2022 Oct 6;19(19):12809.

Sakzewski L, et al. Systematic review and meta-analysis of therapeutic management of upper-limb dysfunction in children with congenital hemiplegia. Pediatrics. 2009 Jun;123(6):e1111-22.

Sánchez-Romero EA, et al. Is a combination of exercise and dry needling effective for knee OA? Pain Med. 2020 Feb 1;21(2):349-363.

Schaafsma FG, et al. Physical conditioning as part of a return-to-work strategy to reduce sickness absence for workers with back pain. Cochrane Database Syst Rev. 2013 Aug 30;(8):CD001822.

Steultjens EEMJ, et al. Occupational therapy for rheumatoid arthritis. Cochrane Database Syst Rev. 2004 Jan 26;(1): CD003114.

Stock R, et al. Early versus late-applied constraint-induced movement therapy: A multisite, randomized controlled trial with a 12-month follow-up. Physiother Res Int. 2018 Jan; 23(1).

Ughreja RA and Prem V. Effectiveness of dry needling technique in patients with knee osteoarthritis: a systematic review and meta-analysis. J Bodyw Mov Ther. 2021 Jul;27:328-338.

United States Department of Education [Internet]. Individuals with Disabilities Education Act (IDEA). Public Law 94-142 [accessed 2025 Oct 09]. Available from: http://idea.ed.gov

Uygur E, et al. Preliminary report on the role of dry needling versus corticosteroid injection, an effective treatment method for plantar fasciitis: a randomized controlled trial. J Foot Ankle Surg. 2019 Mar;58(2):301-305.

Vier C, et al. The effectiveness of dry needling for patients with orofacial pain associated with temporomandibular dysfunction: a systematic review and meta-analysis. Braz J Phys Ther. 2019 Jan - Feb;23(1):3-11.

White-Lewis S, et al. An equine-assisted therapy intervention to improve pain, range of motion, and

quality of life in adults and older adults with arthritis: a randomized controlled trial. Appl Nurs Res. 2019 Oct;49:5-12.

Young I, et al. Spinal manipulation and electrical dry needling as an adjunct to conventional physical therapy in patients with lumbar spinal stenosis: a multi-center randomized clinical trial. Spine J. 2024 Apr;24(4):590-600.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Speech Therapy

Speech-Language Pathology Services for the Treatment of Dysphagia (NCD 170.3) [accessed 2025 Feb 02]

Speech-Language Pathology (LCD L33580) [accessed 2025 Feb 02]

Billing and Coding: Speech-Language Pathology (LCA A52866) [accessed 2025 Feb 02]

Physical and Occupational Therapy

Outpatient Physical and Occupational Therapy Services (LCD L33631) [accessed 2025 Jun 25]

Outpatient Physical and Occupational Therapy Services (LCA Billing and Coding A56566) [accessed 2025 Jun 25]

Acupuncture for Chronic Lower Back Pain (cLBP) (NCD 30.3.3) [accessed 2025 Jun 25]

Pain Management - Injection of tendon sheaths, ligaments, ganglion cysts, carpal and tarsal tunnels (LCD L33622) [accessed 2025 Jun 25]

Peripheral Nerve Blocks (LCD L36850) (Applicable to dry needling) [accessed 2025 Jun 25]

2025 Jun 25]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	• Original effective date

MEDICAL POLICY

Medical Policy Title	**Thermal Ablation for Solid Tumor Treatment**
Policy Number	**7.01.111**
Current Effective Date	**September 1, 2026**
Next Review Date	**August 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.

(Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Radiofrequency Tumor Ablation

A. Radiofrequency ablation (RFA) is considered a **medically appropriate** treatment option for **hepatocellular carcinoma** for **EITHER** of the following conditions:

1. Individual is not a surgical candidate (e.g., location of lesion[s], existence of comorbid conditions) and Milan criteria is met (e.g., a single tumor of less than or equal to 5 cm or up to three [3] lesions no greater than 3 cm in diameter);
2. As a bridge to transplant when the individual meets liver transplant criteria and is awaiting liver transplantation.

B. RFA is considered a **medically appropriate** treatment option for the **primary treatment of hepatic metastases** for **ALL** of the following conditions:

1. Individual is not a surgical candidate (e.g., location of lesions, existence of comorbid conditions);
2. Metastases meet the Milan criteria (e.g., a single tumor of less than or equal to 5 cm or up to three [3] lesions no greater than 3 cm in diameter);
3. The patient has no evidence of uncontrolled extrahepatic systemic metastatic disease.

C. Percutaneous RFA of an **osteoid osteoma** is considered a **medically appropriate** alternative to surgical excision when the individual cannot be managed successfully with medical management.

D. RFA is considered **medically appropriate** when utilized for palliation of pain in individuals with **osteolytic bone metastases** who have failed or are poor candidates for standard treatments such as opioids or radiation.

E. RFA of **localized renal cell carcinoma** is considered **medically appropriate** when the following criteria are met:

1. Lesion size is 4 cm or less in diameter; and **EITHER**

a. The individual is not a surgical candidate (e.g., location of lesion[s], existence of comorbid conditions); **or**

b. Treatment is necessary to preserve kidney function in individuals with significantly impaired renal status (i.e., the individual has one (1) kidney or renal insufficiency as defined by a glomerular filtration rate of <60mL/min/m2); and standard treatment is likely to substantially worsen kidney function.

F. RFA is considered **medically appropriate** to treat **non-small cell lung cancer (NSCLC**) when **BOTH** of the following conditions are met:

1. Isolated and peripheral lesion is 3 cm or less in size;
2. Individual is not a surgical candidate. Surgical resection or radiation treatment with curative intent is considered appropriate based on stage of disease however, medical co-morbidity renders the individual unfit for those interventions.

G. RFA is considered **medically appropriate** to treat **non-pulmonary tumor(s) metastatic to the lung** for any of the following conditions:

1. Surgical resection or radiotherapy is likely to worsen pulmonary status substantially and ablation would be necessary to preserve lung function;
2. The individual is not a surgical candidate (e.g., location of lesion[s], existence of comorbid conditions), and **ALL** of the following criteria are met:
   a. Tumor size is 3 cm or less;
   b. There is no evidence of extrapulmonary metastases;
   c. There are no more than three (3) tumors per lung to be ablated;
   d. Tumors are amenable to complete ablation; **and**
   e. Twelve months have elapsed since the last ablation.

H. Laparoscopic, transcervical ultrasound-guided RFA (e.g., the Acessa System, Sonata Device) is considered **medically appropriate** as an alternative to hysterectomy or myomectomy for the treatment of **uterine fibroid tumors**, when **ALL** the following criteria are met:

1. Individual is aged 18 years or older;
2. Individual is premenopausal;
3. Evidence from ultrasound demonstrates that fibroids are less than 10 cm in diameter for laparoscopic RFA with Acessa or 7 cm for transcervical RFA with Sonata;
4. Symptoms are persistent, directly attributed to the uterine fibroid(s), and include **ANY** of the following:
   a. Excessive menstrual bleeding (menorrhagia);
   b. Pelvic pain or pressure;

c. Gastrointestinal symptoms related to compression of the bowel (e.g., constipation, bloating);

d. Urinary symptoms related to compression of the ureter or bladder (e.g., urinary frequency, urgency); **or**

e. Dyspareunia (pain during sexual relations).

I. RFA is considered **investigational** as a treatment method for any other solid tumors, including, but not limited to pancreatic, thyroid, and breast tumors.

II. Cryosurgical Ablation

A. Cryosurgical ablation (CA) of **localized renal cell carcinoma** is considered **medically appropriate** for the following conditions:

1. Lesion size is 4 cm or less in diameter; and **EITHER**

a. The individual is not a surgical candidate (e.g., location of lesion[s], existence of comorbid conditions); **or**

b. Treatment is necessary to preserve kidney function in individuals with significantly impaired renal status (i.e., the individual has one (1) kidney or renal insufficiency as defined by a glomerular filtration rate of <60mL/min/m2); and standard treatment is likely to substantially worsen kidney function.

B. CA may be considered a **medically appropriate** treatment option for individuals with **lung cancer** for the following conditions:

1. Individual requires palliation for a central airway obstructing lesion;

2. Diagnosis is early-stage non-small cell lung cancer and **BOTH** of the following are met:

a. Individual is not receiving stereotactic radiotherapy or definitive radiation therapy; **and**

b. Individual is considered "high risk" as a poor surgical candidate (see Professional Guidelines section; NCCN Guidelines for NSCLC, for guidance on what is considered "high risk").

C. CA of desmoid tumors is considered **medically appropriate** as part of active therapy when tumor is progressive, morbid or symptomatic.

D. CA of an **osteoid osteoma** is considered a **medically appropriate** alternative to surgical excision when the individual cannot be managed successfully with medical management.

E. CA is considered **medically appropriate** when utilized for palliation of pain in individuals with osteolytic bone metastases who have failed or are poor candidates for standard treatments such as opioids or radiation.

F. CA is considered **investigational** as a treatment method for any other tumor, including but not limited to, primary/metastatic liver malignancies, breast tumors (benign and malignant),

and pancreatic cancer.

III. Microwave Ablation

A. Microwave ablation (MWA) is considered **medically appropriate for primary or metastatic hepatic tumors** when **BOTH** of the following conditions are met:

1. Individual is not a surgical candidate (e.g. location of lesion[s], existence of comorbid conditions);
2. Milan criterion is met (e.g., a single tumor of less than or equal to 5 cm or up to three [3] nodules no greater than 3 cm in diameter).

B. MWA is considered **medically appropriate** for **primary or metastatic lung tumors** when **ALL** the following conditions are met:

1. Individual is not a surgical candidate (e.g. location of lesion[s], existence of comorbid conditions);
2. Individual will not be receiving stereotactic radiotherapy or definitive radiation therapy;
3. Treatment is for a tumor that is 3 cm or less in size.

C. MWA is considered **medically appropriate** for renal cell carcinoma when **ALL** the following conditions are met:

1. Individual is not a surgical candidate (e.g. location of lesion[s], existence of comorbid conditions);
2. Biopsy of lesions is recommended to be done prior to or at time of ablation;
3. Treatment is for a tumor that is 3 cm or less in size.

D. MWA is considered **medically appropriate** when utilized for palliation of pain in individuals with osteolytic bone metastases who have failed or are poor candidates for standard treatments such as opioids or radiation.

E. MWA for the treatment of primary or metastatic tumors other than liver, lung, kidney or bone is considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

7.01.01 Focal Therapies for Prostate Cancer Treatment

7.02.07 Liver Transplantation

7.01.69 Transarterial Radioembolization (TARE) for Hepatic Tumors

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Documentation should include the relevant history and physical demonstrating the tumor type, the rationale of why the tumor is unresectable (if applicable), size of tumor(s) to be treated, and ablation modality to be utilized.

DESCRIPTION

Surgical resection is the standard treatment for many solid tumor types, and despite advances in surgical techniques, many patients are either considered inoperable for surgery or prefer a nonsurgical minimally invasive local treatment. For individuals who meet specific criteria given the location, tumor size and type, thermal ablation can be offered as an alternative. The most common ablative modalities are radiofrequency ablation (RFA), microwave ablation (MWA) and Cryoablation (CA). RF and MWA utilize thermal/heat-based techniques and CA uses thermal/cold-based techniques (i.e., freezing) to destroy tissues. Per the National Comprehensive Cancer Network (NCCN), each ablation energy modality has advantages and disadvantages, therefore, determination of the modality utilized should take into consideration the size and location of the target tumor, risk of complication, as well as local expertise and/or operator familiarity.

Radiofrequency Ablation

RFA is the oldest and most frequently utilized thermal ablative technique and can be administered percutaneously, by open or laparoscopic surgery. This modality relies on heat to destroy tumors by thermal coagulation and protein denaturation. High frequency alternating current flows from un-insulated electrode tips into surrounding tissue. As the tissue ions attempt to follow the change in direction of the alternating current, ionic agitation results in frictional heating. The tissue surrounding the electrode, rather than the electrode itself, is the primary source of heat. It is presumed that tissue heating drives extracellular and intracellular water out of the tissue, resulting in coagulative necrosis.

RFA is typically used to treat inoperable tumors or to treat patients who are ineligible for surgery due to advanced age or co-morbidities. RFA was developed initially to treat inoperable tumors of the liver and is now utilized as a minimally invasive treatment alternative for other solid tumors, such as lung, renal, bone, and uterine fibroids.

Cryosurgical Ablation

Cryosurgical ablation (CA) is a method of thermal tumor ablation in which subfreezing temperatures are delivered through penetrating or surface cryoprobes in which a cryogen is circulated. Cell death is caused by direct freezing, denaturation of cellular proteins, cell membrane rupture, cell dehydration and ischemic hypoxia. Cryosurgical ablation may be used for the destruction of metastatic tumors in situ or for the destruction of microscopic residual carcinoma in the case of close surgical margins. It may be performed as an open surgical technique or as a closed procedure.

Several CA devices have been cleared for marketing by the FDA through the 510(k) process for use in open, minimally invasive, or endoscopic surgical procedures in the areas of general surgery, urology, gynecology, oncology, neurology, dermatology, proctology, thoracic surgery, and surgeries of the ear, nose, and throat. Examples include: Cryocare Surgical System (Endocare); CryoGen Cryosurgical

System (Cryosurgical); CryoHit (Galil Medical) for the treatment of breast fibroadenoma; IceSense3, ProSense, MultiSense Systems (IceCure Medical); SeedNet System (Galil Medical); and Visica System (Sanarus Medical). FDA product code: GEH.

CA has been investigated for its efficacy in the treatment of liver, lung, kidney, bone, breast, cervical cancer, neuroendocrine tumors and prostate cancer. CA for the treatment of prostate cancer is not addressed in this policy.

Microwave Ablation

Microwave ablation (MWA) is similar to RFA and CA as a form of thermal ablation. However, MWA has potential advantages over both. MWA uses microwave energy to heat and coagulate the tissue adjacent to the probe, resulting in a small, 2 cm to 3 cm elliptical area of tissue ablation. In tumors greater than 2 cm in diameter, 2 to 3 antennas may be used simultaneously to increase the targeted area and shorten the operative time. The use of multiple antennas can reduce the operative time by 20%-30%. The higher temperatures reached with MWA (>100°C) can overcome the "heat sink" effect occurring in RFA, in which tissue cooling occurs from nearby blood flow in large vessels, potentially resulting in incomplete tumor ablation. Microwave ablation does not rely on the conduction of electricity for heating and, therefore, does not flow electrical current through patients. Grounding pads are not required because there is no risk of skin burns. Additionally, MWA does not produce electric noise, which allows ultrasound guidance during the procedure without interference, unlike RFA.

Multiple MWA devices have been cleared for marketing by the FDA through the 510(k) process. These devices are indicated for soft tissue ablation, including partial or complete ablation of nonresectable liver tumors. Some devices are specifically cleared for use in open surgical ablation, percutaneous ablation, or laparoscopic procedures. The FDA used determinations of substantial equivalence to existing radiofrequency and MWA devices to clear these devices. Examples include: MedWaves Microwave Coagulation/Ablation System (MedWaves Inc.), MicroThermX Microwave Ablation System (BSD Medical Corporation), Emprint Ablation System (Medtronic), Cetus (Johnson & Johnson), and NEUWAVE Flex Microwave Ablation System (Johnson and Johnson), FDA product code: NEY.

MWA was first used percutaneously as an adjunct to liver biopsy. It has since been investigated for its efficacy in the treatment of hepatocellular carcinoma, breast cancer, colorectal cancer metastatic to the liver, renal cell carcinoma, renal hamartoma, adrenal malignant carcinoma, non-small cell lung cancer, intrahepatic primary cholangiocarcinoma, secondary splenomegaly and hypersplenism, abdominal tumors and other tumors not amenable to resection. It is also being assessed to determine whether it can reduce the incidence of tumor progression while awaiting transplantation to maintain an individual's ability to meet transplant criteria.

SUPPORTIVE LITERATURE

Uterine Fibroids

RFA was FDA approved as a treatment for symptomatic myomas in 2012 and has been shown to

reduce heavy menstrual bleeding, pelvic pain, and other associated symptoms. The RFA system Acessa for uterine fibroids received FDA clearance for marketing in 2012 (K121858). The device is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. The next generation of the Acessa System, The Acessa ProVu System, received FDA clearance in 2018. It is indicated for use in percutaneous, laparoscopic coagulation and ablation of soft tissue, including treatment of symptomatic uterine fibroids under laparoscopic ultrasound guidance. In the Acessa procedure, a controlled volume of heat is applied directly to the fibroid, killing the tissue of the fibroid while leaving healthy surrounding tissue unharmed. The dead tissue is reabsorbed by the body.

Rattray et al (2018) published the results of the TRUST Canada study, reporting on the clinical outcomes of pre-and post-laparoscopic RFA for 45 individuals who were greater than 18 years of age, premenopausal, with symptomatic uterine fibroids less than 10 cm in size, a uterine size less than or equal to 16 gestational weeks, a desire for uterine conservation, and were not pregnant or lactating. RFA was compared to individuals receiving a myomectomy. The primary endpoint of hospitalization time was 6.7 ± 3.0 hours for the RFA group and 9.9 ± 10.7 hours for the myomectomy group. Intraoperative blood loss was less for RFA subjects at 25.2 ± 21.6 versus 82.4 ± 62.5 mL (p=0.0002) for the myomectomy group. RFA procedures took less time (70.0 versus 86.5 minutes for myomectomy procedures). At 3 months, both cohorts reported the same significant symptom severity reduction (-44.8%; P<0.0001). RFA subjects took lesser time from work: 11.1 ± 7.6 versus 18.5 ± 10.6 days (P=0.0193). One myomectomy subject was hospitalized overnight after experiencing a 20-second asystole during the procedure. One RFA subject underwent reintervention. The combined per patient direct and indirect costs of the two procedures were comparable.

The TRUST United States trial had a preliminary analysis with a planned follow-up of 5 years conducted by Yu and associates (2022). The RCT will compare laparoscopic RFA or myomectomy in patients with uterine myoma. Inclusion criteria were the same as the TRUST Canada trial. The study evaluates 29 patients who underwent laparoscopic RFA and 27 patients who underwent myomectomy. Primary outcome was again hospital stay, which was significantly shorter in the laparoscopic RFA group (8.01 ± 5.7 hours) than the myomectomy group (18.8 ± 14.6 hours; P<.05). Outcomes of interest for the primary analysis were symptoms and patient reported quality of life at 12 months. Symptoms improved in both groups at both 3 and 12 months with no statistical difference between the two. Symptom severity and health-related quality of life were significantly better in the myomectomy group at 12 months. Major complications occurred in 2 patients in the myomectomy group and 1 patient who had RFA. The study was limited by its lack of blinding, to both the treatment and treating physician.

Miller and colleagues (2019) investigated the Sonata device for the treatment of symptomatic uterine fibroids with 2-year outcomes. This prospective multicenter single-arm interventional trial included premenopausal women with up to 10 clinically relevant uterine fibroids ranging from 1 to 5 cm in diameter. The individuals were treated with sonography-guided transcervical fibroid ablation (TFA) and were assessed for symptom severity, health related quality of life, general health status, work and activity limitations, treatment satisfaction, adverse events, surgical reintervention, and occurrence of pregnancy and associated outcomes. Of the 147 women who were enrolled, 85%

(125/147) returned for 2-year follow up. Symptom severity decreased from 55 ± 19 to 24 ± 18 (P < 0.001), health-related quality of life increased from 40 ± 21 to 83 ± 19 (P < 0.001). Overall treatment satisfaction at two years was 94%. The mean percentage of missed work time, overall work impairment, and activity impairment significantly decreased at follow-up. Through two years, surgical reintervention for heavy menstrual bleeding was performed in 5.5% of patients. One singleton pregnancy occurred with a normal peripartum outcome. The authors concluded that treatment with the Sonata system provides a significant clinical improvement through two years post-ablation.

Renal Tumors

Renal ablation traditionally has been reserved for patients who are poor candidates for surgery or in whom renal preservation is of utmost priority. However, with some reports on oncologic efficacy approaching that of partial nephrectomy (PN), renal ablation can be considered as a first-line treatment option for patients who meet specific criteria.

Yanagisawa et al (2022) published a systematic review and meta-analysis comparing ablative therapies (cryoablation, radiofrequency ablation, and microwave ablation) to partial nephrectomy. Twenty-seven trials (N=13,996) were included; 12 of those studies directly compared cryoablation with partial nephrectomy, however, the results were not stratified by modality. No significant differences in cancer-specific mortality for cT1a tumors (p=.50) and cT1b tumors (p=.63) were found when comparing partial nephrectomy and ablation therapies. Local recurrence was higher for ablative therapies compared with partial nephrectomy in both cT1a tumors (risk ratio, 0.43; 95% confidence interval [CI], 0.28 to 03.66; p=.0001) and cT1b tumors (risk ratio, 0.41; 95% CI, 0.23 to 0.75; p=.004). There were no significant differences between partial nephrectomy and ablation therapy in terms of rate of metastases, overall complications, and decline in renal function.

Lim et al (2020) completed a study to evaluate the immediate and 3- and 5-year outcomes of patients with clinical stage T1 (cT1) biopsy-proven RCC who were treated by percutaneous cryoablation. A total of 180 patients with 185 separate cT1 RCC lesions were identified. Mean patient age was 68.4 years (range, 34.1 – 88.9 years) and 52 patients (28.9%) were women. There were 168 (90.8%) and 17 (9.2%) cT1a and cT1b lesions, respectively, with a mean lesion size of 28.5 mm (range, 11 – 58 mm). Technical success was achieved in 98.9% of patients. The major complication rate was 2.2%. Residual unablated tumor on the first follow-up scan was identified in four of 183 tumors (2.2%). Estimated local tumor progression-free survival at 3 and 5 years was 98.3% and 94.9%, respectively. No distant metastases or deaths attributable to RCC occurred. Mean estimated glomerular filtration rate before the procedure was 72.4 ± 18.5 (SD) mL/min/1.73 m2 and this was not statistically significantly different after the procedure (69.7 ± 18.8 mL/min/1.73 m2), at 1 year (70.7 ± 16.4 mL/min/1.73 m2), or at 2 years (69.8 ± 18.9 mL/min/1.73 m2 (p> 0.05). The authors concluded that this data adds to the accumulating evidence that image-guided cryoablation is an efficacious treatment for selected cT1 RCC with a low complication rate and robust 3- and 5-year outcomes.

McClure et al (2023) conducted a systematic review and meta-analysis comparing microwave ablation and cryoablation for renal cell carcinoma. Study arms from RCTs, comparative observational, and

single-arm studies were eligible. The outcomes included local tumor recurrence (LTR), overall survival, disease-free survival, overall/major complications, procedure/ablation time, 1- to 3-month primary technique efficacy, and technical success. Baseline characteristics were similar between groups and mean tumor size for MWA and cryoablation were 2.74 and 2.69 cm. Single-arm meta-analyses were similar for LTR and secondary outcomes between cryoablation and MWA. Ablation time was significantly shorter with MWA than with cryoablation (meta-regression weighted mean difference 24.55 minutes, 95% confidence interval -31.71, -17.38, P < .0001). One-year LTR was significantly lower with MWA than cryoablation (odds ratio 0.33, 95% confidence interval 0.10-0.93, P = .04). There were no significant differences for other outcomes. MWA provides significantly improved 1-year LTR and ablation time compared with cryoablation for patients with RCC. Other outcomes appeared similar or favorable for MWA; however, results were not statistically significant. MWA of primary RCC is as safe and effective as cryoablation, which should be confirmed with future comparative studies.

Liver Tumors

The evidence supporting the use of RFA in the treatment of inoperable hepatic metastases includes an RCT, systematic reviews and meta-analyses, prospective cohort series, and retrospective case series. There are no RCTs comparing RFA with alternative treatments for patients who have unresectable colorectal liver metastases. However, an RCT assessing RFA plus chemotherapy found improved survival at eight (8) years compared with chemotherapy alone. In addition, prospective studies have demonstrated that overall survival following RFA is at least equivalent to and likely better than currently accepted systemic chemotherapy in well-matched patients with unresectable hepatic metastatic colorectal cancer (CRC) who do not have extrahepatic disease. Results from a number of uncontrolled case series also have suggested RFA of hepatic CRC metastases produces long-term survival that is at a minimum equivalent to but likely superior to historical outcomes achieved with systemic chemotherapy. Evidence from a comparative study has indicated RFA has fewer deleterious effects on quality of life than chemotherapy and that RFA patients recover their quality of life significantly faster than chemotherapy recipients. It should be noted that patients treated with RFA in different series might have had better prognoses than those who had chemotherapy, suggesting patient selection bias might at least partially explain the better outcomes observed following RFA. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Mohan et al (2015) published a systematic review of RFA as a treatment for unresectable metastases from neuroendocrine tumors. Seven unique studies (N=301 patients), all retrospective case series from a single institution, were included. The most common tumor type was carcinoid (59%), followed by nonfunctional pancreatic tumors (21%) and functional pancreatic tumors (13%). There were 2 periprocedural deaths (rate, 0.7%), and the overall complication rate was 10%, including hemorrhage, abscess, viscus perforation, bile leak, biliopleural fistula, transient liver insufficiency, pneumothorax, grounding pad burn, urinary retention, pneumonia, and pleural effusion. Improvement in symptoms was reported in 92% (117/127) of symptomatic patients, with a median duration of relief ranging from 14 to 27 months. There was a high degree of variability in the length of follow-up and surveillance, and a wide range of local recurrence rates, from less than 5% to 50%;

5-year survival rates ranged from 57% to 80%.

Fairweather et al (2017) compared the overall survival in patients with neuroendocrine liver metastases (N=649) from a large prospective database. Primary treatment modalities included: systemic therapy (n=316), chemoembolization (n=130), observation (n=117), surgical resection (n=58), and RFA (n=28). The most favorable 10-year overall survival estimates were achieved with surgical resection (70%), followed by RFA (55%), systemic therapy (31%), chemoembolization (28%), and observation (20%).

Most reports of RFA treatment for neuroendocrine liver metastases have assessed small numbers of patients or subsets of patients in reports of multiple ablative methods or small subsets of larger case series of patients with various diagnoses. The available evidence has indicated that durable tumor and symptom control of neuroendocrine liver metastases can be achieved using RFA in individuals whose symptoms are not controlled by systemic therapy or who are ineligible for resection.

For individuals who have hepatic metastases, not of colorectal or neuroendocrine origin who receive RFA, the evidence includes a systematic review, small, nonrandomized comparative studies and small case series. Relevant outcomes are overall-survival, disease-specific survival, symptoms, change in disease status, morbid events, quality of life, and treatment-related morbidity. For patients who are ineligible for resection, RFA may provide a survival benefit. However, the evidence is limited by study designs with a high-risk of bias and small sample sizes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Glassberg et al (2019) conducted a systematic review and meta-analysis of 16 trials comparing MWA to resection in adults with confirmed HCC or liver cancer. The review included 1 RCT and 15 observational studies (two prospective and 13 retrospective). The studies represented 965 individuals treated with MWA and 755 resections from a period of 15 months to 5 years. Patients who received MWA had a significantly higher risk of local tumor progression compared to those who received resection. At 1-year, overall survival did not differ between MWA and resection but 3- and 5-year overall survival was significantly higher in patients who had received resection. Complications were lower with MWA compared to resection. Additionally, operative time, intraoperative blood loss, and hospital length of stay were significantly lower with MWA. Some studies included patients that were nonresectable in the MWA treatment arm, but due to limited reporting and patient preference affecting which treatment was performed, the reviewers were not able to calculate the number of patients who were nonresectable or to conduct subgroup analyses by resectable versus unresectable tumors. Microwave ablation was typically selected for patients with smaller and/or deeper tumors, more comorbidities, and a preference for a less invasive procedure. The reviewers concluded that MWA can be an effective and safe alternative to hepatic resection in patients or tumors that are not amenable to resection, but more studies are needed to determine the target population that would benefit most from MWA.

Chong and colleagues (2020) conducted an RCT of 93 patients with HCC who had up to three lesions of 5 cm or smaller, Child-Pugh score A or B, the absence of extrahepatic metastases, and absence of radiologic evidence of major vascular or bile duct invasion. The primary outcome of the study was rate of complete ablation at 1 month, which did not differ significantly for MWA. Rates of overall

survival up to 5 years and rates of disease-free survival up to 3 years were similar between groups. Limitations of the study included that sample size calculations were based on complete ablation at one month, so the study may not have been adequately powered to detect differences in the overall survival or disease-free survival.

The body of evidence indicates that MWA is an effective option in patients for whom resection is not an option. Although studies have methodological limitations, they consistently showed that MWA and RFA had similar outcomes with up to 5 years of follow-up in patients with a single tumor ≤ 5cm or up to three nodules ≤ 3 cm each.

Bridge to Liver Transplant

The Milan criteria are used to identify the tumor burden of patients with hepatocellular carcinoma (HCC) as smaller tumors are more likely to allow for a good outcome after liver transplantation. The Milan criteria state that transplantation should be performed in those with a single tumor of 5 cm or less or three (3) tumors that are each 3 cm or less, with no macrovascular invasion, and no metastasis. Patients who do not meet the Milan criteria are not considered eligible candidates for liver transplantation.

The dropout rates of patients with HCC from liver transplant lists have been reported to range from 20-40% due to tumor progression. Recent studies utilizing RFA as a bridge to transplant have increased days on the transplant list considerably and decreased dropout rates to 12-15%.

The evidence related to the use of RFA specifically to downsize/downgrade tumors to meet priority transplant criteria is insufficient at this time due to inconsistent outcomes reported in the literature. Studies regarding tumor recurrence in this patient population demonstrate a longer-term follow-up are needed.

Bone Tumors

The majority of literature on the use of RFA on patients with bone metastases consists of uncontrolled studies with only a limited number of cases. However, the patient populations enrolled in the studies comprised individuals with limited or no treatment options, for whom short-term pain relief was an appropriate outcome.

Studies investigating the efficacy of RFA for osteoid osteomas provide evidence that RFA achieves outcomes comparable to surgical excision, in terms of tumor destruction and pain relief, and allows for a decrease in hospital stay and quicker postoperative recovery. RFA treatment of osteoid osteoma is not appropriate for large lesions or for those in a location that makes it technically difficult to perform percutaneously.

Jennings et al (2021) reported on a single-arm prospective study of 66 patients with metastatic bone disease who were treated with cryoablation and were not candidates for or had not benefitted from standard therapy. The primary endpoint was the change in pain score from baseline to week 8 and patients were followed for 24 weeks. The mean decrease in pain score from baseline to week 8 was 2.61 points (95% CI, 3.45 to 1.78). Pain scores decreased further after the primary endpoint and reached clinically meaningful levels (more than a 2-point decrease) after week 8. This study had

several limitations, including the lack of a comparator, potential for selection bias, and lack of blinding combined with subjective outcome measures.

Khanmohammadi et al (2023) conducted a systematic review to understand the safety and effects of cryoablation on the pain and quality of life (QoL) of patients with bone metastasis. Inclusion criteria were original studies published until September 8, 2022, studies on patients 18 years and affected by bone metastasis, bone metastasis treated with stand-alone cryoablation, studies reporting patients' pain before and at least one time-point following cryoablation and English language studies. Fifteen studies on 376 patients were included. All studies reported a significant pain reduction between one day and six months after the cryoablation procedure. The highest mean difference between pre- and post-procedure scores was 5.8 (VAS scale) after four weeks. The overall rate of minor and major complications was 12.74%. Cryoablation improved the QoL of cancer patients and decreased the need for analgesics. Authors concluded that cryoablation is a safe and useful procedure for palliating painful bone metastasis and increasing the QoL of cancer patients. Future studies should adopt a standardized pain reporting scale to allow for meta-analysis.

Bianchi et al (2022) conducted a review of current literature and concluded that percutaneous thermal ablation techniques are a safe and effective therapeutic option in the treatment of osteoid osteomas (OO). Among the currently available ablation techniques, RFA is considered the gold standard due to the possibility to perform a preliminary biopsy, whose utility is however still controversial. RFA and cryoablation (CA) have statistically similar outcomes in terms of technical success, clinical efficacy, and low recurrence and complications rate. CA is the only technique allowing real-time visualization of the ablated volume (ice ball sign), which maximizes treatment safety. Furthermore, CA shows promising results in patients submitted to treatment of bone metastases in terms of better medical therapy management, pain relief, and subsequent improvement of life quality. CA brings lower risks of permanent nerve damage when the lesions are located near neural structures. There is even evidence of nerve regeneration after damage caused by cryoablation.

Le Corroller et al (2022) conducted a retrospective single-center study that evaluated 50 consecutive patients with osteoid osteoma treated with CT-guided percutaneous cryoablation. Technical success was achieved in all procedures, and overall clinical success was 96% (48/50 patients). The median VAS pain score was 8 (IQR, 7–8) before the procedure and 0 (IQR, 0–1; P , .001) after the procedure at both primary (6 weeks) and secondary (18–90 months) follow-up. Only one recurrence was reported and was successfully retreated with CA. Authors concluded that CT-guided percutaneous cryoablation has a favorable safety profile with few complications, demonstrated high clinical success and was frequently performed under local anesthesia with conscious sedation.

Lung Tumors

Cryosurgical ablation for the treatment of NSCLC has been studied in a limited number of small studies. Moore, et al (2015) conducted a case series involving 47 subjects with NSCLC. The subjects were followed for a minimum of 5 years after treatment with cryoablation. The authors reported that the five-year survival rate was 67.8% ± 15.3, the cancer-specific survival rate at five years was 56.6% ± 16.5, and the five-year progression-free survival rate was 87.9%. The combined local and

regional recurrence rate was 36.2%. Major complications were reported in 6.4% of subjects, with two cases of hemoptysis and a prolonged placement of a chest tube requiring mechanical sclerosis in one subject. No deaths occurred in the first 30 days after treatment.

A prospective case series conducted by deBaere et al (2015), assessed 40 patients with 60 treated metastatic lung tumors (3.5cm or less in diameter) from a variety of primary origin. The most common origin was colorectal cancer (40%). Follow-up to 12 months was reported, involving 35 patients (90%). At 12 months, overall local tumor control, including stable disease, partial response, and complete response, was seen in 49 of 52 metastases (94.2%) and 32 of 35 patients (91.4%). Local failure was observed in three of 52 metastases (5.8%) at 6 and 12 months with increasing size of the ablation zone. Tumor diameter was not found to be a significant factor in the rate of tumor progression (p=0.41). Additional new treatments were administered to 15 of the 40 patients (38%) including systemic treatment (chemotherapy: n=7 and immunotherapy: n=1) and other focal therapies for new metastatic disease (n=10), including 6 cryoablation procedures. One-year disease-specific survival and overall survival rates were 100% and 97.5% respectively. Pneumothorax requiring chest tube placement occurred in nine of the 48 procedures (18.8%), and chest tubes were removed after one day (n=8) or two days (n=1). Common Terminology Criteria for Adverse Events (CTCAE) grade 3 adverse events within 30 days of the procedure occurred in three of 48 (6%) procedures including a delayed pneumothorax requiring pleurodesis, a thrombosis of a pre-existing hemodialysis access arterio-venous fistula requiring thrombectomy, and a non-cardiac chest pain that spontaneously resolved. No grade 4 or 5 procedure-related adverse events occurred. No procedural-related delayed adverse events were observed. The study outcomes were considered interim results at 1-year follow up.

In 2021, deBaere et al published follow-up 5- year results in a prospective, multicenter, single arm study of the 40 patients from the original 2015 study, using a standardized CA protocol (ECLIPSE). The primary end point was local tumor control both per tumor and per patient. Local failure was defined as a greater than 20% increase in diameter of the ablation zone from baseline imaging. Secondary end points included cancer-specific survival, overall survival, and quality of life. The local tumor control rates per index tumor were 87.9% at 3 years and 79.2% at 5 years; the 5-year overall survival was 46.7% with 78.2% of surviving patients without progression. Five treated patients experienced local progression throughout the duration of the study, with a local control rate of treated tumors of 75.0% per patient and 79.2% per tumor when treating lung metastases up to 3.5 cm. The authors concluded that these results indicate that the rates of local tumor control, recurrence, and progression in 5 years of follow-up were similar to or better than those of the studies of each type of treatment modality previously described. Although the quality-of-life data did not reach significance, the authors concluded that CA is an effective means of local tumor control in patients with metastatic lung disease.

In 2020, Callstrom et al assessed the safety and local recurrence-free survival after cryoablation for the treatment of pulmonary metastases in a multicenter, single-arm, phase II study in 128 patients with 224 lung metastases ≤3.5 cm (SOLSTICE). The median tumor size was 1.0 cm. Local recurrence-free response was 85.1% at 12 months and 77.2% at 24 months. Secondary local recurrence-free response after re-treatment with cryoablation for recurrent tumors was 91.1% at 12

months and 84.4% at 24 months. Overall survival at 12 and 24 months was 97.6% and 86.6%, respectively.

For individuals who have an unresectable primary or metastatic lung tumor who receive MWA, the evidence includes a single RCT, retrospective observational studies, and systematic reviews of these studies. The RCT by Macchi et al (2017) MWA compared to RFA for lung tumors in 52 patients with a single tumor up to 5 cm, and up to 5 metastases up to 5 cm in size. However, at baseline, the mean tumor size was 2.21 cm (standard deviation [SD], 0.89) in the MWA group and 1.64 cm (SD, 0.80) in the RFA group. Mortality rates at 6 and 12 months did not differ between groups, and complications were significantly lower in the MWA group. Limitations of this study include its small sample size, lack of reporting on blinding, and relatively short follow-up period (12 months). Results were not reported by tumor size or the number of metastases. Systematic reviews determined that local recurrence rates for MWA and RFA were similar at a range of 9 to 47 months of follow-up. Authors conclude that RFA and MWA were both effective with a high safety profile. Limitations exist within the body of evidence include lack of controlled studies and heterogeneity across studies. The studies did not report enough information to assess the effectiveness or safety of MWA in subgroups based on the presence of multiple tumors or total tumor burden. Therefore, conclusions cannot be drawn about the comparable effectiveness of MWA in patients that have more than one tumor.

Murphy et al (2023) conducted a bi-institutional retrospective cohort study to evaluate the safety and effectiveness of percutaneous imagine-guided thermal ablation (IGTA) for juxtacardiac lung tumors. The study included 23 consecutive patients with 30 juxtacardiac lung tumors located less than or equal to ten millimeters from the pericardium treated in 28 IGTA sessions (25 sessions of cryoablation and three sessions of microwave ablation). The primary outcome was any adverse cardiac event within 90 days after ablation. Secondary outcomes included noncardiac adverse events, local tumor progression–free survival (LT-PFS), and the cumulative incidence of local tumor progression with death as a competing risk. The median imaging follow-up duration was 22 months. Primary technical success was achieved in 25 (89%) ablations. No adverse cardiac events attributable to IGTA occurred. One patient experienced a phrenic nerve injury. The median LT-PFS duration was 59 months. At one, three, and five years, LT-PFS was 90% (95% CI, 78%–100%), 74% (CI, 53% – 100%), and 45% (CI, 20% – 97%), respectively, and the cumulative incidence of local tumor progression was 4.3% (CI, 0.29% – 19%), 11% (CI, 1.6% – 30%), and 26% (CI, 3.3% – 58%), respectively.

Breast Tumors

The available literature on the use of cryosurgery in the treatment of breast cancer has shown that complete ablation can be achieved in most cases for variably defined small tumors, but studies have not included control groups or compared outcomes of cryosurgery with alternative strategies for managing similar patients. Therefore, no conclusions can be made on the net health outcome of cryosurgery for breast cancer. For the treatment of fibroadenomas, there is a small body of evidence. This evidence has demonstrated that most fibroadenomas become "nonpalpable" following cryoablation. However, there is a lack of comparative trials. Comparative trials are needed to assess this technology and determine how this approach compares with standard treatments.

Pancreatic Tumors

The available evidence on cryosurgery for pancreatic cancer consists of retrospective case series that used cryosurgery for palliation of inoperable disease and a systematic review of these studies. These studies reported that pain relief was achieved in most cases and that complications such as delayed gastric emptying, are common but the true rate of complications is uncertain. Because these studies did not include control groups or compare outcomes of cryosurgery with alternative strategies for managing similar patients, no conclusions can be made on the net health outcome of cryosurgery for pancreatic cancer.

Desmoid Tumors

In a 2024 update to the global evidence-based consensus guidelines for desmoid tumor management, Kasper et al introduced significant changes reflecting current clinical practices. Notably, cryoablation is now recognized as a valid local therapy option, especially for patients with inoperable, symptomatic, or progressive tumors where systemic therapy is not preferred. The guidelines emphasize the importance of multidisciplinary care and recommend treatment at specialized centers to ensure optimal outcomes. Additionally, the update marks a shift away from surgery as the default first-line treatment, favoring more conservative and individualized approaches that prioritize patient quality of life.

Tremblay et al (2019) conducted a retrospective review of 23 patients treated with CT-guided cryoablation between 2014 and 2018. These patients, aged 16 to 77, had extra-abdominal desmoid tumors and underwent a total of 30 cryoablation sessions, either as first-line (61%) or salvage therapy (39%). The study found that cryoablation achieved technical success in all cases, with a median follow-up of 15.4 months. Symptomatic improvement was reported in 89% of patients, and imaging showed an average 80% reduction in viable tumor volume at 12 months. Tumor response rates included 36% complete response, 36% partial response, and 28% stable disease, with no cases of rapid post-ablation growth or track seeding. Although two patients experienced significant neuropraxia, overall morbidity was low. The authors concluded that cryoablation is a safe and effective treatment option for extra-abdominal desmoid tumors, offering strong symptom relief and local control with minimal complications.

The CRYODESMO-01 study, a prospective, open-label phase II trial led by Kurtz et al (2020), evaluated cryoablation in patients with desmoid tumors that had progressed after prior medical therapy. The study enrolled 45 patients across multiple centers, all of whom had symptomatic or progressive disease and were not candidates for surgery. Cryoablation achieved a 12-month local control rate of 86.7%, with 71.1% of patients experiencing a partial response and 24.4% achieving stable disease. Importantly, 91% of patients reported symptom improvement, particularly in pain and functional limitations. Adverse events were mostly mild to moderate, with no treatment-related deaths. These results support cryoablation as a safe and effective local therapy for select desmoid tumor patients, especially when systemic options are limited or not preferred.

Schmitz et al (2016) reviewed outcomes from a decade of treating patients with extra-abdominal desmoid tumors using CT-guided cryoablation. The retrospective analysis included 23 patients who underwent a total of 30 cryoablation procedures. The study reported a 100% technical success rate,

with 89% of patients experiencing symptomatic improvement, particularly in pain and mobility. Imaging follow-up showed an average 80% reduction in viable tumor volume at 12 months. Tumor response rates included 36% complete response, 36% partial response, and 28% stable disease, with no cases of rapid post-ablation growth or track seeding. Authors concluded that this analysis supports cryoablation as a safe and effective treatment option for extra-abdominal desmoid tumors.

Other Solid Tumors

The evidence on the use of RFA for malignant solid tumors other than liver, consist of case studies, which have reported only short-term outcomes such as tumor response and immediate tumor control. These studies have not determined RFA's effect on the overall survival and net health benefit of these patients compared to the well-established local and systemic treatments currently available for these tumors. More rigorous scientific reviews, long-term follow-up and randomized prospective trials are needed to help better define the role of RFA in the treatment of other solid tumors.

The current evidence on cryoablation for all other indications consists largely of non-comparative, case series and is insufficient to permit conclusions concerning the effect of cryoablation on health outcomes. The outcomes of these case series are inconclusive due to heterogeneity of the patient populations studied and to the lack of long-term data on the effectiveness of cryosurgical ablation on overall survival. Most case series report only short-term outcomes such as tumor response in terms of shrinkage and tumor recurrence. Comparative studies with already established treatments, larger numbers of subjects, and longer follow-up are needed.

There are well-established local or systemic treatment options available for each of the malignancies in which MWA has been investigated. Potential advantages of MWA include improved local control and the minimally invasive nature of the modality to preserve normal organ tissue, decrease morbidity, and shorten the length of hospitalization, however there is insufficient evidence and a need for further studies to confirm that MWA does indeed improve health outcomes over other standard treatments in indications other than hepatic and lung tumors.

PROFESSIONAL GUIDELINE(S)

The American College of Gynecology (ACOG) released an updated practice bulletin in mid-2021 stating that laparoscopic RFA can be considered as a minimally invasive treatment option for the management of symptomatic leiomyomas in patients who desire uterine preservation and are counseled about the limited available data on reproductive outcomes.

The American Association of Gynecologic Laparoscopists (AAGL) (2022) commented that current review of the literature suggests RFA offers a safe and effective alternative treatment option for patients with symptomatic fibroids who seek uterine preservation. Although RFA is not yet approved by the FDA as a fertility-enabling treatment, subsequent successful pregnancy outcomes have been reported in the literature. More robust fertility data is required to confirm its safety for those who actively desire future pregnancy.

The Society of Interventional Radiology (2020) published a position statement on the role of percutaneous ablation in renal cell carcinoma. Their relevant recommendations are as follows:

- "In patients with small renal tumors (stage T1a), percutaneous thermal ablation is a safe and effective treatment with fewer complications than nephrectomy and acceptable long-term oncological and survival outcomes. (Level of Evidence: C; Strength of Recommendation: Moderate)"
- "In selected patients with suspected T1a renal cell carcinoma, percutaneous thermal ablation should be offered overactive surveillance. (Level of Evidence: C; Strength of Recommendation: Moderate)"
- "In high-risk patients with T1b renal cell carcinoma who are not surgical candidates, percutaneous thermal ablation may be an appropriate treatment option; however, further research in this area is required. (Level of Evidence: D; Strength of Recommendation: Weak)"
- "Radiofrequency ablation, cryoablation, and microwave ablation are all appropriate modalities for thermal ablation, and method of ablation should be left to the discretion of the operating physician. (Level of Evidence: D; Strength of Recommendation: Weak)"

The 2021 American Urological Association guidelines on Stage I renal masses indicate that cryoablation may be offered as an option for the management of cT1a solid renal masses < 3 cm in size, with the percutaneous technique being preferred over a surgical approach wherever feasible to minimize morbidity (Moderate Recommendation; Evidence Level: Grade C). Counseling about thermal ablation should include information regarding an increased likelihood of tumor persistence or local recurrence after primary thermal ablation relative to surgical excision, which may be addressed with repeat ablation if further intervention is elected. (Strong Recommendation; Evidence Level: Grade B).

The American College of Radiology Appropriateness Criteria (2009, updated 2021) for post-treatment follow-up and active surveillance of renal cell carcinoma (RCC) indicates that "ablative therapies, such as radiofrequency ablation, microwave ablation, and cryoablation, have been shown to be effective and safe alternatives (to surgical resection) for the treatment of small, localized RCCs.

In 2018, The American Association for the study of Liver Disease released guidelines for the diagnosis, staging and management of HCC. The guidelines suggest that patients who do not meet Milan criteria can be treated with ablative therapy to induce tumor death and deter tumor progression beyond the Milan criteria. In regard to the criteria, the association states, "Thermal ablation is superior to ethanol injection. Thermal ablative techniques have the best efficacy in tumors with maximum diameter less than 3 cm, although microwave ablation potentially provides better tumoral response than RFA. Patients that are post-ablation are at high risk for recurrence and surveillance should be performed with contrast-enhanced CT or MRI every 3-6 months".

NCCN Guidelines for NSCLC (V.6.2026) notes that the use of image-guided thermal ablation (IGTA), which includes radiofrequency ablation, microwave ablation, and cryoablation, may be a treatment option for NSCLC. IGTA may be an option for select patients who are deemed "high risk"-those patients with tumors that are for the most part surgically resectable but rendered medically inoperable due to comorbidities. IGTA has been successfully accomplished in patients considered "high risk," objectively defined with a single major and/or two or more minor criteria. Major criteria for high risk included an FEV1 or DCLO ≤ 50 percent and minor criteria included less depressed FEV1

or DCLO between 51-60 percent, advanced age ≥ 75 years, pulmonary hypertension, VEF ≤ 40 percent, resting or exercise paO2 <55mmHg, and PCO2>45 mmHg.

The NCCN guidelines (V.1.2027) for kidney cancer indicate that thermal ablation (eg, cryosurgery, radiofrequency ablation, microwave ablation) is an option for the management of clinical stage T1 renal lesions. Thermal ablation is an option for clinical T1b masses in select patients not eligible for surgery. Biopsy of lesions is recommended to be done prior to or at time of ablation. Ablative techniques may require multiple treatments to achieve the same oncologic outcomes as conventional surgery.

The NCCN guidelines for soft tissue sarcoma (V.4.2026) recognizes cryoablation as the recommended ablation modality for desmoid tumors.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) has cleared hundreds of RFA devices for the general indication of soft tissue cutting, coagulation, and ablation by thermal coagulation necrosis. Under this general indication, RFA can be used to ablate tumors. Some RFA devices have been cleared for additional specific treatment indications, including partial or complete ablation of nonresectable liver lesions and palliation of pain associated with metastatic lesions involving bone. FDA product code: GEI.

The Sonata Sonography-Guided Transcervical Fibroid Ablation System (Gynesonics) received FDA clearance for marketing in 2018. This device is intended for diagnostic intrauterine imaging and transcervical treatment of symptomatic uterine fibroids, including those associated with heavy menstrual bleeding.

The RFA system Acessa for uterine fibroids, received FDA clearance for marketing in 2012 (K121858). The next generation of the Acessa System, The Acessa ProVu System, received FDA clearance in 2018.

The United States Food and Drug Administration (FDA) regulates medical devices. All thermal ablation related devicesincluding related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Jul 10]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Jul 10]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
19105 (E/I)	Ablation, cryosurgical, of fibroadenoma, including ultrasound guidance, each fibroadenoma
20982	Ablation therapy for reduction or eradiation of one or more bone tumors (e.g., metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; radiofrequency
20983 (E/I)	Ablation therapy for reduction or eradication of 1 or more bone tumors (e.g., metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation
32994	Ablation therapy for reduction or eradication of 1 or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, unilateral; cryoablation
32998	Ablation therapy for reduction or eradication of one or more pulmonary tumor(s) including pleura or chest wall when involved by tumor extension, percutaneous, including imaging guidance when performed, radiofrequency, unilateral
47370	Laparoscopy, surgical, ablation of one or more liver tumor(s); radiofrequency
47371 (E/I)	Laparoscopy, surgical ablation of one or more liver tumor(s); cryosurgical
47380	Ablation, open, of one or more liver tumor(s); radiofrequency
47381 (E/I)	Ablation, open, of one or more liver tumor(s); cryosurgical
47382 (*E/I)	Ablation, one or more liver tumor(s), percutaneous, radiofrequency (*E/I when utilized for Cryosurgical Ablation)
47383 (E/I)	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation
50250	Ablation, open, one or more renal mass lesion(s), cryosurgical, including intraoperative ultrasound guidance and monitoring, if performed
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed
50592	Ablation, one or more renal tumor(s), percutaneous, unilateral, radiofrequency
50593	Ablation, renal tumor(s), unilateral, percutaneous, cryotherapy
58674 (*E/I)	Laparoscopy, surgical, ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency (*E/I when utilized for Microwave Ablation)

Code	Description
60660 (E/I)	Ablation of 1 or more thyroid nodule(s), one lobe or the isthmus, percutaneous, including imaging guidance, radiofrequency
60661 (E/I)	Ablation of 1 or more thyroid nodule(s), additional lobe, percutaneous, including imaging guidance, radiofrequency (List separately in addition to code for primary procedure) (
60699 (*E/I)	Unlisted procedure, endocrine system (*E/I when used for adrenal or thyroid ablation [RF, CA, or MWA])
76940 (*E/I)	Ultrasound guidance for, and monitoring of, parenchymal tissue ablation (*E/I when utilized for Microwave Ablation)
77013	Computed tomography guidance for, and monitoring of, parenchymal tissue ablation
77022	Magnetic resonance imaging guidance for, and monitoring of, parenchymal tissue ablation
0581T (E/I)	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral
58580 (*E/I)	Transcervical ablation of uterine fibroid(s), including intraoperative ultrasound guidance and monitoring, radiofrequency (*E/I when utilized for CA or MWA)

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HCPCS Codes

Code	Description
C2618	Probe/needle, cryoablation
C1886	Catheter, extravascular tissue ablation, any modality (insertable)

ICD10 Codes

Code	Description
Multiple Codes	

REFERENCES

Agency for Healthcare Research and Quality (AHRQ) [Internet]. Comparative effectiveness review

number 112. Local nonsurgical therapies for stage 1 and symptomatic obstructive non-small-cell lung cancer. 2013 [accessed 2026 Jul 10]. Available from: https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/lung-cancer-nonsurgical-therapies_executive.pdf

American College of Radiology (ACR) [Internet] appropriateness criteria: post-treatment follow-up and active surveillance of renal cell carcinoma. 2021 [accessed 2026 Jul 10]. Available from: https://acsearch.acr.org/docs/69365/Narrative/

American Urological Association (AUA) [Internet]. Renal mass and localized renal cancer: evaluation, management, and follow up. 2021 [accessed 2026 Jul 10]. Available from: https://www.auanet.org/guidelines-and-quality/guidelines/renal-mass-and-localized-renal-cancer-evaluation-management-and-follow-up#x15425

Anderson C, et al. Treatment of localized hepatocellular carcinoma: resection vs. ablation vs. radiation. Ann Pall Medicine. 2024 Jan 22;13(2):344-354.

Arnreiter C, Oppelt P. A systematic review of the treatment of uterine myomas using transcervical ultrasound-guided radiofrequency ablation with the Sonata System. J Minim Invasive Gynecol. 2021 Aug;28(8):1462-1469.

Bianchi G, et al. Interventional radiology's osteoid osteoma management: percutaneous thermal ablation. J Clin Med. 2022;11(3):723.

Callstrom MR, et al. Multicenter study of metastatic lung tumors targeted by interventional cryoablation evaluation (SOLSTICE). J Thorac Oncol. 2020 Jul;15(7):1200-1209.

Chong CCN, et al. Prospective double-blinded randomized control trial of microwave vs radiofrequency ablation for hepatocellular carcinoma (McRFA trial). HPB. 2020 Aug; 22(8):1121-1127.

deBaere T, et al. Evaluating cryoablation of metastatic lung tumors in patients-safety and efficacy: the ECLIPSE trial-interim analysis at 1 year. J Thorac Oncol. 2015;10:1468-1474.

deBaere T, et al. The ECLIPSE study: efficacy of cryoablation on metastatic lung tumors with a 5-year follow-up. J Thorac Oncol. 2021;16(11)1840-1849.

Di Martino M, et al. Systematic review and meta-analysis of local ablative therapies for resectable colorectal liver metastases. Eur J Surg Oncol. 2020 May;46(5):772-781.

Duan H, et al. Cryoablation for advanced non-small cell lung cancer: a protocol for a systematic review. BMJ Open. 2020 Sep 6;10(9):e033460.

Fairweather M, et al. Management of neuroendocrine tumor liver metastases: long-term outcomes and prognostic factors from a large prospective database. Ann Surg Oncol. 2017 Aug;24(8):2319-2325.

Genshaft SJ, et al. Society of International Radiology quality improvement standards on percutaneous ablation of non-small cell lung cancer and metastatic disease to the lung. J Vasc Interv Radiol. 2021;32:1242.e1-1242.e10.

Glassberg MB, et al. Microwave ablation compared with hepatic resection for the treatment of hepatocellular carcinoma and liver metastases: a systematic review and meta-analysis. World J Surg Oncol. 2019 Jun 10; 16(1):98.

Guo J, et al. Percutaneous microwave ablation of category T1a renal cell carcinoma: intermediate results on safety, technical feasibility, and clinical outcomes of 119 tumors. AJR AM J Roentgenol. 2021 Jan;216(1):117-124.

Habrawi Z, et al. Cryoablation: A promising non-operative therapy for low-risk breast cancer. Am J Surg. 2021 Jan;221(1):127-133.

Holmes DR. Breast cancer care during a pandemic: an opportune time for cryoablation? Breast Cancer Res Treat. 2020 Aug;182(3):515-521.

Jacoby VL, et al. Laparoscopic radiofrequency ablation of uterine leiomyomas: clinical outcomes during early adoption into surgical practice. J Minim Invasive Gynecol. 2020 May-Jun;27(4):915-925.

Jennings JW, et al. Cryoablation for palliation of painful bone metastases: the MOTION multicenter study. Radiology: Imaging Center. 2021;3(2):e200101.

Kasper B, et al. Current management of desmoid tumors: a review. JAMA Oncol. 2024;10;(8):1121-1128.

Kandil E, et al. Efficacy and safety of radiofrequency ablation of thyroid nodules: a multi-institutional prospective cohort study. Ann Surg. 2022 Oct 1;276(4):589-596.

Khanmohammadi S, et al. Cryoablation for the palliation of painful bone metastasis: a systematic review. Cardiovasc Intervent Radiol. 2023 Nov;46(11)1469-1482.

Kurtz JE, et al. CRYODESMO-01: A prospective, open phase II study of cryoablation in desmoid tumor patients progressing after medical treatment. JAMA Oncol. 2024;10(3):e246789.

Le Corroller T, et al. Osteoid osteoma: percutaneous CT-guided cryoablation is a safe, effective, and durable treatment option in adults. Radiology. 2022;302(2):392-399.

Lim E, et al. Outcomes of renal tumors treated by image-guided percutaneous cryoablation: Immediate and 3- and 5-year outcomes at a regional center. American Journal of Roentgenology. 2020 215:1, 242-247.

Macchi M, et al. Radiofrequency versus microwave ablation for treatment of the lung tumors: LUMIRA randomized trial. Med Oncol. 2017 May;34(5):96.

McClure T, et al. A comparison of microwave ablation and cryoablation for the treatment of renal cell carcinoma: a systematic literature review and meta-analysis. Urology. 2023 Oct:180:1-8.

Miller CE, et al. Transcervical radiofrequency ablation of symptomatic uterine fibroids: 2-year results of the SONATA pivotal trial. J Gynecol Surg. 2019 Dec 1;35(6):345-349.

Mohan H, et al. Radiofrequency ablation for neuroendocrine liver metastases: a systematic review. J Vasc Interv Radio. 2015 Jul;26(7):935-942.

Morris CS, et al. Society of interventional radiology position statement on the role of percutaneous

ablation in renal cell carcinoma. J Vasc Interv Radiol. 2020 Feb;31(2):189-194.

Moore W, et al. Five-year survival after cryoblation of stage I non-small cell lung cancer in medically inoperable patients. J Vasc Interv Radiol. 2015 Mar;26(3): 312-9.

Murphy MC, et al. Safety and effectiveness of percutaneous image-guided thermal ablation of juxtacardiac lung tumors. J Vasc Interv Radiol. 2023 May;34(5):750-7583.

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology Biliary tract cancers. V.1.2026 [accessed 2026 Jul 10]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology Bone cancer. V.2.2026 [accessed 2026 Jul 10]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/bone.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology Breast cancer. V.5.2026 [accessed 2026 Jul 10]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology Colon cancer. V.2.2026 [accessed 2026 Jul 10]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology Head and neck cancers. V.2.2026 [accessed 2026 Jul 10]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/head-and-neck.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology Kidney cancer. V.1.2027 [accessed 2026 Jul 110]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology Neuroendocrine and adrenal tumors. V.1.2026 [accessed 2026 Jul 10]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology Non-small cell lung cancer. V.6.2026 [accessed 2026 Jul 10]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology Pancreatic adenocarcinoma tumors. V.2.2026 [accessed 2026 Jul 10]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology Small cell lung cancer. V.1.2027 [accessed 2026 Jul 10]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf

National Comprehensive Cancer network (NCCN) [Internet]. Clinical practice guidelines in oncology Thyroid carcinoma. V.2.2026 [accessed 2026 Jul 10]. Available from:

https://www.nccn.org/professionals/physician_gls/pdf/thyroid.pdf

National Comprehensive Cancer network (NCCN) [Internet]. Clinical practice guidelines in oncology soft tissue sarcoma. V.4.2026 [accessed 2026 Jul 10]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf

National Institute for Health and Clinical Excellence (NICE) [Internet]. Percutaneous cryotherapy for renal cancer. 2011 Jul [accessed 2026 Jul 10] Available from: https://www.nice.org.uk/guidance/htg269

National Institute for Health and Clinical Excellence (NICE) [Internet]. Percutaneous radiofrequency for renal cancer. 2010 Jul [accessed 2026 Jul 10] Available from: https://www.nice.org.uk/guidance/HTG226

National Institute for Health and Clinical Excellence. (NICE) [Internet]. Percutaneous radiofrequency ablation for primary and secondary lung cancers. Dec 2010 [accessed 2026 Jul 10] Available from: https://www.nice.org.uk/guidance/HTG244

National Institute for Health and Excellence (NICE) [Internet]. Radiofrequency ablation for colorectal liver metastases. Dec 2009 [accessed 2026 Jul 10] Available from: Ohttps://www.nice.org.uk/guidance/htg208

National Institute for Health and Clinical Excellence (NICE) [Internet]. Laparoscopic cryotherapy for renal cancer. 2011 Aug [accessed 2026 Jul 10] Available from: https://www.nice.org.uk/guidance/htg271

National Institute for Health and Clinical Excellence (NICE) [Internet]. Cryotherapy for the treatment of liver metastases. 2010 Dec [accessed 2026 Jul 10] Available from: Ohttps://www.nice.org.uk/guidance/HTG241

Rattray DD, et al. Clinical outcomes and health care utilization pre- and post- laparoscopic radiofrequency ablation of symptomatic fibroids and laparoscopic myomectomy: a randomized trial of uterine-sparing techniques (TRUST) Canada. Clinicoecon Outcomes Res. 2018 April 5;10:201-212.

Reis J, et al. Radiofrequency ablation vs microwave ablation for osteoid osteomas: long-term results. Skeletal Radiol. 2020 Dec;49(12):1995-2000.

Schmitz JJ, et al. Percutaneous cryoablation of extra-abdominal desmoid tumors: a 10-year experience. AJR Am J Roentgenol. 2016;207(1):190–195.

Seager M, et al. Renal cryoablation-a practical guide for interventional radiologists. Br J Radio. 2020:94 20200854.

Shifrin G, et al. Transcervical fibroid ablation with the Sonata system for treatment of submucous and large uterine fibroids. Int J Gynaecol Obstet. 2021 Oct;155(1):79-85.

Tremblay D, et al. Percutaneous cryoablation for the treatment of extra-abdominal desmoid tumors. J surg oncol. 2019;120:366-375.

Wang F, et al. Percutaneous cryoablation of subcapsular hepatocellular carcinoma: a retrospective

study of 57 cases. Diagn Interv Radiol. 2020:26(1):34-39.

Yanagisawa T, et al. Differential efficacy of ablation therapy versus partial nephrectomy between clinical T1a and T1b renal tumors: a systematic review and meta-analysis. Uro Oncol. 2022;40:315-330.

Yu S, et al. Clinical and patient reported outcomes of pre- and postsurgical treatment of symptomatic uterine leiomyomas: a 12 month follow up review of TRUST, a surgical randomized clinical trial comparing laparoscopic radiofrequency ablation and myomectomy. J Minim Invasive Gynecol. 2022 Jun;29(6):726-737.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

There is no specific regional or national coverage determination addressing Thermal Tumor Ablation other than the national coverage determination for cryosurgery of the prostate which is highlighted in a separate corporate medical policy.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 5/26

Revised:

Reviewed:

Date	Summary of Changes
9/1/2026	• New

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

MEDICAL POLICY

Medical Policy Title	**Tibial Nerve Stimulation (TNS) for Voiding Dysfunction**
Policy Number	**8.01.22**
Current Effective Date	**January 1, 2027**
Next Review Date	**April 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service.
(Link to Product Disclaimer)

Transcutaneous Posterior Tibial Nerve Stimulation is not addressed in this policy.

POLICY STATEMENT(S)

I. Percutaneous posterior tibial nerve stimulation (PPTNS) is considered **medically appropriate** as a treatment modality for patients with urinary urge incontinence, nonobstructive urinary retention, or overactive bladder (OAB) symptoms who meet **BOTH** of the following criteria:

   A. Failure of conservative behavioral therapies of at least three (3) months' duration;

   B. Failure of pharmacological therapy **or** patient has a contraindication to pharmacological therapy. For urinary urge incontinence and OAB, that includes at least two (2) anticholinergic or beta-3 adrenergic agonist medications or smooth muscle relaxants.

II. Percutaneous posterior tibial nerve stimulation (PPTNS) is considered **investigational** for all other uses, including, but not limited to, **ALL** of the following:

   A. Voiding dysfunction due to a neurological condition;

   B. Constipation;

   C. Fecal incontinence (FI).

III. An implanted TNS is considered **investigational** for all indications.

RELATED POLICIES

Corporate Medical Policy

1.01.19 Pelvic Floor Electrical Stimulation as a Treatment for Urinary or Fecal Incontinence

1.01.55 Electrical Stimulation as a Treatment for Pain and Other Medical Conditions

7.01.10 Sacral Nerve Stimulation

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Twelve weekly office visits for PPTNS treatment sessions are considered the standard treatment plan. Then, once monthly maintenance therapy will be considered if the patient has exhibited at

least a 50% improvement in voiding symptoms (based on documentation such as patient voiding diaries) after the initial 12 sessions.

II. Maintenance therapy is dependent on documentation of a continued treatment response.

DESCRIPTION

PPTNS is an office-based procedure that utilizes electrical neuromodulation in the treatment of voiding dysfunction in patients who have failed conservative therapies (e.g., behavioral, pharmacological). Voiding dysfunction includes urinary frequency, urgency, incontinence, and nonobstructive retention and is usually initially treated with behavioral interventions and/or medications such as anticholinergics. Behavioral therapies include (but are not limited to) fluid management, bladder training/timed voiding, and physiotherapy.

The procedure for PPTNS consists of the insertion of a needle above the medial malleolus into the posterior tibial nerve, followed by the application of low-voltage (10mA, 1–10 Hz frequency) electrical stimulation that produces sensory and motor responses (e.g., a tickling sensation and plantar flexion or fanning of all toes). The recommended course of treatment is an initial series of 12 weekly, office-based treatments, followed by an individualized maintenance treatment schedule.

While the posterior tibial nerve is located near the ankle, it is derived from the lumbar-sacral nerves (L4-S3), which control the bladder detrusor and perineal floor. Altering the function of the posterior tibial nerve with PPTNS is believed to improve voiding function and control.

PPTNS has also been proposed as treatment for individuals with non-neurogenic and neurogenic bladder syndromes and fecal incontinence.

The eCoin Peripheral Neurostimulator (Valencia Technologies Corporation) is a coin-sized leadless stimulator that is implanted subcutaneously using local anesthetic in the lower leg and delivers 30-minute treatments without the need for users to manipulate to deliver stimulation.

SUPPORTIVE LITERATURE

Randomized Control Trials for PPTNS

Peters and colleagues published an industry sponsored RCT in 2010 (SUmiT trial). The eligibility criteria included a score of at least four on the overactive bladder questionnaire (OAB-q) short form for urgency, self-reported bladder symptoms lasting at least three months, and failure of conservative care. A total of 220 patients were randomized, 110 to the PPTNS group and 110 to the sham group. Both groups received 12 weekly, 30-minute intervention sessions. The 12-week course of treatment was completed by 103 of 110 (94%) in the PPTNS group and 105 of 110 (95%) in the sham group. The primary study outcome was response to treatment based on a single-item global response assessment (GRA). The proportion of patients who responded to treatment based on the GRA (i.e., answered that symptoms were moderately or markedly improved) was 60 of 110 (54.5%) in the PPTNS group and 23 of 110 (20.9%) in the sham group; this difference was statistically significant, $p<0.001$. Intention-to-treat analysis was used for the primary endpoint only. Several secondary outcomes also favored the PPTNS group. The mean reduction in a symptom severity score (a lower score indicates less severity) was 36.7 in the PPTNS group and 29.2 in the sham group, $p=0.01$.

Similarly, the mean reduction in a quality-of-life scale, the SF-36 (a higher score indicates higher quality of life), was 34.2 in the PPTNS group and 20.6 in the sham group, p=0.006. A limitation to this study was that the primary outcome, the GRA, was a single-item subjective measure. In addition, the SUmiT trial only reported comparative data immediately following the initial course of treatment; the study did not evaluate the long-term effectiveness of PPTNS. Unlike medication, which can be taken on an ongoing basis, PPTNS involves an initial 12-week course of treatment, followed by maintenance therapy, which, to date, has not been well-defined. Therefore, the assumption cannot be made that short-term treatment effects will be maintained.

In 2010, MacDiarmid and colleagues reported one-year follow-up data for patients from the OrBIT trial who had been assigned to the PPTNS group and had responded to the initial course of treatment, defined as reporting symptom improvement at 12 weeks. Thirty-three of the 35 responders were included. They received a mean of 12.1 (SD=4.9) treatments between the 12-week and 12-month visits, with a median of 17 days between treatments. Data was available for 32 of the 33 (97%) participants at six months and 25 of the 33 (76%) participants at 12 months. The mean reduction in number of voids per day from baseline (the original primary outcome of the study) was 3.2 (SD=3.7) at six months and 2.8 (SD=3.7) at 12 months. Other voiding diary outcomes at 12 months, based on 25 responses, were mean changes in nocturia episodes of -0.8, in episodes of moderate to severe urgency per day of -3.7, and in episodes of urge incontinence per day of -1.6. As noted above, this analysis was limited in that no data from the tolterodine group was available to compare long-term outcomes. Another limitation was that only PPTNS responders were included, rather than all of the patients assigned to PPTNS treatment.

The evidence for using PPTNS in individuals with fecal incontinence includes several RCTs and systematic reviews. The available RCTs have not found a clear benefit of PPTNS. Neither of the sham-controlled trials found that active stimulation was superior to sham for achieving the primary outcome, at least a 50% reduction in mean weekly fecal incontinence episodes. The evidence is insufficient to determine that this technology results in an improvement in the net health outcome. There are currently no PPTNS devices cleared by the FDA for the treatment of fecal incontinence.

Zyczynski et al (2022) conducted the Neuromodulation for Accidental Bowel Leakage (NOTABLe) sham-controlled trial of percutaneous posterior tibial nerve stimulation (PTNS) in women with fecal incontinence (N=166). Women with greater than or equal to three months of moderate-to-severe fecal incontinence were randomized to PTNS (n=111) or sham stimulation (n=55). Stimulation was delivered in 12 weekly 30-minute sessions to a single lower extremity. The primary outcome was change from baseline in St. Mark score (a 7-item, validated patient-reported outcome) measured after 12 weekly treatments. Secondary outcomes included stool consistency, bowel movement, and stool leakage episodes per week. There was no significant difference between the PTNS group (-5.3 points) and the sham group (-3.9 points) in terms of improvement from baseline in St. Mark scores (adjusted difference -1.3;95% CI, -2.8 to 0.2). There also was no significant difference in reduction in weekly fecal incontinence episodes from baseline between the PTNS group (-2.1 episodes) and sham group (-1.9 episodes) (adjusted difference -0.26; 95% CI, -1.85 to 1.33).

Implantable Peripheral Neurostimulators for the Treatment of Voiding Dysfunction:

Approval for the eCoin Peripheral Neurostimulator was granted based on a prospective, open-label,

multi-site, single arm clinical trial (NCT03556891) of 132 individuals. The primary outcome of the interventional study was the percentage of individuals experiencing 50% or better improvement in urgency urinary incontinence episodes after subcutaneous stimulation of the tibial nerve using the eCoin device, as measured by a 3-day voiding diary capturing the number of Urgency Incontinence Episodes/day, voids per/day, urgency episodes/day, nocturia episodes/day as well as quality of life (via Overactive Bladder Questionnaire). All individuals were successfully implanted with the device. Data was collected at baseline and the primary outcome assessment occurred 48 weeks after device activation. Device activation occurred 4 weeks after implantation. The analysis demonstrated 68% of the individuals were considered responders, experiencing a 50% or better improvement in their symptoms. Measured at 52 weeks post-implantation, 17/133 (12.78%) had experienced an adverse event, which mostly consisted of skin infection (3.01%) and issues with the device itself (14.7%) such as stimulation issues, device dislocation, or device malfunction. The study was funded by the vendor, was unblinded, without a comparator group and limited length of follow-up. Studies with longer-term follow-up and sound methodology are needed.

PROFESSIONAL GUIDELINE(S)

The American Gastroenterological Association (2017) issued an expert review and clinical practice update on surgical interventions and device-aided therapy for the treatment of fecal incontinence. The update stated that "until further evidence is available, percutaneous tibial nerve stimulation should not be used for managing FI in clinical practice."

The American Urological Association and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (2020) published updated guidelines on the diagnosis and treatment of non-neurogenic overactive bladder in adults. The guidelines included a statement that clinicians may offer PTNS as a third-line treatment option in carefully selected patients. The statement carried a grade C rating, indicating that the balance of benefits and risks/burdens are uncertain.

According to the American Urological Association (AUA) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) 2021 guidelines on adult neurogenic lower urinary tract dysfunction (NLUTD), clinicians may offer posterior tibial nerve stimulation to select spontaneous voiding NLUTD individual with urgency, frequency, and/or urgency incontinence. (Conditional Recommendation; Evidence Level: Grade C). PTNS is approved for patients with non-neurogenic OAB, however, it has been shown to offer benefit to select individuals with NLUTD where bladder problems are mainly isolated to storage symptoms. This benefit has primarily been demonstrated in individuals with neurologic diagnoses such as Multiple Sclerosis, Parkinson Disease, and Stroke who have OAB symptoms and continue to volitionally void.

REGULATORY STATUS

In July 2005, the Urgent PC Neuromodulation System (Uroplasty, Inc.) received Section 510(k) marketing clearance from the U.S. Food Drug Administration (FDA) for PPTNS to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence. In 2010, the cleared indication was changed to overactive bladder (OAB) and associated symptoms of urinary urgency, urinary frequency, and urge incontinence. The Urgent PC Neuromodulation System is not FDA-

cleared for other indications, such as the treatment of fecal incontinence.

eCoin received FDA approval on March 1, 2022. This device is indicated for the treatment of urgency urinary incontinence in individuals who are intolerant to or having an inadequate response to other more conservative treatments who have undergone a successful trial of PPTNS.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming
64590	Insertion or replacement of peripheral, sacral or gastric neurostimulator pulse generator or receiver, requiring pocket creation and connection between electrode array and pulse generator or receiver
0587T (E/I)	Percutaneous implantation or replacement of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0588T (E/I)	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve
0589T (E/I)	Electronic analysis with simple programming of implanted integrated neurostimulation system (e.g., electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 1-3 parameters
0590T (E/I)	Electronic analysis with complex programming of implanted integrated neurostimulation system (e.g., electrode array and receiver), including contact group(s), amplitude, pulse width, frequency (Hz), on/off cycling, burst, dose lockout, patient-selectable parameters, responsive neurostimulation, detection

Code	Description
	algorithms, closed-loop parameters, and passive parameters, when performed by physician or other qualified health care professional, posterior tibial nerve, 4 or more parameters
0816T (E/I)	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (e.g., array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous
0817T (E/I)	when performed, posterior tibial nerve; subfascial
0818T (E/I)	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous
0819T (E/I)	when performed, posterior tibial nerve; subfascial
0988T (E/I)	Open insertion or replacement of integrated neurostimulation system for bladder dysfunction including electrode(s) (e.g., array or leadless), and pulse generator or receiver, including analysis, programming, and imaging guidance, when performed, posterior tibial nerve; subcutaneous and subfascial (Effective 01/01/26)
0989T (E/I)	Revision or removal of integrated neurostimulation system for bladder dysfunction, including analysis, programming, and imaging, when performed, posterior tibial nerve; subcutaneous and subfascial (Effective 01/01/26)

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
N32.81	Overactive bladder
N39.41	Urge incontinence
R35.0	Frequency of micturition
R35.81	Nocturnal polyuria

Code	Description
R35.89	Other polyuria
R39.15	Urgency of urination

REFERENCES

American Urological Association (AUA) and Society of Urodynamics FPMURS. [Internet]. Diagnosis and treatment of overactive bladder (non-neurogenic) in adults/AUA/SUFU guideline 2019. [accessed 2026 Mar 12]. Available from: https://www.auanet.org/guidelines-and-quality/guidelines/archived-documents#incontinence

Cottrell AM, et al. Benefits and harms of electrical neuromodulation for chronic pelvic pain: a systematic review. Eur Urol Focus 2020 May 15;6(3):559-571.

Ginsberg DA, et al. The AUA/SUFU guideline on adult neurogenic lower urinary tract dysfunction: treatment and Follow-up. J Urol. 2021 Nov;206(5):1106-1113.

Ho FCS, et al. Efficacy of sacral neuromodulation (SNM) and percutaneous tibial nerve stimulation (PTNS) in the treatment of chronic nonobstructive urinary retention: A systematic review. Neuro Urodyn 2021 Feb 18;40:1078-1088.

Leo CA, et al. Randomized pilot study: anal inserts versus percutaneous tibial nerve stimulation in patients with fecal incontinence. Dis Colon Rectum 2021;64(4):466-474.

MacDiarmid S, et al. Long-term durability of percutaneous tibial nerve stimulation for the treatment of overactive bladder. J Urol. Jan 2010;183(1):234-240.

MacDiarmid S, et al. Feasibility of a fully implanted, nickel sized and shaped tibial nerve stimulator for the treatment of overactive bladder syndrome with urgency urinary incontinence. J Urol. 2019 May;201(5):967-972.

Peters K, et al. Randomized trial of percutaneous tibial nerve stimulation versus sham efficacy in the treatment of overactive bladder syndrome: results from the SUmiT trial. J Urol Apr 2010;183(4):1438-1443.

Rogers A, et al. Pivotal study of leadless tibial nerve stimulation with eCoin for urgency urinary incontinence: An open-label, single arm trial. The Journal of Urology. 2021 Aug;206:399-408.

Solon, JG, et al. Percutaneous tibial nerve stimulation can improve symptoms and quality of life in selected patients with faecal incontinence - A single-centre 5-year clinical experience. Surgeon. 2020 Jun;18(3):154-158.

van Breda HMK, et al. A new implanted posterior tibial nerve stimulator for the treatment of overactive bladder syndrome: 3-month results of a novel therapy at a single center. J Urol. 2017 Jul;198(1):205-210.

Zyczynski HM, et al. Percutaneous tibial nerve stimulation vs sham stimulation for fecal incontinence

in women: neuromodulation for accidental bowel leakage randomized clinical trial. Am J Gastroenterol. 2022 Apr 01;117(4):654-667.

SEARCH TERMS

Percutaneous/peripheral posterior tibial nerve stimulation, SANS, Stoller afferent stimulation

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

LCD - Posterior Tibial Nerve Stimulation for Voiding Dysfunction (L33396) [accessed 2026 Mar 11]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates	
01/01/27	
Date	**Summary of Changes**
01/01/27	Original effective date

MEDICAL POLICY

Medical Policy Title	**Transarterial Radioembolization (TARE) for Hepatic Tumors**
Policy Number	**7.01.69**
Current Effective Date	**January 1, 2027**
Next Review Date	**February 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

This policy does not address Transarterial Chemoembolization (TACE). Also, this policy does not address arterially directed therapies other than TARE.

POLICY STATEMENT(S)

I. Transarterial Radioembolization (TARE) using radioactive Yttrium-90 (^{90}Y) microspheres is considered **medically necessary** as a treatment for **EITHER** of the following indications (Refer to Policy Guidelines):

Primary Hepatic Tumors

A. Treatment of unresectable or medically inoperable hepatic tumors including **ANY** of the following:

1. Hepatocellular carcinoma (HCC);
2. As a bridge to transplant for patients with HCC who:
    a. Meet liver transplant criteria and are waiting liver transplantation; **or**
3. Intrahepatic cholangiocarcinoma (ICC);

OR

Metastatic Hepatic Tumors

B. Treatment of unresectable or medically inoperable hepatic metastases when **ALL** of the following criteria are met:

1. Individual is not a candidate for chemotherapy or other systemic therapies, or is refractory to chemotherapy; with **ANY** of the following indications:
    a. Neuroendocrine tumors (e.g., carcinoids, pancreatic islet cell tumors, endocrine tumors)
    b. Colorectal carcinoma;
    c. Breast carcinoma; **or**
    d. Melanoma (ocular or cutaneous).

II. A second (repeat) TARE is considered **medically necessary** when **ALL** of the following criteria

are met (Refer to Policy Guidelines):

A. Treatment is for a new, progressive primary or metastatic hepatic tumor;

B. A previous satisfactory response to an initial radioembolization treatment was attained as evidenced by **all** of the following criteria:

1. Completion of a computed tomography (CT) scan or positron emission tomography (PET)-CT scan, performed 3 months following the previous procedure; **and**
2. Response should be graded according to the revised Response Evaluation Criteria in Solid Tumors (RECIST) guideline (Version 1.1);

C. There are no other effective systemic or liver-directed treatment options available;

D. The individual has compensated liver function tests;

E. Estimated lung dose and combined lung dose from previous radiation are within acceptable dose volume constraints; **and**

F. Treatment should be given to a targeted tumor volume.

III. A third TARE is considered **not medically necessary**.

IV. TARE as a treatment for all other metastatic or primary hepatic tumors is considered **investigational**.

RELATED POLICIES

Corporate Medical Policy

7.01.111 Thermal Ablation for Solid Tumor Treatment

7.02.07 Liver Transplantation

11.01.03 Experimental or Investigational Services

11.01.10 Clinical Trials

POLICY GUIDELINE(S)

I. TARE should be reserved for patients with:

A. An Eastern Cooperative Oncology Group (ECOG) performance status no greater than 2 or Karnofsky Performance Status (KPS) of 70 or above;

B. Adequate liver function and reserve, and liver-dominant metastases;

C. Life expectancy of greater than three (3) months.

II. Radioactive Yttrium-90 (90Y) microspheres treatment is allowed only in the outpatient setting unless the documentation supports the medical necessity of inpatient treatment.

DESCRIPTION

Hepatic tumors can arise either as primary liver cancer or by metastasis to the liver from other tissues or organs. At present, surgical resection with tumor-free margins and liver transplantation are the only potentially curative treatments for hepatic cancer. Unfortunately, most hepatic tumors are not amenable to resection or transplantation at diagnosis, due to their anatomic location, tumor size, the number of lesions, concurrent nonmalignant liver disease, or insufficient hepatic reserve. Patients with hepatic tumors may require treatments to downstage disease to meet criteria for a liver transplant (Milan criteria, etc.) and those individuals who do meet become candidates often require bridge therapy due to the long waiting time to obtain the transplant. Various minimally invasive ablative techniques have been investigated that seek to cure or palliate unresectable hepatic tumors by improving loco-regional control. Examples of these techniques include TARE, transarterial chemoembolization, and thermal ablative techniques such as radiofrequency ablation, cryotherapy, and microwave ablation.

The content of this policy addresses the use of TARE, is also known in the literature as Selective Internal Radiation Therapy (SIRT), and arterial radioembolization with yttrium-90 (^{90}Y). TARE relies on targeted delivery of small beads (microspheres) impregnated with ^{90}Y, a radioactive beta emitter with a short half-life of 64.2 hours (2.67 days). TARE uses local anesthesia and fluoroscopic guidance to inject the radioactive material into the left, right or common hepatic artery via a percutaneous (femoral or gastroduodenal) catheter. This allows the delivery of a concentrated dosage of radiation directly into the tumor bed, while conserving the normal liver tissue that surrounds the tumor. The size of the microspheres causes them to become entrapped within the tumor vasculature and retained. The treatment goals with TARE can include curative intent, bridging to transplant, downsizing disease to assist with resection, inform the treatment approach and to provide valuable information for radiation dosimetry. TARE can usually be performed in an outpatient setting, as there is no radiation exposure to others once the microspheres have been infused.

Eastern Cooperative Oncology Group (ECOG) Performance Status (Oken et al 1982)

Performance Status	Description
0	Fully active; no performance restrictions
1	Strenuous physical activity restricted; fully ambulatory and able to carry out light work
2	Capable of all self-care but unable to carry out any work activities Up and about > 50% of waking hours.
3	Capable of only limited self-care; confined to bed or chair > 50% of waking hours
4	Completely disabled; cannot carry out any self-care; totally confined to bed or chair

SUPPORTIVE LITERATURE

Hepatocellular Carcinoma (HCC)

TARE has been studied for its use in all stages of HCC and has demonstrated comparable outcomes to the historical therapies of choice, including transarterial chemoembolization for intermediate stage HCC, and systemic therapy in patients with advanced HCC.

In 2016, Salem and colleagues conducted a randomized phase II trial (PREMIERE) comparing TARE to TACE in 179 patients with HCC with a Barcelona Clinic Liver Cancer stage of A or B. There was no difference noted in overall survival (OS), but authors found that TARE provided significantly longer time to progression (TTP) over TACE, patients had fewer related adverse events, and improved quality of life. Authors concluded that given these outcomes, TARE provides better tumor control, and further, that it could reduce the number of patients who drop out of the liver transplant waitlists.

The LEGACY Study (Salem 2021) evaluated TARE as a primary treatment of naïve solitary HCC tumors less than or equal to 8 cm in size. The retrospective single arm study evaluated the overall response (OR) rate and duration of response and determined an OR of 88.3% with 62.2% of the lesions having a duration of response greater than six months, which again, is critical for patients awaiting transplant. The patients that had received surgical resection or transplant had an overall survival of 86.6% and 92.8%. Authors concluded that radioembolization for solitary HCC is safe and efficacious when neoadjuvant to transplant or resection, or as a stand-alone treatment.

Trials have demonstrated that there is no difference in OS or progression free survival (PFS) when comparing TARE with the use of the use of tyrosine kinase inhibitor sorafenib (Vilgrain 2017) for the treatment of HCC. Additionally, better treatment tolerance, and less adverse effects were noted with TARE.

Neuroendocrine Tumors

While studies investigating TARE for neuroendocrine tumors have limitations such as heterogeneous patient populations, studies report relief of symptoms from carcinoid syndrome in a proportion of patients. Surgical debulking of liver metastases has shown palliation of hormonal symptoms; debulking by radioembolization may lead to symptom relief in some patients (e.g., Sato et al 2008; Kennedy et al 2009; Cao et al 2010; Cramer et al 2016).

Metastatic Colorectal Cancer

A major cause of morbidity and mortality in patients with colorectal disease when metastatic to the liver is liver failure, as this disease tends to progress to diffuse, liver-dominant involvement. The literature demonstrates that the use of TARE to decrease tumor bulk or halt TTP and liver failure, may lead to prolonged PFS and OS in patients with no other treatment options (e.g., those with chemotherapy refractory liver-dominant disease). Other uses include palliation of symptoms (e.g., Kennedy et al 2009, 2016; Mulcahy et al 2009; Hendlisz et al 2010; Damm et al 2016; Jakobs et al 2017).

In a 2021 randomized phase III trial, Mulcahy et al investigated the role of TARE when combined with standard-of care second-line systemic chemotherapy for the treatment of colorectal liver

metastases. The study was conducted in over 95 centers internationally and included 488 patients whose disease had progressed despite first-line chemotherapy. The patients were randomly assigned to chemotherapy with or without TARE. Primary end points were PFS and hepatic PFS (hPFS) from the time of group assignment using RECIST 1.1. Results demonstrated that the primary end points of PFS and hPFS were longer with the addition of TARE to second-line chemotherapy. Further, TTP was observed for tumors with KRAS mutation, left-side primary tumor, hepatic tumor burden of 10%-25%, ≤ 3 lesions, addition of a biologic agent, and resected primary disease. The study was limited by its design, in that it was not powered for OS, and higher rates of additional local therapy (including TARE) occurred in the control arm; which prevents the ability to draw strong conclusions based on the results. Authors determined that although the addition of TARE to systemic therapy improved PFS and hPFS in second-line settings for colorectal liver metastases, further studies are needed to identify the optimal second-line patient population that would most benefit from treatment.

Bridge Therapy

Gabr et al (2020) performed a retrospective review reporting the long-term outcomes of 207 liver transplantation patients with HCC who were bridged or down staged with TARE from 2004 to 2018. The median OS from liver transplant was 12.5 years, with a median time to liver transplantation of 7.5 months (interquartile range, 4.4 to 10.3). Overall, 169 patients were bridged and 38 were down staged. The OS rates at 3, 5, and 10 years were 84%, 77%, and 60%, respectively. Disease specific mortality was 6%, 11%, and 16% at 3, 5, and 10 years. No differences were noted in recurrence free survival and OS for patients who were bridged or down staged. Recurrence free survival was greater in patients with complete/extensive tumor necrosis vs. partial. Authors came to the concluded TARE is an effective treatment for HCC in the setting of bridging/downstaging to liver transplant.

Lopez et al conducted a systematic literature review (2023) to analyze relevant data regarding patient selection, HCC features and outcomes after TARE for downstaging or bridging in liver transplant. A total of 14 studies representative of 204 patients were included in the analysis, which was made up of the following treatments included in the studies: downstaging (n=7), bridging (n=3), and mixed (downstaging and bridging, n=4). For patients with remaining viable tumor after imaging, or for those who had planned staged procedures due to bilobar disease, multiple TARE interventions were required (16.7% to 28% of patients). A total of 55 patients were transplanted after undergoing TARE for downstaging. The percentage of patients who received a response, by study group and type is as follows:

Study Group	Complete Response	Partial Response	Stable Disease	Progressive Disease
Downstaging	26.7%	49.2%	13.4%	10.7%
Bridging	41.8%	34.1%	17.6%	6.6%
Mixed	30.8%	35.9%	33.3%	0%

Despite limitations including study design, high dropout rates due to death or tumor progression, and authors believing comparisons to be underpowered, they concluded that the use of TARE is an alternative treatment in patients with advanced HCC who were not initially suitable for resection or

liver transplant.

Other Hepatic Metastases

A 2024 study (NCT 02685631) by Zhou et al aimed to evaluate the response and survival outcomes of TARE on unresectable liver-dominant metastases from primary neoplasms other than colorectal carcinoma (m-non-CRC). The study included 1474 patients from the Radiation-Emitting Society of Interventional Radiology SIR-Spheres in Nonresectable Liver Tumor registry (RESiN). Of the study participants, 33% had liver metastases of non-colorectal origin, 34% had metastatic colorectal cancer, 34% had HCC). Responses were identified in 12 unique cancer types, most of which were identified as refractory to several lines of systemic therapies. Outcomes provided within the study were as follows:

Study Group	**Complete Response**	**Partial Response**	**Stable Disease**	**Progressive Disease**	**Objective Response Rate**	**Disease Control Rate**	**Median Duration of Response**
m-CRC n=248	Not Available	Not Available	Not Available	31%	31%	69%	9 months (95% CI, 6–13 months)
m-non-CRC n=250	6%	39%	28%	27%	46%	73%	11.5 months (95% CI, 8–19 months) for m-non-CRC (P = .04 for comparison between mCRC and m-non-CRC groups).
HCC n=255	Not Available	Not Available	Not Available	21%	50%	79%	16 months (95% CI, 11–19 months) for HCC

The study demonstrated better outcomes with the m-non-CRC group for duration of response, PFS, TTP, and OS when compared to the reference standard for metastatic colorectal cancer. Metastatic

neuroendocrine tumor, sarcoma, ovarian, renal, prostate, and breast cancers were associated with superior treatment outcomes. Worse treatment outcomes were observed in metastatic lung, gastric, pancreatic, and esophageal cancers. Although promising for certain indications, this study did have several limitations including its design which did not include a control arm or predefined number of patients for each cancer type. The patient population was heterogeneous and obtained from RESiN, a non- randomized observational registry and therefore, differences in patient's extent of disease, treatment timing and use of other therapies does not allow for applicability to the general population. Authors concluded that despite its limitations, the use of TARE in m-non-CRC patients may provide an important option for some patients with late-stage disease whose malignancies are rarer.

Melanomas

A 2017 systematic review by Jia et al aimed to assess the effectiveness of TARE in the treatment of unresectable liver metastases from melanoma. A total of 12 reports were included in the analysis, of which, 7 were observational studies and 5 were conference abstracts. The reports represented 255 patients with primary sites of melanoma consisting of cutaneous (8.6%), ocular (77.3%), rectal (1.2%) and unknown (12.9%). Among the 207 patients, complete response was seen in 1.0% (2/207), partial response was seen in 19.3% (40/207), stable disease was seen in 46.9% (97/207), and progressive disease was seen in 32.9% (68/207). The median survival was 10 months (range, 7-13.4 months), and the median 1-year survival rate was 34.6% (range, 23%-80%). Authors concluded that TARE is a promising alternative therapy with encouraging effects on disease control and survival in patients with melanoma, given the lack of alternative treatments for this patient population.

A prospective phase II trial (NCT01473004) from Gonsalves and colleagues (2019) aimed to assess the safety and effectiveness of TARE for the treatment of uveal melanoma hepatic metastases by studying the level of response, PFS, and OS after TARE, comparing treatment naïve participants (Group A, n=23) to patients who progressed after immmunoembolization, who had less than a 50% tumor burden (Group B, n=24). Patients were followed for 1 month and then every 3 months for toxicities, with MRI, CT and PET performed every 3 months. Patients were followed for a minimum of 2 years or until death. A median OS of 18.5 months and 19.2 months with a 1-year survival of 60.9% and 69.6% was achieved in treatment Groups A and B, respectively. Survival outcomes were attributed to the stabilization of hepatic tumors in 87.0% and 58.3% of participants in groups A and B, respectively. Additionally, PFS was 8.1 months and 5.2 months for group A and B participants, respectively. Despite the stabilization noted, greater than 90% of participants developed new hepatic and extrahepatic metastases following treatment. The treatment was well tolerated with no instances of radiation-induced liver disease and clinically significant treatment-related toxicities were temporary and uncommon. The authors concluded that given there are no effective systemic treatments available for metastatic uveal melanoma, radioembolization is a safe and effective first-or second-line treatment for uveal melanoma hepatic metastases.

A retrospective analysis (Ponti et al 2020) of a prospectively collected cohort was conducted evaluating 22 patients with uveal melanoma metastatic to the liver and treated with first-line TARE. Authors set to investigate the safety and efficacy of TARE as a first-line therapy, given data were lacking when compared to its use as salvage therapy. According to the European Association of the

Study of Liver Disease (EASL) Criteria, disease control at 6 months after TARE was achieved in 15 of the 29 TARE patients and was predictive of survival. Median overall survival from the first TARE was 18 months (95% confidence interval [CI], 8–28 months). At the time of the analysis, 5 patients (23%) had survived. In multivariate analysis, largest lesion size (hazard ratio [HR], 1.22; 95%CI, 0.98–1.53], liver tumor volume (HR, 1.002; 95%CI, 1.0004–1.003), subsequent systemic therapy (HR, 0.04; 95%CI, 0.006–0.24), and liver-directed locoregional therapy (HR, 0.204; 95%CI, 0.04–0.94) were predictive of survival. The authors concluded that based on study results, TARE is safe and produced promising outcomes in patients with uveal melanoma metastatic to the liver, but that prospective trials using first-line TARE are desirable.

Intrahepatic Cholangiocarcinoma (ICC)

To investigate the efficacy and survival profile of TARE for unresectable ICC, Schartz et al 2022 conducted a systematic review and meta-analysis of 21 studies representing 921 patients using a random effects model. The study measured for disease control rate (DCR), down staged-to resectable rate, cancer antigen CA 19-9 response rate, pooled median OS, pooled median PFS, and mean reported survival rates from 3 to 36 months. The overall DCR was 82.3%. In 11% of the cases, patients were down staged to being surgically resectable. The CA 19-9 response rate was 67.2%. From the time of radioembolization, PFS was 7.8 months and median OS was 12.7 months. The mean overall reported survival proportions were 84% at 3 months, 69% at 6 months, 47% at 12 months, 31% at 18 months, 30% at 24 months, 21% at 30 months, and 5% at 36 months. The authors conclude that TARE for unresectable ICC results in substantial downstaging, disease control, and survival.

In an effort to identify factors associated with an improved median OS in ICC patients receiving radioembolization, Schaarschmidt and colleagues (2023) conducted a retrospective study of five major tertiary care centers. The study analyzed outcomes of 138 radioembolizations conducted in 128 patients with ICC. Radioembolization was performed as first-line treatment in 25.4%, as second-line treatment in 38.4%, and as salvage treatment in 36.2%. The disease control rate was 68.6%, 52.8%, and 54.0% respectively, after 3 months; 31.4%, 15.1%, and 12.0% after 6 months; and 17.1%, 5.7%, and 6.0% after one year. In patients receiving radioembolization as first-line, second-line, and salvage treatment, Median OS was 12.0 months for patients receiving radioembolization as first-line treatment, 11.8 months for patients receiving second-line treatment, and 8.4 months for those with salvage treatment. No significant differences were observed between the three groups (P=0.15). Limitations of the study were noted, including its retrospective design, with selection bias potential due to a high probability that radioembolization was reserved for patients who were ineligible for surgery or chemotherapy, and the likelihood that patients with comorbidities were included in the cohort for a first-line radioembolization. Given the limitations, authors conclude that second-line and salvage radioembolization may be an important option for advanced ICC, and that its use as a first-line therapy requires further investigation.

Breast

Liu et al (2022) published a systematic review and meta-analysis assessing the evidence for TARE in liver metastatic breast cancer. A total of 24 studies (N=412) were included, most of which were retrospective or non-comparative. Patient demographic information was not summarized. The median

survival time after TARE was 9.8 months. The cumulative OS rates at 6 months and one, two, and three years were 65.6% (95% CI, 60.8% to 70.0%), 39.0% (95% CI, 34.3% to 43.7%), 13.3% (95% CI, 10.3% to 16.8%), and 4.4% (95% CI, 2.7% to 6.6%), respectively. Patients who had a hepatic metastatic burden exceeding 25% experienced a median survival time of 6.8 months, while those with a burden less than 25% had a median survival time of 10.5 months (p<.0001).

PROFESSIONAL GUIDELINE(S)

The National Comprehensive Cancer Network (NCCN) V.2.2025 Guidelines for Hepatocellular Carcinoma recommend TARE as bridge therapy to decrease tumor progression and the dropout rate from the liver transplantation waiting list.

The NCCN V.2.2025 Guidelines for Biliary Tract Cancers (Intrahepatic Cholangiocarcinoma) recommends arterially directed therapies alone or followed by systemic chemotherapy with the intention to prolong survival or downstage ICC to curative resection.

The NCCN Guidelines for Uveal Melanoma V.6.2025 recommends TARE. Recommendations are based upon disease control rates being consistently greater than 50% in retrospective studies. Additionally, the treatment is well tolerated, with most toxicities being grade 1-2 and self-limiting, with no treatment related deaths.

The American Association for the Study of Liver Diseases (AASLD), in an updated 2023 practice guideline regarding the prevention, diagnosis, and treatment of individuals with HCC, states that the use of TARE with Yttrium-90 has been established as an acceptable treatment for solitary unresectable HCC, and there are increasing data for its utilization to enhance the future liver remnant size. Enhancing the future liver remnant size before resection ensures the remaining liver can adequately function after diseased tissue removal. Additionally, regarding use of TARE as a bridge to transplant, the AASLD highlights that due to the mandatory 6-month wait time prior to the awarding of Model for End-Stage Liver Disease (MELD) exception, neoadjuvant treatment is typically used as a bridge to control tumor growth and reduce the risk of waitlist dropout (Singal et al 2023).

A joint practice parameter on the use of TARE for the treatment of liver malignancies was published by the American College of Radiology (ACR), American Brachytherapy Society (ABS), American College of Nuclear Medicine (ACNM), American Society for Radiation Oncology (ASTRO), Society of Interventional Radiology (SIR), and Society of Nuclear Medicine and Molecular Imaging (SNMMI) (Hong et al 2021). The practice parameter defines indications for TARE which include the following:

- The presence of unresectable or inoperable primary or secondary liver malignancies (particularly colorectal cancer and neuroendocrine tumor metastases).
- The tumor burden should be liver dominant, not necessarily exclusive to the liver.
- Patients should also have a performance status that will allow them to benefit from such therapy.
- Life expectancy of at least 3 months.

The American College of Radiology (ACR) (Koepsel et al 2022) published ACR Appropriateness Criteria for the Management of Liver Cancer stating that TARE is appropriate for the treatment of the

following indications:

HCC

- Solitary tumor less than 3 cm, cirrhotic
- Solitary tumor 3 to 5 cm, cirrhotic
- Multifocal, bilobar disease, at least 1 tumor greater than 5 cm, cirrhotic
- Solitary or multifocal disease with vascular invasion, cirrhotic

Intrahepatic Cholangiocarcinoma

- Peripheral hepatic lobar cholangiocarcinoma, less than 3 cm; no biliary ductal dilatation, macroscopic vascular invasion, regional lymphadenopathy, or distant metastases

Ductal Cholangiocarcinoma

- Hilar cholangiocarcinoma, greater than 3 cm with poorly defined margins, vascular invasion, and periportal lymphadenopathy

Metastatic Liver Disease

- Multifocal metastatic neuroendocrine tumor (includes carcinoid tumors as well as islet cell tumors of the pancreas)
- Multifocal bilobar colorectal carcinoma (liver dominant or isolated)

REGULATORY STATUS

There are currently two types of Yttrium microspheres (glass and resin) that have been approved by the FDA and are classified as brachytherapy devices: TheraSpheres (Theragenics; Atlanta, GA) and SIR-Spheres (Sirtex Medical Limited; Lake Forest, IL). The FDA granted premarket approval of SIR-Spheres in 2002 for use in combination with 5-floxuridine (5-FUDR) chemotherapy to treat unresectable hepatic metastases from colorectal cancer. In contrast, the FDA approved TheraSpheres under the humanitarian device exemption (HDE) in 1999 for use as monotherapy to treat unresectable HCC. In January 2007, the HDE for TheraSpheres was expanded to include patients with HCC who have partial or branch portal vein thrombosis. In March of 2021, the FDA granted approval of the TheraSphere Y-90 Glass Microspheres, developed for the treatment of patients with HCC expanding access to this which previously could only have been used under an HDE.

The U.S. Food and Drug Administration (FDA) regulates these as medical devices. All devices including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Jan 15]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Jan 15]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
37243	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infraction
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation
77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed
79445	Radiopharmaceutical therapy, by intra-arterial particulate administration

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HCPCS Codes

Code	Description
A9543	Yttrium Y-90 ibritumomab tiuxetan, therapeutic, per treatment dose, up to 40 mCi
C2616	Brachytherapy source, nonstranded, yttrium-90, per source
S2095	Transcatheter occlusion or embolization for tumor destruction, percutaneous, any method, using yttrium-90 microspheres

ICD10 Codes

Code	Description
C18.0	Malignant neoplasm of cecum
C18.1	Malignant neoplasm of appendix
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure

Code	Description
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C22.0	Liver cell carcinoma
C22.1	Intrahepatic bile duct carcinoma
C22.2	Hepatoblastoma
C22.3	Angiosarcoma of liver
C22.4	Other sarcomas of liver
C22.7	Other specified carcinomas of liver
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
Z76.82	Awaiting organ transplant status

REFERENCES

American College of Radiology: Appropriateness Criteria for the Management of Liver Cancer [Internet]. [2022; accessed 2025 Jan 14]. Available from: ACR Appropriateness Criteria® Management of Liver Cancer: 2022 Update

Cao CQ, et al. Radioembolization with yttrium microspheres for neuroendocrine tumour liver metastases. Br J Surg. 2010 Apr;97(4):537-43.

Cramer B, et al. Prospective longitudinal quality of life assessment in patients with neuroendocrine tumor liver metastases treated with 90Y radioembolization. Clin Nucl Med. 2016 Dec;41(12):e493-e497.

Damm R, et al. Y90 radioembolization in chemo-refractory metastatic, liver dominant colorectal cancer patients: outcome assessment applying a predictive scoring system. BMC Cancer. 2016 July 20;16:509.

Davisson NA, et al. Predictors of survival after Y-ttrium 90 radioembolization of chemotherapy-refractory hepatic metastases from breast cancer. J Vasc Interv Radiol. 2020 Jun;31(6):925-933.

Gabr A, et al. Liver transplantation following yttrium-90 radioembolization: 15-year experience in 207-

patient cohort. Hepatology. Mar 2021;73(3): 998-1010.

Gonsalves CF, et al. A prospective phase II trial of radioembolization for treatment of uveal melanoma hepatic metastasis. Radiology. 2019 Oct;293(1):223-231

Hendlisz A, et al. Phase III trial comparing protracted intravenous fluorouracil infusion alone or with yttrium-90 resin micro-spheres radioembolization for liver-limited metastatic colorectal cancer refractory to standard chemotherapy. J Clin Oncol. 2010 Aug 10;28(23):3687-94.

Hong K, et al. ACR-ABS-ACNM-ASTRO-SIR-SNMMI practice parameter for selective internal radiation therapy or radioembolization for treatment of liver malignancies. Brachytherapy. 2021 May-Jun;20(3):497-511.

Jakobs TF, et al. Robust evidence for long-term survival with 90Y radioembolization in chemorefractory liver-predominant metastatic colorectal cancer. Eur Radiol. 2017 Jan;27(1):113-119.

Jeyarajah DR, et al. Role of yttrium-90 selective internal radiation therapy in the treatment of liver-dominant metastatic colorectal cancer: an evidence-based expert consensus algorithm. J Gastrointest Oncol. 2020 Apr;11(2):443–460.

Jia Z, et al. Radiation segmentectomy for hepatic malignancies: Indications, devices, dosimetry, procedure, clinical outcomes, and toxicity of yttrium-90 microspheres. J Interv Med. 2019 Jun 27;2(1):1-4.

Johnson BW and Wright GP. Regional therapies for the treatment of primary and metastatic hepatic tumors: A disease-based review of techniques and critical appraisal of current evidence. Am J Surg. 2019 Mar;217(3):541-545.

Kennedy AS, et al. Treatment parameters and outcome in 680 treatments of internal radiation with resin 90Y-microspheres for unresectable hepatic tumors. Int J Radiat Oncol Biol Phys. 2009 Aug 1;74(5):1494-500.

Kennedy AS, et al. A first report of radioembolization for hepatic metastases from ocular melanoma. Cancer Invest. 2009 Jul;27(6):682-90.

Liu C, et al. Selective internal radiation therapy of metastatic breast cancer to the liver: a meta-analysis. Front Oncol. 2022;12:887653.

Lopez-Lopez, et al. Selecting the appropriate downstaging and bridging therapies for hepatocellular carcinoma: what is the role of transarterial radioembolization? A pooled analysis. Cancers. 2023 Apr 2;15(2122):1-15.

Mulcahy MF, et al. Radioembolization of colorectal hepatic metastases using yttrium-90 microspheres. Cancer. 2009 May 1;115(9):1849-58.

Mulcahy MF, et al. Radioembolization with chemotherapy for colorectal liver metastases: a randomized, open-label international, multicenter, phase III trial. J Clin Oncol. 2021;39:3897-3907.

National Institute for Health and Clinical Excellence (NICE) [Internet]. Selective internal radiation therapy for unresectable colorectal metastases in the liver. 2020 Mar 4 [accessed 2024 Dec 23] Available from: https://www.nice.org.uk/guidance/ipg672

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology: Biliary Tract Cancers. V.2.2025. 2025 Jul 2. [accessed 2026 Jan 15] Available from: https://www.nccn.org/professionals/physician_gls/pdf/btc.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology: Hepatocellular Carcinoma. National Comprehensive Cancer Network (NCCN) Guidelines V.2.2025. 2022 Oct 22. [accessed 2026 Jan 15] Available from: https://www.nccn.org/professionals/physician_gls/pdf/hcc.pdf

National Comprehensive Cancer Network NCCN [Internet]. Clinical Practice Guidelines in oncology: Melanoma: Uveal. V2.2025. 2025 Nov 06 [accessed 2026 Jan 15] Available from: https://www.nccn.org/professionals/physician_gls/pdf/uveal.pdf

Oken, MM, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. Am J Clin Oncol. 1982;5:649-655.

Pellegrinelli J, et al. Transarterial radioembolization of hepatocellular carcinoma, liver-dominant hepatic colorectal cancer metastases, and cholangiocarcinoma using yttrium90 microspheres: eight-year single-center real-life experience. Diagnostics (basel). 2021 Jan 14;11(1):122.

Ponti A, et al. First-line selective internal radiation therapy in patients with uveal melanoma metastatic to the liver. J Nuclear Med. 2020 Mar;61(3):350-356.

Salem R, et al. Y90 radioembolization significantly prolongs time to progression compared with chemoembolization in patients with hepatocellular carcinoma. Gastroenterology. 2016 Dec;151(6):1155-1163.

Salem R, Johnson GE, Kim E, et al. Yttrium-90 radioembolization for the treatment of solitary, unresectable HCC: the LEGACY study. Hepatology. Nov 2021;74(5):2342-2352. PMID 33739462

Sato KT, et al. Unresectable chemorefractory liver metastases: radioembolization with 90 Y microspheres-safety, efficacy, and survival. Radiology. 2008 May;247(2):507-15.

Schaarschmidt BM et al. Real-life experience in the treatment of intrahepatic cholangiocarcinoma by ^{90}Y radioembolization: a multicenter retrospective study. J Nucl Med. 2023;64:529-535.

Singal AG, et al. AASLD practice guidance on prevention, diagnosis, and treatment of hepatocellular carcinoma. Hepatology. 2023 May 1;78:1922-1965.

Vilgrain V, et al. Efficacy and safety of selective internal radiotherapy with yttrium-90 resin microspheres compared with sorafenib in locally advanced and inoperable hepatocellular carcinoma (SARA): an open label randomized controlled phase 3 trial. Lancet Onc. 2017;18:1624-1636.

Zhou W, et al. Outcomes analysis of yttrium-90 radioembolization for tumors other than metastatic colorectal cancer from the radiation-emitting SIR-spheres in Nonresectable (RESiN) registry. J Vasc Interv Radio. 2024;35:1591-1600.

SEARCH TERMS

TARE-Y90

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Selective Internal Radiation Therapy is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 9/26

Revised:

Reviewed:

Date	Summary of Changes
1/1/2027	• New

MEDICAL POLICY

Medical Policy Title	Transcranial Magnetic Stimulation and Cranial Electrotherapy Stimulation
Policy Number	3.01.09
Current Effective Date	September 1, 2026
Next Review Date	January 2027

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Major Depressive Disorder (MDD)

I. An initial course of transcranial magnetic stimulation (TMS) is considered **medically appropriate** as a treatment for MDD, severe when **ALL** of the following have been met:

   A. TMS is administered by a U.S. Food and Drug Administration (FDA) cleared device in accordance with the FDA labeled indications;

   B. Member is 15 years or older;

   C. Documented diagnosis of major depressive disorder, severe (single or recurrent), without psychosis, confirmed by standardized rating scales that reliably measure depressive symptoms;

   D. During the current episode of depression, there is a documented failure of **both** of the following:

      1. An adequate trial of an evidence-based psychotherapy known to be effective for major depressive disorder, without clinically significant improvement; **and**

      2. An adequate trial of medication, as documented by **one (1)** of the following:

         a. For adults (age 18 years or older), failure to respond to **both** of the following:

            i. Two (2) or more separate and distinct trials of antidepressant medication from two different classes, each at minimum therapeutic dose for at least 8-weeks, unless there is a documented serious side effect; **and**

            ii. One (1) augmentation with a different class of antidepressant or another agent known to improve depression outcomes, at or above the minimal therapeutic dose for at least 8-weeks, unless there is a documented serious side effect; **or**

         b. For adolescents (age 15 to 17 years), failure to respond to two (2) or more trials of FDA-approved anti-depressant medications at or above the minimal therapeutic dose for at least 8-weeks, unless there is a documented serious side effect;

E. Absence of an absolute contraindication to TMS, and relative contraindications (if applicable) were assessed and deemed safe for administering TMS (see Policy Guideline I.).

II. TMS retreatment is considered **medically appropriate** for the treatment of MDD, severe when **ALL** of the following criteria are met:

A. TMS is administered by an FDA-cleared device in accordance with the FDA labeled indications;

B. All criteria for an initial course of TMS treatment were met (See Policy Statement I.);

C. A new episode of major depression, severe is documented by standardized rating scales;

D. The member responded to prior treatments, as evidenced by a greater than 50% improvement in standard rating scale measurements for depressive symptoms;

E. It has been at least three (3) months since the end of the initial TMS treatment course.

Obsessive-Compulsive Disorder (OCD)

III. An initial course of transcranial magnetic stimulation (TMS) is considered **medically appropriate** as a treatment for OCD when **ALL** of the following have been met:

A. TMS is administered by an FDA-cleared device, in accordance with the FDA labeled indications;

B. Member is 18 years or older;

C. Documented diagnosis of OCD as defined by the most recent edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM);

D. Resistance to treatment evidenced by persistent OCD symptoms is documented by a Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) score after **both** of the following:

1. An adequate trial of evidenced-based psychotherapy known to be effective for OCD, without clinically significant improvement (e.g., exposure response prevention [ERP], cognitive behavioral therapy [CBT], acceptance and commitment therapy [ACT]); **and**

2. Two (2) or more separate and distinct trials of psychopharmacologic medications known to treat OCD, each at the minimum therapeutic dose for at least 8 weeks, unless there is a documented serious side effect;

E. Absence of any absolute contraindication to TMS, and relative contraindications (if applicable) were assessed and deemed safe for administering TMS (see Policy Guideline I.).

IV. TMS retreatment is considered **medically appropriate** for the treatment of OCD when **ALL** of the following criteria are met:

A. TMS is administered by an FDA-cleared device, in accordance with the FDA labeled indications;

B. All criteria for initial course of TMS treatment were met (see Policy Statement III.);

C. The member responded to prior treatments, as evidenced by **both** of the following:
   1. At least a 30% reduction in the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) score; **and**
   2. It has been at least three (3) months since the end of the initial TMS treatment course.

Not Medically Necessary

V. TMS is considered **not medically necessary** for **EITHER** of the following:
   A. As a treatment for major depressive disorder or obsessive-compulsive disorder that does not meet all the above criteria;
   B. Reassessment of motor threshold following the first TMS treatment session, unless medical records document a clinical concern indicating a potential change in stimulation requirements (e.g., medication adjustments).

Investigational

VI. TMS is considered **investigational** for **ANY** of the following:
   A. TMS sessions beyond the standard course of 36 sessions, as continuation of the initial course or as maintenance/preservation therapy;
   B. TMS as a treatment for all other psychiatric and/or neurological disorders, including but not limited to: bipolar disorder, borderline personality disorder, schizophrenia, substance use or addictive disorders substance use or addictive disorders (e.g., alcohol, caffeine, cannabis, tobacco, gambling), migraine headaches (via single-pulse), stroke);
   C. Use of any TMS device or stimulation protocol not FDA-cleared, including but not limited to: bilateral stimulation, EEG-synchronized TMS, low-frequency protocols, Magnetic e-Resonance Therapy (MeRT), precuneus-targeted magnetic stimulation, priming techniques, and quadripulse stimulation);
   D. Magnetic resonance imaging (MRI)-guided TMS, including but not limited to functional connectivity MRI (fc-MRI)-guided stimulation;
   E. Accelerated treatment protocols, delivering more than one (1) TMS session per day, including the Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT) protocol;
   F. Adjunct use of ketamine with TMS;

VII. Cranial electrotherapy stimulation (CES) (also known as transcranial electrical stimulation [tES] or cranial electrical stimulation) is considered **investigational** for **ALL** indications, including but not limited to anxiety, depression, and insomnia.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

Electroconvulsive Therapy, 1370/20.000464

Non-Covered Technologies, 1370/20.000444

POLICY GUIDELINE(S)

I. Contraindications of TMS include the following:

   A. Absolute:

      1. Presence of ferromagnetic or magnetic sensitive metal in the head or neck areas in close proximity to the TMS coil magnetic fields (e.g., metal/bullet fragments, cochlear implants, brain stimulators or electrodes, aneurysm clips or coils, vagus nerve stimulator);

      2. Presence of acute or chronic psychotic symptoms or disorders (e.g., schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode.

   B. Relative:

      1. Implanted cardiac pacemaker or implantable cardiac defibrillator (ICD);

      2. History of seizures with increased risk of seizure);

      3. Neurologic conditions (e.g., epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, history of repetitive head trauma or with primary or secondary tumors in the central nervous system;

      4. Presence of a brain lesion (vascular, traumatic, neoplastic, infectious, or metabolic.

II. TMS must be performed by physicians who are adequately trained and experienced in the specific techniques used. The order for treatment (or re-treatment) should be written by a physician (MD or DO) who has examined the patient and reviewed the record. The treatment must be given under the direct supervision of the ordering physician, i.e., the physician must be in the area and be immediately available.

III. Accelerated TMS delivers multiple TMS sessions per day, completing the full therapeutic dose in days rather than weeks. This approach aims to achieve faster symptom relief for MDD while reducing the treatment burden/barrier of near-daily clinic visits over several weeks.

   A. Accelerated deep intermittent theta burst (iTBS), using the BrainsWay Deep System, is an FDA-cleared treatment protocol for MDD that does not require image-guided targeting or automated session delivery.

   B. Accelerated iTBS, using the Magnus Medical SAINT Neuromodulation System (known as the SAINT protocol), is an FDA-cleared treatment protocol requiring resting-state functional connectivity MRI (fcMRI) and neuronavigation.

IV. When requesting TMS, providers are required to submit documentation of prior medication trials, including the approximate duration (start and end dates), dosing, and side effects. An adequate trial of medication is based on a combination of appropriate duration (typically 4 to 6 weeks),

therapeutic dosage, tolerance, and clinical response.

V. Standardized rating scales considered reliable in rating depressive symptoms include validated depression monitoring scales such as: Geriatric Depression Scale (GDS); Personal Health Questionnaire Depression Scale (PHQ-9); Beck Depression Scale (BDI); Hamilton Rating Scale for Depression (HAM-D); Montgomery Asberg Depression Rating Scale (MADRS); Quick Inventory of Depressive Symptomatology (QIDS); and Inventory for Depressive Symptomatology Systems Review (IDS-SR).

DESCRIPTION

Transcranial Magnetic Stimulation (TMS)

TMS is a noninvasive neuromodulation technique that uses a coil placed on the scalp to deliver rapidly alternating electrical currents. These currents generate a magnetic field that passes through the scalp and skull without resistance, inducing localized electrical activity in the underlying cortical neurons. By modulating neural circuits involved in mood regulation and cognitive function, TMS alters brain activity in targeted regions, making it a valuable therapeutic tool in the treatment of neuropsychiatric conditions such as major depressive disorder (MDD).

Stimulation parameters, including cranial location, stimulation frequency, pattern, duration, intensity, and the state of the brain under the coil can be adjusted to influence excitability in specific cortical regions. The standard figure-8 coil primarily stimulates superficial cortical areas and penetrates only 1.5–2 cm beneath the skull, limiting its ability to reach deeper structures. H-coils were developed to address this limitation, which to enable broader and deeper stimulation (up to 4–5 cm) and are available in different models for specific indications, including: the H1 coil targets bilateral dorsolateral prefrontal cortices for MDD, the H7 coil focuses on medial prefrontal and anterior cingulate regions for obsessive-compulsive disorder (OCD), and other coils (e.g., H4) are used for smoking cessation.

Standard repetitive TMS (rTMS) delivers repeated electromagnetic pulses through a coil positioned on the scalp, typically targeting the dorsolateral prefrontal cortex (DLPFC), a region associated with mood regulation. The therapeutic effect depends on stimulation frequency, with high-frequency rTMS (≥10 Hertz [Hz]) being excitatory and enhances neural activity, while low-frequency rTMS (≤1 Hz) is inhibitory and reduces neural excitability. At total of 30 sessions with an optional 6 session taper are delivered over 20–40 minutes once daily over 4–6 weeks. When both high- and low-frequency stimulation are applied to opposite hemispheres during the same session, the protocol is referred to as bilateral rTMS.

Standard Deep TMS (dTMS) uses an H-coil to deliver magnetic pulses to deeper and broader brain regions, reaching 4–5 cm beneath the skull. Depending on indication, dTMS targets cortical and subcortical structures such as the DLPFC and medial prefrontal cortex. At total of 30 sessions with an optional 6 session taper are delivered once daily over 4–6 weeks.

Theta Burst Stimulation (TBS) is a patterned form of rTMS that delivers bursts of high-frequency pulses designed to mimic the brain's natural theta rhythms associated with learning and synaptic

plasticity. The two main subtypes include:

- Standard intermittent TBS (iTBS) is FDA-cleared for MDD and is distinct from accelerated protocols. While not considered accelerated, it is delivered significantly faster than traditional rTMS, targeting the left DLPFC using short bursts of 50 Hz pulses repeated at 5 Hz. A typical session delivers 600 pulses of iTBS over approximately 3 minutes, administered once daily for a total of 36 sessions (30 sessions plus an optional 6 session taper).
- Continuous TBS (cTBS) has inhibitory effects and delivers bursts continuously 40 seconds (600 pulses total). This protocol is not FDA-cleared at this time.

Accelerated TMS (aTMS) refers to multiple TMS sessions per day within a condensed timeframe, aiming to deliver the full therapeutic dose in days rather than weeks. This approach addresses two major limitations of standard TMS: delayed antidepressant effect and treatment burden, which often impairs adherence and access. Two accelerated TMS subtypes have received FDA clearance for MDD:

- Accelerated deep TMS with intermittent theta burst stimulation (ad-iTBS), using the BrainsWay Deep TMS System (H1 coil) without neuronavigation, was FDA-cleared in 2025. The protocol utilizes iTBS stimulation delivered in 5 sessions per day for 6 consecutive days (acute phase), followed by 2 sessions per day weekly for 4 weeks (continuation phase), totaling 38 sessions and approximately 75,000 pulses. Each session delivers approximately 1,980 pulses and lasts under 10 minutes.
- Accelerated iTBS (aiTBS) with resting-state functional connectivity MRI (fcMRI) and neuronavigation, using the Magnus Medical SAINT Neuromodulation System, was FDA-cleared in 2022. The SAINT protocol delivers 1,800 pulses per session at 90% of resting motor threshold, adjusted for cortical depth, with 10 sessions per day spaced 50 minutes apart for 5 consecutive days, totaling 50 sessions, each lasting about 3 minutes.

For TMS targeting, the location of stimulation determines TMS effects. For depression, the left DLPFC is commonly targeted, while the medial prefrontal cortex and anterior cingulate cortex are targeted for OCD. Early methods like the "5 cm rule" (and updated 5.5–6 cm rules) fail to account for anatomical variability. Alternatives include scalp-based strategies (Beam F3), anatomical MRI with neuronavigation, and emerging approaches using resting-state fMRI to personalize targeting based on functional connectivity.

Preservation strategies aim to sustain therapeutic response post-acute treatment and include maintenance, continuation, relapse-prevention, and rescue TMS. These approaches are used in clinical practice but are not FDA-approved as formal protocols.

Bilateral TMS applies high-frequency stimulation to the left DLPFC and low-frequency stimulation to the right DLPFC within the same treatment session, either sequentially or simultaneously. This approach is based on the hypothesis that enhancing excitatory activity on the left and reducing hyperactivity on the right may engage complementary mechanisms to improve clinical outcomes. Investigated for conditions like attention deficit hyperactivity disorder (ADHD), Parkinson's disease, and tinnitus, but remains experimental.

Single-pulse TMS delivers a single magnetic pulse to the cortex to induce a brief neuronal response, for diagnostic and research purposes, assessing cortical excitability and conduction pathways. It does not produce lasting neuromodulatory effects and is not considered a therapeutic intervention.

Cranial Electrotherapy Stimulation (CES)

CES differs from TMS primarily in its delivery method: CES is a non-invasive neuromodulation technique that applies low-level electrical currents through electrodes placed on the earlobes or scalp, whereas TMS uses magnetic fields to stimulate specific brain regions.

CES is conceptually similar to transcranial electrical stimulation (tES), an umbrella term that includes methods such as transcranial direct current stimulation (tDCS) and transcranial alternating current stimulation (tACS), all of which aim to modulate brain activity through externally applied electrical currents. From a regulatory perspective, the FDA classifies CES devices as Class II (special controls) for indications such as anxiety and insomnia, while depression requires Premarket Approval (PMA). The approved Flow FL-100 device (PMA P230024, December 8, 2025) operates using tDCS technology, but the FDA officially lists it under the CES category. This means that while the mechanism is tDCS, the regulatory classification is CES. CES and tDCS are therefore similar in concept but differ in current intensity, electrode placement, and historical regulatory pathways. CES has been evaluated for conditions including anxiety, insomnia, depression, pain, and functional constipation, with FDA clearance for anxiety and insomnia and PMA approval for major depressive disorder.

SUPPORTIVE LITERATURE

Standard TMS for Adults with Major Depressive Disorder (MDD)

The evidence supporting TMS for patients with treatment resistant MDD is robust. Multiple double-blind, randomized, sham-controlled trials demonstrate that stimulation of the left dorsolateral prefrontal cortex (DLPFC) produces a clinically meaningful reduction in depressive symptoms, with a large effect size (e.g., Ontario Health 2007; O'Reardon 2007; Lam 2008; Avery 2008; Janicak 2010; George 2010; Kedzior 2015; Voigt 2021). Overall, the evidence is sufficient to conclude that rTMS leads to a significant improvement in net health outcomes and is considered an appropriate treatment option for patients with MDD who meet established clinical criteria.

Papakostas et al (2024) identified a critical evidence gap regarding the comparative effectiveness of pharmacological and non-pharmacological augmentation strategies versus switching antidepressants in TRD. To address this, they conducted a multi-site, 8-week, randomized, open-label trial comparing augmentation with aripiprazole or rTMS to switching to venlafaxine XR (or duloxetine for those ineligible for venlafaxine). The primary outcome was the change in Montgomery–Asberg Depression Rating Scale (MADRS) scores. A total of 278 participants with treatment resistant depression (TRD) of at least 12 weeks' duration were randomized in a 1:1:1 ratio to one of the three interventions. Of these, 260 participants (rTMS: n=70; aripiprazole: n=92; venlafaxine/duloxetine: n=98) were included in the modified intention-to-treat (MITT) analysis. Post-baseline assessments occurred at weeks 1, 2, 3, 4, 6, and 8, with MADRS evaluations conducted by raters blinded to treatment assignment. Results showed that rTMS augmentation was significantly superior to switching on

MADRS scores (p = 0.015), whereas aripiprazole augmentation did not reach statistical significance (p = 0.069). Conversely, aripiprazole augmentation was significantly superior to switching on self-reported depressive symptoms (p = 0.003), while rTMS showed a trend toward significance (p = 0.031). The authors concluded that rTMS augmentation demonstrated moderate-to-large superiority over switching to venlafaxine XR/duloxetine in clinician-rated depressive symptoms. However, the study's open-label design with only blinded raters, and the limited scope of pharmacological comparators were noted as key limitations.

Standard TMS for Adolescents with Major Depressive Disorder (MDD)

In 2024, the FDA cleared TMS as a first-line adjunctive treatment for MDD in adolescents aged 15 and older, based on a real-world study of 1,120 patients aged 15–21 treated at 35 U.S. centers (Trapp 2025). Participants completed 36 sessions over approximately 4–6 weeks using either high-frequency deep TMS or iTBS stimulation. The PHQ-9 was administered at baseline and immediately after the treatment course, which showed an average 12-point reduction, a 66% response rate, and notable improvements in anxiety symptoms, with a safety profile consistent with adult TMS use and no new concerns. No long-term follow-up beyond the treatment period was reported.

Croarkin et al (2021) conducted the largest randomized, double-blind, sham-controlled trial to date investigating TMS for TRD in adolescents. The study assessed the feasibility, safety, and efficacy of 10 Hz left prefrontal TMS monotherapy across 13 sites, enrolling 103 participants aged 12 to 21 years who had failed one to four adequate antidepressant trials. Participants were randomized to receive either active TMS (n=48) or sham treatment (n=55) over 30 sessions across six weeks. Treatments were administered using the NeuroStar XPLOR TMS Therapy System (Neuronetics, Inc.), with coil placement guided by the 5-cm rule. Stimulation was delivered at 120% of the resting motor threshold (reducible to 110% for tolerability during the first week), at 10 Hz for 4 seconds per train, with a 26-second intertrain interval, totaling 3,000 pulses per 37.5-minute session. The primary outcome was change in the Hamilton Depression Rating Scale (HAM-D-24) score. Both groups showed similar symptom improvement (P=0.8), with response rates of 41.7% (active) and 36.4% (sham), and remission rates of 29.2% and 29.0%, respectively. No new safety or tolerability concerns were identified. While TMS produced clinically meaningful reductions in depressive symptoms, it did not significantly outperform sham treatment. The authors highlighted the need for future research to address high placebo response rates and refine dosing strategies for adolescents with TRD.

Systematic reviews and meta-analyses have evaluated the efficacy and safety of rTMS in adolescents with MDD. Cao et al (2023) analyzed randomized controlled trials (RCTs) of rTMS combined with antidepressants in children and adolescents, reporting significant improvements in depressive symptoms compared to medication alone, with no major safety concerns. Sun et al (2023) focused on first-episode adolescent MDD and found adjunctive rTMS significantly enhanced treatment response and remission rates versus standard therapy. Sigrist et al (2022) pooled data from 10 individual studies (2 randomized trials) for quantitative synthesis of mainly uncontrolled studies, concluding that rTMS appears well tolerated and associated with a statistically significant overall treatment response rate (p<0.001) from baseline to post-treatment. Though evidence quality is limited by small sample sizes and heterogeneity. All three analyses are limited by small sample sizes,

high statistical heterogeneity, and methodological weaknesses. Overall, authors concluded that rTMS showed significant treatment effect and response rate compared to antidepressants alone, and larger, high-quality trials are needed to establish optimal protocols and long-term safety.

Garzon et al (2025) conducted the largest long-term follow-up study to date. This six-month, multisite, open-label trial evaluated the durability of TMS in adolescents and young adults with TRD. The study enrolled participants aged 12–21 who achieved at least a partial response (≥25% reduction on the Hamilton Depression Rating Scale-24 [HAMD24]) during a prior randomized controlled trial of sham or active TMS. Those experiencing partial relapse (≥1-point increase on Clinical Global Impression–Severity) received retreatment with daily 10 Hz TMS sessions until symptoms returned to baseline or after 30 treatments. Of 84 eligible participants, 66 enrolled and 41 completed the six-month follow-up; 42% required retreatment, with a mean of 22 sessions. At six months, depressive symptoms remained improved (mean HAMD24 = 5.24) compared to baseline at entry into follow-up (mean HAMD24 = 8.21). Higher baseline severity predicted relapse risk, while prior TMS exposure did not. TMS was well tolerated, and the authors concluded that these findings support the feasibility and clinical benefit of a structured retreatment protocol following an initial course of TMS in adolescents with TRD.

Roth et al (2025) conducted the largest naturalistic post-marketing outcomes study to date evaluating the safety and efficacy of deep TMS (dTMS) for MDD in younger populations. The study analyzed data from 1,257 patients treated between January 2012 and November 2024 across 56 geographically diverse clinical sites in the United States. Eligible participants were aged 11–21 years and met criteria for treatment-resistant MDD, having failed to respond to an average of 4.5 antidepressant medications. All patients received dTMS using the BrainsWay H1 Coil (BrainsWay, Jerusalem, Israel), delivered via either the Magstim Rapid2 stimulator (Magstim, Spring Gardens, UK) or the BrainsWay 104 stimulator. Treatment protocols included either 18 Hz or intermittent theta burst stimulation (iTBS), with a mean of 35.6 sessions administered. At baseline, 76% of participants exhibited moderate to severe depressive symptoms (PHQ-9 ≥15). Following treatment, only 16% remained in this severity range, while 65% met criteria for mild or subthreshold depression. Statistically significant improvements were observed across all clinical measures. The treatment was well tolerated, with an adverse event profile comparable to that observed in adult populations. Despite certain limitations, the authors concluded that dTMS represents a safe and effective therapeutic option for adolescents and young adults with treatment-resistant MDD, contributing significantly to the growing empirical support for this therapeutic modality.

Buyuktaskin et al (2025) conducted an exploratory RCT to assess the effects of rTMS frequency on suicidal ideation in adolescents with MDD. Given the elevated suicide risk in youth and limitations of current treatments, including the potential for increased suicidal thoughts with antidepressants, this study compared low-frequency (1 Hz) and high-frequency (10 Hz) TMS protocols. A total of 41 adolescents between the ages of 12 and 18 were randomized to receive either 1 Hz (n=22) or 10 Hz (n=19) TMS, and scheduled for 30 sessions over six weeks, with a mean of 28.00 sessions completed (range: 8–30). Treatment was delivered over the left DLPFC using the NeuroStar system, with localization achieved via the Beam F3 method. Suicidal ideation intensity was measured weekly using the Columbia Suicide Severity Rating Scale (C-SSRS). Over the treatment period, both TMS protocols

were associated with a significant reduction in suicidal ideation intensity, approximately 24.6% for 10 Hz TMS ($p = 0.0015$) and 22% for 1 Hz TMS ($p = 0.0016$), independent of changes in depression severity. However, when adjusting for depression severity, these reductions were no longer statistically significant (10 Hz: $p = 0.572$; 1 Hz: $p = 0.844$). No significant differences were found between the two protocols in their impact on suicidal ideation ($p > 0.7$), and treatment group assignment did not moderate outcomes ($p > 0.95$). The findings suggest that TMS may be a promising intervention for suicidal ideation in adolescent depression, with comparable effects across stimulation frequencies. This study contributes to the growing body of research on TMS as a potentially safe and effective intervention for suicide prevention in adolescents, highlighting the need for further investigation into optimal stimulation parameters.

Accelerated Non-Deep Coil TMS for MDD

Theleritis et al (2017) conducted a single-center, parallel-group, randomized, sham-controlled trial (n=98) to evaluate the efficacy of administering one versus two daily sessions of HF-rTMS for treating MDD. Eligible participants were aged 18–59, right-handed, diagnosed with treatment-resistant nonpsychotic MDD, had no prior exposure to TMS, and were free of contraindications. Where clinically appropriate, participants were encouraged to discontinue antidepressants prior to enrollment; otherwise, they remained on a minimal regimen for at least four weeks before study entry. Treatment involved 10 Hz HF-rTMS using a Magstim Rapid stimulator with a figure-8 coil targeting the left DLPFC. Sessions were delivered on weekdays over three weeks: either once daily (A1 group; n=27) or twice daily (A2 group; n=27), totaling 15 or 30 sessions, respectively. Sham stimulation was administered using a rotated coil either once daily (S1 group; n=20) or twice daily (S2 group; n=24). Response was defined as ≥50% reduction in HDRS and CGI-S ≤3; remission was defined as HDRS <8 and CGI-S ≤2. Assessments were conducted at baseline, weekly during treatment, and at five weeks post-treatment. Nine participants discontinued due to protocol violations, headache exacerbation, scheduling conflicts, or illness. Intent-to-treat analysis (n=96) revealed no significant baseline differences between groups. Active treatment groups showed significantly greater improvements in HDRS and CGI-S scores compared to sham ($p<0.001$). Only one participant (2.5%) in the sham groups met HDRS response criteria, versus 29 (59.2%) in the active groups ($p<0.001$). Remission likelihood was significantly associated with baseline severity ($p=0.001$) and number of daily sessions (CGI-S: $p=0.018$; HDRS: $p=0.066$). Adverse events were mild, including scalp discomfort and headache. Study limitations included lack of blinding for treatment administrators, absence of a sham coil mimicking rTMS sensations, no cognitive assessments, short follow-up, and potential confounding from concurrent pharmacotherapy. Further research is warranted to assess the safety and efficacy of multiple daily rTMS sessions.

Fitzgerald et al (2018) conducted a parallel-group RCT comparing accelerated and standard rTMS protocols in patients with MDD. A total of 115 outpatients were randomized to receive either accelerated rTMS (n=58) or standard rTMS (n=57). Stimulation localization followed standard procedures. Both groups received an equal total pulse dose of 63,000. In the accelerated group, each session involved 83–84 trains of 10 Hz rTMS applied to the left DLPFC using 4.2-second trains at 120% of the resting motor threshold, with 15-second inter-train intervals. Sessions were spaced 15–30 minutes apart, delivering 10,500 pulses per day across six treatment days. In contrast, the

standard group received 20 sessions over four weeks (five sessions per week), each consisting of 75 trains of 10 Hz rTMS with 25-second inter-train intervals, delivering 3,150 pulses per day. The accelerated group showed earlier symptom improvement within the first two weeks, though overall response rates were similar between groups. No serious adverse events occurred, although the accelerated group reported more discomfort and had a slightly higher dropout rate. Cognitive performance remained stable across both groups. Study limitations included short follow-up, lack of blinding, and potential confounding due to session spacing and individual variability in response. Overall, accelerated rTMS delivered over a condensed three-week schedule produced antidepressant effects comparable to standard four-week protocols, with slightly increased treatment discomfort but low dropout rates, supporting the need for larger multisite trials to confirm its clinical utility.

Sonmez et al (2019) conducted a systematic review and meta-analysis to evaluate the efficacy of accelerated TMS protocols for MDD. The review included 18 publications describing 11 unique studies, some with overlapping samples. Studies were eligible if they involved more than one rTMS or TBS session per day and targeted depressive disorders. Three RCTs were included in the meta-analysis, yielding a pooled effect size of Hedges' g = 0.39, indicating a modest but statistically significant antidepressant effect of aTMS compared to control. When open-label studies and active arms of RCTs were analyzed separately, the pooled effect size increased to g = 1.27, suggesting stronger symptom improvement in less controlled settings. The review found that accelerated TMS (aTMS) protocols varied widely in terms of stimulation parameters, coil types, and session spacing. Despite this heterogeneity, most studies reported positive clinical outcomes, with some showing rapid symptom reduction within days. Adverse effects were generally mild and transient, including headache and scalp discomfort. Limitations included small sample sizes, lack of blinding in many studies, and variability in protocol design, which may affect generalizability. The authors noted that many of the included studies had short or limited follow-up periods, which limited the ability to assess long-term efficacy and durability of antidepressant effects from accelerated TMS protocols. Concluding that aTMS is a promising approach for treating MDD, the study emphasized the need for larger, well-controlled trials to establish optimal protocols and confirm efficacy.

Prato et al (2025) conducted a single-center, parallel, two-arm, single-blind RCT in Italy comparing aTMS with the standard rTMS protocol for TRD. The standard protocol consisted of one session per weekday for four weeks, delivering 75 trains of 10 Hz to the left DLPFC at 120% motor threshold per session. The accelerated protocol delivered four sessions per day, separated by one-hour breaks, for five consecutive days, using identical parameters. Both arms were designed to deliver the same cumulative pulse count, 60,000 over 20 sessions, to maintain consistency with foundational rTMS trials. rTMS was delivered using the Magstim Rapid2 stimulator and a 70 mm air-cooled double coil. Participants (ages 18–70) had moderate to severe major depressive episodes (unipolar or bipolar) and were nonresponsive to either fluvoxamine or venlafaxine during the current episode. A total of 33 patients were randomized to aTMS (n = 18) or standard rTMS (n = 15, n=13 after two withdrawals). Clinical outcomes were assessed using the MADRS and Beck Depression Inventory II (BDI-II) at baseline, daily during the first week, weekly through week 4, and at week 8. SSI was measured at baseline, day 1, day 5, and weekly thereafter. Response was defined as ≥50% MADRS reduction; remission as MADRS <10. Analysis included 31 patients (18 aTMS; 13 rTMS). Results

showed a significantly faster decline in MADRS and BDI-II during the first five days (p = 0.001 and p = 0.048, respectively). At day 56, aTMS patients maintained lower scores than rTMS (MADRS: p = 0.001; BDI-II: p = 0.032). Response rates favored aTMS at day 28 (72% vs. 38.5%, p = 0.040) and day 56 (83.3% vs. 38.5%, p = 0.011). Remission rates were also higher for aTMS at day 28 (67% vs. 15.4%, p = 0.0001) and day 56 (61% vs. 30.8%, p = 0.006). No significant differences emerged for suicidal ideation (p = 0.621), and subgroup analysis showed similar benefits for unipolar and bipolar patients. Despite delivering 300 trains per day in the accelerated arm versus 75 in the standard arm, no serious adverse events occurred, and tolerability was comparable. Limitations included small sample size, single-center design, reliance on self-reported measures, and lack of sham control. The authors concluded that aTMS may offer a clinically meaningful advantage by achieving rapid symptom improvement within five days without compromising safety or tolerability, addressing the latency challenge of antidepressant therapy.

Accelerated Deep iTBS for MDD (BrainsWay Deep TMS System)

In 2025, the FDA expanded treatment stimulation protocols for MDD to include accelerated deep iTBS (ad-iTBS) stimulation, delivered by the modified BrainsWay Deep TMS System. Accelerated iTBS was supported by unpublished clinical data from a multicenter, randomized, blinded, controlled study (Protocol No. CTP-ACCiTBS-00). The study was designed as a prospective, 6-week trial, in which the accelerated iTBS stimulation protocol was compared to the standard of care HF stimulation protocol for treating MDD. A total of 104 subjects were enrolled, with 89 completing the study and included in the per-protocol analysis. Participants had moderate or greater depression (HDRS-21 ≥ 20), with a mean age of 48.6 years. The primary endpoint was the change in HDRS-21 scores from baseline to six weeks. Both groups showed significant improvement from baseline to week 6. The between-group difference was non-significant (p = 0.7783), meeting predefined non-inferiority criteria. Common adverse events included headaches and application site pain; none classified as severe. Two subjects discontinued due to anxiety and hypomania. Overall, the study demonstrated that the accelerated iTBS protocol is safe, effective, and non-inferior to the standard high-frequency protocol for MDD treatment.

Bahun et al (2022) reported that accelerated TMS protocols have shown to be as effective as standard rTMS in reducing depression symptoms and achieving remission; however, comparative studies between different accelerated protocols are limited. To investigate whether two- or three-week accelerated deep TMS (a-dTMS) protocols differ in cognitive outcomes, the authors conducted a randomized controlled pilot study in 32 adult psychiatric inpatients with treatment-resistant MDD). Participants (ages 20–70, all on at least one antidepressant) were assigned to receive dTMS twice daily for either two weeks (10 sessions) or three weeks (15 sessions), using the FDA-approved H1-coil protocol targeting the left DLPFC (20-minute sessions, 18 Hz, 120% motor threshold, 1980 pulses per session). Cognitive function was assessed at baseline and post-treatment using a battery of neuropsychological tests. Statistically significant improvements were observed in most cognitive domains, except numeric short-term memory, verbal fluency, and errors on Benton visual retention test (BVRT) and Trail Making Test (TMT). The 3-week protocol showed greater improvement in psychomotor speed, while the 2-week protocol led to significantly better verbal fluency. These findings suggest the shorter protocol may be more efficient and equally or more beneficial in specific

cognitive areas. Limitations of the study include the absence of a control group, small sample size, lack of long-term follow-up, potential placebo effects, use of non-parallel cognitive tests, concurrent pharmacotherapy, and confounding factors such as medication variability and mood-related cognitive changes. The authors concluded that a-dTMS may offer mild to moderate cognitive benefits without adverse effects in TRD patients, but further sham-controlled studies are needed to confirm these findings.

Standard iTBS, without Functional Connectivity MRI

Blumberger et al (2018) conducted the THREE-D trial, which led to U.S. FDA clearance of iTBS for MDD. This multicenter, randomized, non-inferiority study compared high-frequency (10 Hz) rTMS with iTBS for treatment-resistant MDD. A total of 414 participants were randomized to rTMS (n=205) or iTBS (n=209), administered five times per week over 4–6 weeks. Treatment resistance was defined as failure to respond to at least one adequate antidepressant trial or intolerance to two or more trials. Patients who had failed more than three adequate trials were excluded. Participants continued stable antidepressant regimens during the trial, and medication adjustments were permitted. Prior to treatment, all participants underwent high-resolution anatomical MRI, and neuronavigation targeted the left dorsolateral prefrontal cortex using reverse co-registration from the MNI152 coordinate. rTMS sessions lasted 37.5 minutes, whereas iTBS sessions lasted just over 3 minutes. The primary outcome was change in the 17-item Hamilton Rating Scale for Depression (HRSD-17). Both groups showed similar improvements: rTMS (mean reduction: 10.1 points) and iTBS (10.2 points), with an adjusted difference of 0.01, confirming non-inferiority of iTBS. iTBS was associated with slightly higher self-reported pain (mean score: 3.8 vs. 3.4; p=0.011). Headache was the most common adverse event in both groups (rTMS: 64%; iTBS: 65%). Serious adverse events included one myocardial infarction (rTMS) and three psychiatric events (iTBS), with no significant difference in overall adverse event rates. The study did not include a placebo control group. The authors concluded that iTBS is a safe, well-tolerated, and time-efficient alternative to standard rTMS, with comparable clinical effectiveness for treatment-resistant depression.

The 2025 consensus review from the National Network of Depression Centers Neuromodulation Task Group acknowledged that the THREE-D trial employed MRI-guided neuronavigation and a larger B70 figure-8 coil to enhance targeting precision (Trapp 2025). Although these elements are not considered standard clinical practice in the United States and are not required for adherence to the FDA-cleared once-daily iTBS protocol, the clinical efficacy of iTBS has been replicated with protocols that do not utilize neuronavigation guidance and confirmed through meta-analyses of sham-controlled trials.

Accelerated iTBS with Functional Connectivity MRI- (SAINT)

Cole et al (2020) conducted an open-label clinical trial evaluating the Stanford Accelerated Intelligent Neuromodulation Therapy (SAINT) protocol, which uses iTBS guided by functional connectivity MRI (fcMRI) targeting. The study included 21 participants with major depressive disorder. Each participant received 60 cycles of ten bursts of three pulses at 50 Hz, delivered in ten sessions per day (18,000 pulses/day) over five consecutive days. This represents a total pulse dose that is five times greater than the FDA-cleared iTBS protocol (which delivers 18,000 pulses over six weeks).

On average, participants met standard response criteria within 2.3 days of treatment, approximately 23 ten-minute sessions. Despite the small sample size, significant reductions in suicidality was observed, as measured by the Columbia Suicide Severity Rating Scale (C-SSRS) suicidal ideation subscale ($p < 0.001$). The response rate, defined as a ≥50% reduction in depressive symptoms, was 90.48% and all responders achieved remission immediately post-treatment, with 70% maintaining remission at one month. Intent-to-treat analysis showed 86.4% remission, with 80–100% sustained at one-month follow-up. Participants with prior nonresponse to conventional rTMS required more time to respond but 83% achieved response by day five. No adverse events or cognitive impairments were detected on neuropsychological testing. The authors concluded that SAINT appears preliminarily safe, feasible, and associated with high remission rates in treatment-resistant depression, recommending larger randomized controlled trials to confirm these findings.

Cole et al (2022) conducted a double-blind, randomized, sham-controlled trial to assess the antidepressant efficacy of the accelerated Stanford Neuromodulation Therapy (SNT) protocol, also known as the SAINT protocol, combines intermittent theta burst stimulation (iTBS) with individualized targeting based on functional connectivity MRI (fcMRI). The study enrolled 29 participants with major depressive disorder (MDD), randomized to active (n=14) or sham (n=15) treatment groups. Before treatment, all participants underwent structural and resting-state functional MRI to identify individualized stimulation targets using fcMRI. The intervention consisted of 10 daily sessions over five consecutive days, delivering 1,800 pulses per session (18,000 pulses per day) at 90% of the resting motor threshold, adjusted for cortical depth. The trial was stopped early after a planned interim analysis revealed a large effect size (Cohen's $d > 0.8$) favoring active treatment. At four-week follow-up, 79% of active participants (11 of 14) achieved remission compared to 13% (2 of 15) in the sham group. No serious adverse events occurred, though headaches were more frequent in the active arm. Limitations included small sample size, single-site design, and comorbid psychiatric conditions in 45% of participants. The authors concluded that SNT produced significantly greater symptom reduction than sham stimulation and highlighted the need for larger trials to confirm efficacy and clarify the role of fcMRI-guided targeting.

Geoly et al (2025) conducted a prospective observational follow-up study evaluating the durability of response and remission in participants who previously underwent Stanford Neuromodulation Therapy (SNT, also known as SAINT) in open-label or randomized controlled trials conducted by Cole et al (2020, 2022). SNT is an accelerated, high-dose, resting-state functional connectivity–guided intermittent theta burst stimulation (iTBS) protocol that achieves high acute remission rates after five days of treatment; however, durability beyond four weeks without continuation therapy has been unclear. This study included 46 adults with TRD from prior SNT trials (21 open-label, 14 active RCT, 11 sham crossover). Each participant received five days of SNT (10 sessions/day, 18,000 pulses/day at 90% rMT, depth-adjusted) or sham, with individualized targeting of the left dorsolateral prefrontal cortex most anticorrelated with the subgenual anterior cingulate cortex using resting-state fMRI. The 6-item Hamilton Depression Rating Scale (HDRS-6) scores were collected biweekly for up to 24 weeks and relapse was defined as two consecutive HDRS-6 scores ≥5. Results revealed that 70% (32/46) achieved remission the week following treatment and 33% (15/46) remained in remission at 12 weeks. Limitations include small sample size, lack of follow-up beyond 12 weeks, and limited

generalizability due to demographic and clinical characteristics. Findings suggest that SNT's antidepressant effect is durable, with 12-week remission rates comparable to ECT and potentially exceeding acute outcomes of standard iTBS.

Preservation / Maintenance TMS for Adults with Major Depressive Disorder

A variety of maintenance schedules are currently being studied, with the role of maintenance TMS not been fully established and high heterogeneity in administration between studies.

Fitzgerald et al (2013) reported a prospective, open-label trial of clustered maintenance rTMS for patients with treatment-resistant depression. All patients had received a second successful course of rTMS following relapse and were then treated with monthly maintenance therapy consisting of five rTMS treatments over a 2.5-day period (Friday evening, Saturday, and Sunday). Of 35 patients, 25 (71%) relapsed at a mean of 10.2 months (range, 2- 48 months).

Dunner et al (2014) reported one-year follow-up with maintenance therapy from a large, multi-center observational study (42 sites) of rTMS for patients with treatment-resistant depression. A total of 257 of the 307 patients initially studied who were treated with rTMS agreed to participate in the follow-up study. Of these, 205 patients completed the 12-month follow-up, and 120 patients met the Inventory of Depressive Symptoms-Self Report response or remission criteria at the end of treatment. Ninety-three of the 257 patients (36.2%) who enrolled in the follow-up study received additional rTMS (mean, 16.2 sessions). Seventy-five of the 120 patients (62.5%) who met response or remission criteria at the end of the initial treatment phase (including a two-month taper phase) continued to meet response criteria through follow-up.

Two RCTs investigated outcomes of maintenance TMS sessions, concluding that periodic TMS appears feasible in some cases, but once-monthly TMS is not superior to "watchful waiting" (Philip 2016) and rTMS could represent a novel strategy for preventing relapse in treatment resistant depression (Benadhira 2017). Further studies are needed to confirm the benefits of rTMS maintenance and to clarify effectiveness and feasibility.

D'Andrea et al (2023) conducted a systematic review to evaluate maintenance TMS protocols for MDD and TRD. Fourteen studies were included (3 randomized sham-controlled trials, 8 open-label studies, 2 case reports, 1 case series). Most studies suggested maintenance TMS may reduce relapse risk, but protocols varied widely in timing (starting 1 week to 1-month post-acute treatment), duration (12 weeks to >1 year), and structure (cluster, tapering, continuous, rescue), making it difficult to identify optimal parameters. Cluster and continuous approaches appeared to show lower relapse risk, though evidence remains inconclusive. Relapse risk was highest after five months post-acute treatment, and no superiority was observed among left, right, or bilateral DLPFC stimulation. Limitations included small sample sizes (n=1–281), heterogeneity, and risk of bias (3 low, 4 moderate, 3 severe). Overall, despite methodological limitations, the authors concluded that maintenance TMS is a promising strategy to sustain antidepressant effects and reduce relapse, but standardized protocols and high-quality trials are needed.

Yamazaki et al (2023) published a study protocol for a multicenter open-labelled parallel-group trial with a planned recruitment of 300 patients with MDD who have responded or remitted to acute rTMS

therapy. This study aims to evaluate whether maintenance rTMS is effective in maintaining the treatment response in patients with MDD with a large sample size and feasible study design. The protocol of maintenance rTMS therapy is once a week for the first six months and once biweekly for the second six months.

TMS for Adults with Obsessive-Compulsive Disorder (OCD):

Carmi et al (2018) conducted a double-blind pilot study comparing low-frequency deep TMS (LF-dTMS; 1 Hz), high-frequency deep TMS (HF-dTMS; 20 Hz), and sham stimulation in patients with obsessive-compulsive disorder (OCD). A total of 41 adults with a score of 20 or more on the Yale Brown Obsessive Compulsive Scale (YBOCS) were recruited at the Chaim Sheba Medical Center in Israel and randomized to one of three groups to receive one Hz stimulation (LF), 20 Hz stimulation (HF), or a sham stimulation. All participants received five sessions per week for five weeks (25 sessions total). Final analysis included only the HF group (n=16) and sham group (n=14) due to lack of response in the LF group. After five weeks, 43.8% of HF participants (7/16) met predefined response criteria compared to 7.1% of sham participants (1/14). However, at one-month follow-up, significance was lost, with four HF participants and none in the sham group classified as responders. The authors concluded that HF-dTMS is safe, tolerable, and potentially effective for reducing OCD symptoms, but emphasized the need for larger trials. Limitations included small sample size, single-center design, and short follow-up.

Carmi et al (2019) conducted a multicenter randomized double-blind placebo-controlled evaluating HF-dTMS in OCD. A total of 94 eligible patients were randomized to active high-frequency (n=47) or sham (n=47) dTMS for six weeks. Clinical response was assessed using the Yale-Brown Obsessive-Compulsive Scale (YBOCS). At six weeks, Y-BOCS scores decreased significantly in both groups (active: −6.0 points; sham: −3.3 points), with a between-group difference of 2.8 points (p=0.01; effect size = 0.69). Full response rates at follow-up were 45.2% (19/42) for active treatment versus 17.8% (8/45) for sham (p=0.006). Partial response rates were 59.5% vs. 42.2% (p=0.106). Clinical Global Impressions–Improvement (CGI-I) analysis showed 49% of active participants reported moderate to "very much" improvement compared to 21% in sham (p=0.011). CGI-Severity scores also favored active treatment (61% vs. 32.6%; p=0.022). No serious adverse events occurred. Limitations included lack of control for symptom provocation and absence of brain activity recording, limiting mechanistic insights. The authors concluded that HF-dTMS should be considered as an adjunctive treatment for OCD when response to standard psychological or pharmacological interventions is inadequate.

Fitzsimmons et al (2022) conducted a systematic review and pairwise/network meta-analysis to evaluate the efficacy and safety of rTMS as a treatment option for OCD. Eligible studies were peer-reviewed, randomized, sham-controlled trials enrolling patients with a primary OCD diagnosis and delivering any rTMS protocol with at least five treatment sessions. A comprehensive database search through February 2021 identified 21 studies involving 662 participants (368 active rTMS; 294 sham). Across these trials, 11 different stimulation protocols were investigated. The certainty of evidence was rated Moderate, primarily due to potential publication bias. Meta-analysis of post-treatment Yale-Brown Obsessive-Compulsive Scale (Y-BOCS) scores demonstrated a significant improvement with active rTMS compared to sham (Hedges' g = -0.502). Dropout rates did not differ between active and

sham groups. For comorbid depression, scores on the HDRS and MADRS showed a small but statistically significant benefit for active rTMS (g = -0.21); however, due to limited reporting, subgroup and network meta-analyses were not performed for this outcome. CGI-S scores revealed a large and significant improvement favoring active rTMS (g = -0.86). Limitations included missing primary outcome data in three studies, moderate heterogeneity, and variability in methodology (12 different stimulation protocols). The authors concluded that rTMS is an efficacious treatment for OCD, producing an average 4-point reduction in Y-BOCS scores compared to sham, and noted that these findings align with prior systematic reviews and meta-analyses supporting rTMS efficacy for OCD.

Steuber and McGuire (2023) conducted a meta-analysis of RCTs to evaluate the therapeutic benefit of rTMS in patients with OCD and to identify moderators of treatment effects. The analysis included 25 RCTs published through December 2022, encompassing 860 participants. Using a random-effects model, effect sizes for treatment efficacy and response were calculated based on clinician-rated Y-BOCS scores. Across studies, rTMS demonstrated a moderate effect on OCD symptom severity (Hedges' g = 0.65; $p < .001$) and a large effect on treatment response, with response rates of 39.5% for rTMS versus 8.8% for sham conditions ($p < .0001$). Moderator analysis revealed that longer rTMS session duration (in minutes) was associated with greater improvement in OCD severity, accounting for 24% of variance in treatment effects. Conversely, a higher number of rTMS sessions was negatively associated with symptom reduction, explaining 28% of modeled variance. No significant relationship was found between total pulse count and OCD severity reduction. Limitations included diagnostic heterogeneity, exclusion of four RCTs due to missing pre-post data, and lack of long-term follow-up (ranging from 1 to 12 weeks). The authors concluded that rTMS offers a threefold greater likelihood of treatment response compared to sham, and its efficacy, favorable safety profile, accessibility, and potential for treatment-refractory cases suggest rTMS as a promising therapeutic option for OCD, particularly for patients unresponsive to first-line interventions.

Functional Magnetic Resonance Imaging (fMRI) for OCD

Fitzsimmons et al (2024) conducted a blinded, randomized, proof-of-concept trial to evaluate and compare treatment-induced changes in task-based functional magnetic resonance imaging (tb-fMRI) activation following three different repetitive transcranial magnetic stimulation (rTMS) protocols. The study enrolled 61 participants diagnosed with obsessive-compulsive disorder (OCD) resistant to first-line treatments. Participants were randomized into three parallel arms: high-frequency rTMS to the left dorsolateral prefrontal cortex (DLPFC) (n=19), high-frequency rTMS to the left supplementary motor area (preSMA) (n=23), or low-intensity rTMS to the vertex as a control condition (n=19). Each participant received 16 rTMS sessions immediately prior to exposure and response prevention (ERP) psychotherapy over an 8-week period. Task-based fMRI scans and clinical assessments were conducted at baseline (T0), after eight combined rTMS/ERP sessions (4 weeks, T1), after 16 sessions (8 weeks, T2), and at 12 weeks post-treatment (T3). OCD symptom severity was measured using the Yale-Brown Obsessive-Compulsive Scale (Y-BOCS), and depression symptoms were assessed concurrently. Results showed a significant reduction in mean OCD symptom severity across all groups at each time point compared to baseline ($p < .001$), with no significant differences between treatment arms. Depression symptoms also decreased significantly across the entire sample ($p = .0006$) and within each group. ERP adherence, measured by the Patient Exposure and Response

Prevention Adherence Scale, did not differ between groups for homework or in-session exposure exercises. Side effect frequency was similar across groups, and no serious adverse events occurred. The authors concluded that combined rTMS and ERP produced substantial symptom reduction, with 57.4% of participants classified as responders; however, no differences in clinical outcomes were observed between stimulation sites. Limitations included the relatively small sample size, limited number of treatment sessions, short follow-up duration, and insufficient statistical power to detect between-group differences, which restricts the ability to draw firm clinical conclusions.

TMS for Adults with Migraine Headaches:

Saltychev et al (2022) conducted a systematic review and meta-analysis of eight RCTs (n=339 participants) that compared rTMS to sham stimulation in patients with migraine. All RCTs applied high-frequency rTMS to the left dorsolateral prefrontal cortex, and all studies except one included patients with chronic migraine. All studies except one had a low risk of bias and the risk of publication bias was nonsignificant. Results for the frequency of migraine days per month and the intensity of migraine pain both favored rTMS; however, the authors stated that the difference in migraine pain intensity was clinically insignificant.

TMS for Smoking Cessation

TMS to aid in smoking cessation is being investigated as a non-pharmacological treatment option. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome (Li 2020; Shevorykin 2022).

Bellini et al (2024) conducted a double-blind, randomized, sham-controlled trial to test the effect of dTMS on adult smokers. A total of 100 participants were randomized to active (n=50) or sham (n=50) treatment of up to 21 sessions administer over 6 weeks. Participants completed abstinence, mood, and cognition scales at determined timepoints during follow-up. No serious adverse events occurred during this study. Three participants in the active treatment group were withdrawn from the study in the first week for forearm movements during the application of the pulse series. Based on study results the authors concluded that that use of rTMS, with the parameters used and the H4 coil, was not effective in treatment smoking cessation.

Addicott et al (2024) conducted a randomized sham-controlled trial to evaluate the clinical efficacy and safety of administering iTBS for tobacco use disorder, 38 patients received 28 sessions of active (n=25) or sham (n=13) iTBS over 14 visits. Both active and sham groups reported reduced cigarette consumption, cigarette craving, and tobacco withdrawal symptoms. The authors concluded that there were no differences in cigarette consumption between the active and sham iTBS groups, both groups decreased cigarette consumption similarly, and further research is needed to compare iTBS to standard high-frequency rTMS.

TMS for Other Indications

An updated Cochrane Review (Walton 2021) assessed the evidence for use of TMS in individuals with drug-resistant epilepsy compared with other available treatments in reducing seizure frequency, epileptiform discharges, anti-epileptic medication use and side effects, as well as improving quality of life. Eight RCTs (n=241 participants), seven of which were blinded, were included. Two of the studies

showed a statistically significant reduction in seizure rate from baseline (72% and 78.9% reduction of seizures per week from the baseline rate). The remaining six studies did not show a significant reduction in seizure frequency with rTMS compared to controls. Three studies did show a statistically significant reduction in epileptic discharges after active rTMS treatment and adverse events were rare, but an increase in seizure frequency did occur in a small number of individuals. No significant change in medication use was reported. The authors concluded that even though there is reasonable evidence that rTMS is effective at reducing epileptiform discharges, the evidence for the efficacy of rTMS for seizure reduction is low, and further research is needed.

Evidence related to the efficacy of rTMS is limited for other indications. Studies have methodological limitations (e.g., small samples sizes and limited follow-up). The role that TMS has in the treatment of these indications has not yet been established. Alzheimer's disease (Ahmed 2012), amyotrophic lateral sclerosis (ALS) (Fang 2013; Di Lazzaro 2024), anxiety (Trevizol 2021), chronic pain (O'Connell 2018), gambling (Concerto 2023), insomnia (Krone 2023), fibromyalgia (Short 2011; Knijnik 2016; Salychev and Laimi 2017), migraine (Lan 2017), Parkinson's disease (Benninger 2012; Xie 2020; Chen 2021, Zhang 2022), schizophrenia (Matheson 2010; He 2017; Guan 2020; Hua 2022; Johnstone 2022), stroke (Yang 2013; Shen 2022), tinnitus (Peng 2012), Tourette syndrome (Kwon 2011).

Cranial Electrotherapy Stimulation (CES)

Additional evidence is needed to permit conclusions about whether CES improves outcomes for individuals with anxiety or depression. The evidence for depression and anxiety does not support the use of CES. The most direct evidence related to CES for anxiety and depression comes from 5 sham-controlled randomized trials (Barclay 2014; Mishoulon 2015; Lyon 2015; Kim 2021; Morriss 2023) and systematic reviews.

A 2022 meta-analysis by Ching et al. reviewed 11 RCTs (N=794) evaluating CES in patients with anxiety. Anxiety and depressive symptoms were significantly reduced with CES versus control (Hedges' g, -0.625 and -0.648, respectively); however, the analysis is limited by high variability in the number of sessions (14 to 126), session duration (10 to 60 minutes), outcomes scale, and the small number of patients in each trial.

Liu et al (2025) conducted the first meta-analysis of 16 RCT (n=1148) to explore efficacy of CES for primary and secondary depression in adults. Eight trials assessed CES as adjunctive therapy with antidepressants, while others examined CES as monotherapy. Treatment parameters varied widely: stimulation frequency ranged from 0.5 to 15,000 Hz; session duration from 20 to 60 minutes; session frequency from 3 to 7 times per week; and study duration from 2 to 24 weeks. Overall, CES significantly reduced depressive symptoms compared with non-CES treatment, though the effect size was small (Hedges' g = –0.33). CES showed no significant impact on quality of life (g = 0.13). Subgroup analyses suggested greater benefit among females, patients with secondary depression (g = –0.42), and protocols using frequency >100 Hz (g = –0.50), session length ≤30 minutes (g = –0.39), ≤5 sessions per week (g = –0.34), and study duration ≤5 weeks (g = –0.45). The authors concluded CES is an effective, safe, and well-tolerated intervention for reducing depressive symptoms in adults; however, larger, long-term RCTs are needed to confirm efficacy, optimize treatment parameters, and clarify mechanisms within broader mental health contexts.

PROFESSIONAL GUIDELINE(S)

Major Depressive Disorder

The American Psychiatric Association (APA) published a legacy clinical practice guideline, in 2010, for treatment of patient with major depressive disorder supports the use of TMS as a safe and well tolerated treatment in the acute phase.

In 2022, the Department of Veterans Affairs Department of Defense (VA/DoD) issued clinical practice guidelines for the management of MDD.

- A weak recommendation was made for rTMS for treatment for patients who have demonstrated partial or no response to two or more adequate pharmacologic treatment trials.
- The VA/DoD found that there is insufficient evidence to recommend for or against theta-burst stimulation.
- A weak recommendation against choosing Ketamine as an initial pharmacotherapy and for augmentation use of Ketamine for patients with MDD who have not responded to several adequate pharmacologic trials.

In 2025, the Clinical TMS Society (CTMSS) issued a supportive statement for rTMS for the treatment of MDD. Summarizing published evidence, CTMSS concluded that the evidence supports that using rTMS early in the treatment algorithm leads to better treatment outcomes and should be offered to patients after one antidepressant trial that does not result in remission of the depressive episode.

In 2025, an updated consensus review and considerations on TMS to treat depression was endorsed by the National Network of Depression Centers, the CTMSS, and the International Federation of Clinical Neurophysiology (Trapp 2025). Recommendations include:

- A general recommendation that patients receive the full treatment course of 30–36 sessions. There is conflicting evidence about prediction of response after a portion of sessions.
- Although maintenance TMS is promising, the frequency of maintenance treatments needed to sustain benefit is unclear, and larger scale RCT examining efficacy as a function of treatment interval are needed to establish the utility of maintenance protocols.
- Combining psychotherapy with rTMS may have additional benefits, though further research is needed before this is broadly recommended.
- No medication augmentation strategies have enough evidence to be broadly applied, although use of stimulants and glutamate receptor modulators is promising
- Various accelerated protocols are being investigated, and there is some evidence that increased dose (either by number of pulses or number of sessions) is associated with greater antidepressant effect. A novel and FDA-cleared highly accelerated protocol that also incorporates individualized targeting based on functional connectivity has shown high remission rates in an outpatient setting. Larger trials in other settings are underway, and this on-brand protocol only recently became commercially available in April 2024

- Intermittent theta burst stimulation is an FDA-cleared protocol of short duration and is non-inferior to standard high-frequency protocols. Standard high-frequency rTMS and iTBS are equally recommended as an initial antidepressant protocol.

Obsessive-Compulsive Disorder

The APA's legacy practice guideline (2013) for the treatment of patient with OCD states that the overall strength of evidence for somatic therapies (e.g., rTMS) is low and the therapies should be considered only after first- and second-line treatments, and well-supported augmentation strategies have been exhausted.

In 2020, the National Institute for Health and Care Excellence (NICE) published interventional procedures guidance for TMS for OCD, stating that the evidence on the safety of TMS raises no major safety concerns; however, the evidence on efficacy is inadequate in quantity and quality. NICE recommends that TMS should only be used in the context of research.

In 2021, the Clinical TMS Society (CTMSS) issued coverage guidance for TMS for OCD including:

- TMS is reasonable and necessary for a minimum of 29 visits over a 6-week period. Extensions in 2 to 4-week increments are based on clinical need with evidence of response from the first 29 sessions.
- If patients cannot come in five days a week, treatments may be administered three days a week over a longer period of time.
- Retreatment may be considered for patients who met the guidelines for initial treatment and experienced at least a 30% reduction in the YBOCS score, as long as the improvement persisted for at least one month after the prior treatments ended.
- TMS for adolescents with OCD may be appropriate if there is a higher level of treatment resistance. These cases should be reviewed individually for medical necessity and considered a compassionate use.

Theta Burst Stimulation

In 2022, the Clinical TMS Society (CTMSS) acknowledged FDA clearance of the SAINT Neuromodulation System, using the Magnus Medical Saint Neuromodulation System, for treatment-resistant MDD. SAINT differs from conventional iTBS protocols by requiring structural and functional MRI, neuronavigation, and a proprietary algorithm to individualize targeting based on functional connectivity. Whether similar outcomes can be achieved with other devices or standard targeting methods remains unknown and off-label SAINT-like protocols without neuronavigation or targeting methodology consistent with FDA-clearance is unknown

In 2023, the CTMSS issued a statement that iTBS was FDA-cleared for severe MDD based on a non-inferiority study comparing it to a standard 10 Hz TMS, with subsequent studies confirming its efficacy and safety. CTMSS states that there is a clear preponderance of evidence supporting once per day iTBS delivered to left dorsolateral prefrontal cortex (DLPFC) provides comparable acute outcomes to 10 Hz stimulation and should be considered a valid alternative for depression treatment.

Maintenance/Preservation TMS

The 2018 National Network of Depression Centers (NNDC) and APA Council on Research (CoR) consensus recommendations for the application of rTMS found limited evidence regarding maintenance strategies following response or remission with acute rTMS (McClintock 2018). One RCT compared a once-monthly scheduled approach with a re-introduction approach and found that both approaches were approximately equivalent in prolonging clinical benefits. The study also found that "rescue therapy" (re-introduction of daily rTMS triggered by symptom relapse) was effective in 69% of instances.

The Clinical TMS Society (2021) indicates that for patients who demonstrate a late response to TMS, subsequent treatment extensions in ten (10) treatment increments are allowed based on clinical need.

Other Indications

The APA published several clinical practice guidelines to provide evidence-based recommendation for the assessment and treatment of psychiatric disorders. TMS requires further study for use in treating bipolar disorder (2002) and TMS is not addressed in the practice guidelines for borderline personality disorder (2024), eating disorders (2023), schizophrenia (2020), post-traumatic stress disorder (2000), Alzheimer's disease (2000).

The 2018 NNDC and APA CoR consensus recommendation for the application of rTMS reported that there is some evidence of the safe and therapeutic use and clinical benefit of TMS for other neuropsychiatric disorders, but the current evidence is insufficient to support routine clinical rTMS in these populations (McClintock 2018).

In 2023, the Department of Veterans Affairs Department of Defense (VA/DoD) issued clinical practice guidelines for the management of bipolar disorder. A weak recommendation was made to offer rTMS as an adjunctive treatment for individuals with bipolar disorder who have demonstrated partial or no response to pharmacologic treatment for depressive symptoms.

In 2023, the Clinical TMS Society issued coverage guidance (indication, limitations, and medical necessity) for TMS as a treatment for smoking.

REGULATORY STATUS

Devices for TMS have been cleared for marketing by the U.S. Food and Drug Administration (FDA) for the treatment of major depressive disorder in adults who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode.

The United States Food and Drug Administration (FDA) regulates TMS and CES devices and protocols as medical devices. All TMS and CES devices and protocols require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2025 Nov 3]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most

serious type of recalls. on our website by the date that the FDA posts the information on our website. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls [accessed 2025 Nov 3]

The U.S. Food and Drug Administration (FDA) has not determined the safety or efficacy of ketamine hydrochloride injection for the treatment of a psychiatric disorder(s) and is considered off-label use for these indications (FDA 2023).

TMS devices have been FDA cleared for the treatment of major depressive disorder (Product Code: OBP), migraine headache pain (Product Code: OKP), obsessive-compulsive disorder (Product Code: QCI), and short-term smoking cessation for adults (Product Code: QMD).

TMS Devices FDA-cleared for Major Depressive Disorder:

Device	Manufacturer	FDA Clearance	Clearance Date
BrainsWay Deep TMS System with accelerated iTBS protocol	BrainsWay	K251449	09/13/2025
BrainsWay Deep TMS System	BrainsWay	K222196	05/31/2025
NeuroStar Advanced Therapy System *ages 15-21	Neuronetics	K231926	03/22/2024
Horizon 3.0 TMS Therapy System	Magstim	K222171	01/13/2023
Magnus Nueromodulation System with SAINT Technology	Magnus Medical	K220177	09/01/2022
ALTMS Magnetic Stimulation Therapy System	REMED Co., Ltd	K220625	04/06/2022
MagVenture TMS Therapy	Tonica Elektronik	K193006	08/09/2020
Horizon TMS Therapy System with iTBS protocol	Magstim	K182853	03/15/2019
Mag Vita TMS Therapy System with Theta Burst Stimulation	Tonica Elektronik	K173620	8/14/2018
Apollo TMS Therapy System *age 15 and older	Magstim	K180313 K243700	05/04/2018 09/04/2025
Nexstim	Magstim	K171902	11/10/2017
Horizon	Magstim	K171051	09/13/2017
Neurosoft	TeleEMG	K160309	12/22/2016
Magvita	Tonica Elektronik	K150641	07/31/2015

Rapid Therapy System	Magstim	K143531	05/08/2015
Brainsway H-Coil Deep TMS System	BrainsWay	K122288	01/07/2013
NeoPulse, now known as Neurostar	Neuronetics	K083538	12/16/2008

TMS Devices FDA-cleared for Adults with Obsessive-Compulsive Disorder (OCD):

Device	**Manufacturer**	**FDA Clearance**	**Clearance Date**
CloudTMS for OCD	TeleEMG	K221129	03/10/2023
Horizon 3.0 TMS Therapy System	Magstim	K222171	01/13/2023
Neurostar	Neuronetics	K212289	05/06/2022
MagVenture TMS Therapy	Tonica Elektronik	K193006	08/09/2020
Brainsway H-Coil Deep TMS System	Brainsway	K183303	03/08/2019

TMS Devices FDA-cleared for Migraine Headache with an Aura:

Device	**Manufacturer**	**FDA Clearance**	**Clearance Date**
Savi Dual Migraine Therapy	ENeura	K230358	05/16/2023
Brainsway H-Coil Deep TMS System	Brainsway	K183303	03/08/2019
Springtms Total Migraine System	Eneura	K140094	05/21/2014
Cerena	eNeura Therapeutics	K130556	03/05/2013

TMS Devices FDA-cleared to Aid in Smoking Cessation for Adults

Device	**Manufacturer**	**FDA Clearance**	**Clearance Date**
Brainsway Deep TMS System	Brainsway	K200957	08/21/2020

CES Devices FDA-cleared (select indications)

Device	**Manufacturer**	**FDA Clearance**	**Clearance Date**
Alpha-Stim CS, for anxiety and insomnia	Electromedical Products International, Inc.	K903014	05/12/1992
Flow FL-100, for moderate to severe	Flow	PMA P230024	12/08/2025

Major Depressive Disorder in adults	Neuroscience		

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0889T (E/I)	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold–starting location, neuronavigation files and target report, review, and interpretation
0890T (E/I)	Accelerated, repetitive high-dose functional connectivity MRI–guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day
0891T (E/I)	subsequent treatment day
0892T (E/I)	subsequent motor threshold redetermination with delivery and management, per treatment day
0997T (E/I)	Precuneus magnetic stimulation; treatment planning using magnetic resonance imaging-guided neuronavigation to determine optimal location, dose, and intensity for magnetic stimulation therapy, derived from evoked potentials from single pulses of electromagnetic energy recorded by 64-channel electroencephalogram, including automated data processing, transmission, analysis, generation of treatment parameters with review, interpretation, and report (effective 01/01/26)
0998T (E/I)	Precuneus magnetic stimulation; personalized treatment delivery of magnetic stimulation therapy to a prespecified target area derived from analysis of evoked potentials within the precuneus, utilizing magnetic resonance imaging-based neuronavigation, with management, per day (effective 01/01/26)

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Code	Description
90867	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial, including cortical mapping, motor threshold determination, delivery, and management
90868	subsequent delivery and management, per session
90869	subsequent motor threshold re-determination with delivery and management

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HCPCS Codes

Code	Description
E0732	Cranial electrotherapy stimulation (CES) system, any type

ICD10 Codes

Code	Description
F17.20 - F17.29 (E/I)	Nicotine dependence (code range)
F32.0 - F32.9	Major depressive disorder, single episode (code range)
F33.0 - F33.9	Major depressive disorder, recurrent (code range)
F41.0 - 41.9 (E/I)	Anxiety disorders (code range)
F42.0 - F42.9	Obsessive-compulsive disorder (code range)
F51.0 - F51.09 (E/I)	Insomnia (code range)
G30.0 -G30.9 (E/I)	Alzheimer's disease (code range)
G43.0 – G43.9 (E/I)	Migraine, with and without aura (code range)

REFERENCES

Addicott MA, et al. A randomized controlled trial of intermittent theta burst stimulation to the medial prefrontal cortex for tobacco use disorder: Clinical efficacy and safety. Drug Alcohol Depend. 2024 May 1;258:111278. Epub 2024 Mar 30.

Ahmed MA, et al. Effects of low versus high frequencies of repetitive transcranial magnetic stimulation on cognitive function and cortical excitability in Alzheimer's dementia. J Neurol. 2012 Jan;259(1):83-92.

American Psychiatric Association [Internet]. Legacy practice guidelines. Major Depressive Disorder. 2010 May [accessed 2025 Dec 15]. Available from: https://www.psychiatry.org/psychiatrists/practice/clinical-practice-guidelines

American Psychiatric Association [Internet]. Legacy practice guidelines. Treatment of patients with obsessive-compulsive disorder. 2007 [accessed 2025 Dec 15]. Available from: https://www.psychiatry.org/psychiatrists/practice/clinical-practice-guidelines

American Psychiatric Association [Internet]. Policy Finder. Position Statement on Transcranial Magnetic Stimulation (TMS). 2024 Jul [accessed 2025 Dec 15]. Available from: https://www.psychiatry.org/about-apa/policy-finder

American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM-5-TR). Washington, DC, American Psychiatric Association, 2022.

Avery DH, et al. A controlled study of repetitive transcranial magnetic stimulation in medication-resistant major depression. Biol Psychiatry. 2006 Jan 15;59(2):187-94.

Avery DH, et al. Transcranial magnetic stimulation reduces pain in patients with major depression: a sham-controlled study. J Nerv Ment Dis. 2007 May;195(5):378-81.

Avery DH, et al. Transcranial magnetic stimulation in the acute treatment of major depressive disorder: clinical response in an open-label extension trial. J Clin Psychiatry. 2008 Mar;69(3):441-51.

Bahun I, et al. A pilot study of accelerated deep transcranial magnetic stimulation effects on cognitive functioning in patients diagnosed with treatment resistant major depressive disorder. Psychiatry Res. 2022 Oct;316:114750.

Barclay TH and Barclay RD. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. J Affect Disord. 2014 Aug;164:171-177.

Bellini BB, et al. Does deep TMS really works for smoking cessation? A prospective, double blind, randomized, sham controlled study. Prog Neuropsychopharmacol Biol Psychiatry. 2024 Jun 8;132:110997. Epub 2024 Mar 24. PMID: 38531486.

Berlim MT, et al. Efficacy of theta burst stimulation (TBS) for major depression: An exploratory meta-analysis of randomized and sham-controlled trials. J Psychiatr Res. 2017 Jul;90:102-109.

Benninger DH, et al. Controlled study of 50-Hz repetitive transcranial magnetic stimulation for the treatment of Parkinson disease. Neurorehabil Neural Repair. 2012 Nov-Dec;26(9):1096-1105.

Berlim MT, et al. High frequency repetitive transcranial magnetic stimulation as an augmenting

strategy in severe treatment-resistant major depression: a prospective 4-week naturalistic trial. J Affect Disord. 2011 Apr;130(1-2):312-7.

Blumberger DM, et al. Effectiveness of theta burst versus high-frequency repetitive transcranial magnetic stimulation in patients with depression (THREE-D): a randomised non-inferiority trial. Lancet. 2018 Apr 28;391(10131):1683-1692.

Blumberger DM, et al. Effectiveness of standard sequential bilateral repetitive transcranial magnetic stimulation vs bilateral theta burst stimulation in older adults with depression the FOUR-D randomized noninferiority clinical trial. JAMA Psychiatry. 2022;79(11):1065-1073.

Bulteau S, et al. Intermittent theta burst stimulation (iTBS) versus 10 Hz high-frequency repetitive transcranial magnetic stimulation (rTMS) to alleviate treatment-resistant unipolar depression: A randomized controlled trial (THETA-DEP). Brain Stimul. 2022;15(3):870-880

Buyuktaskin D, et al. Repetitive transcranial magnetic stimulation frequency effects on suicidal ideation in adolescents with major depressive disorder. J Affect Disord. 2025 Aug 15;383:101-107.

Cao P, et al. Efficacy and safety of repetitive transcranial magnetic stimulation combined with antidepressants in children and adolescents with depression: A systematic review and meta-analysis. J Affect Disord. 2023 Sep 1;336:25-34.

Carmi L, et al. Clinical and electrophysiological outcomes of deep TMS over the medial prefrontal and anterior cingulate cortices in OCD patients. Brain Stimul. 2018 Jan - Feb;11(1):158-165.

Carmi L, et al. Efficacy and safety of deep transcranial magnetic stimulation for obsessive-compulsive disorder: A prospective multicenter randomized double-blind placebo-controlled trial. Am J Psychiatry. 2019;176(11):931-938.

Chen J, et al. Non-pharmacological treatment for Parkinson disease patients with depression: a meta-analysis of repetitive transcranial magnetic stimulation and cognitive-behavioral treatment. Int J Neurosci. 2021 Apr;131(4):411-424.

Ching PY, et al. Efficacy and tolerability of cranial electrotherapy stimulation in the treatment of anxiety: a systemic review and meta-analysis. Front Psychiatry. 2022 Jun 9;13:899040.

Clinical TMS Society [Internet]. Clinical standards. Revised statement regarding SAINT protocol. 2022 Dec 08 [accessed 2025 Dec 10]. Available from: https://clinicaltmssociety.org/committees-clinical-standard/

Clinical TMS Society [Internet]. Clinical standards. rTMS clarifying statement. 2023 Feb 10 [accessed 2025 Dec 10]. Available from: https://clinicaltmssociety.org/committees-clinical-standard/

Clinical TMS Society [Internet]. Clinical standards. Theta burst statement from the Clinical TMS Society. 2023 Mar 09 [accessed 2025 Dec 10]. Available from: https://clinicaltmssociety.org/committees-clinical-standard/

Clinical TMS Society [Internet]. Clinical standards. Preservation of TMS statement. 2023 Dec 8 [accessed 2025 Dec 10]. Available from: https://clinicaltmssociety.org/committees-clinical-standard/

Clinical TMS Society [Internet]. Clinical standards. Supportive statement for rTMS for MDD.

Optimizing depression treatment: clinical and economic benefits of early repetitive transcranial magnetic stimulation. 2025 Apr 7 [accessed 2025 Dec 10]. Available from: https://clinicaltmssociety.org/committees-clinical-standard/

Clinical TMS Society [Internet]. Coverage guidance for TMS for OCD. 2021 Feb 2 [accessed 2025 Dec 10]. Available from: https://clinicaltmssociety.org/wp-content/uploads/2024/08/CTMSS-Recommended-OCD-Coverage-Policy_Approved-02-02-2021.pdf

Clinical TMS Society [Internet]. Coverage guidance for TMS for smoking cessation. 2023 Oct 9 [accessed 2025 Dec 10]. Available from: https://clinicaltmssociety.org/wp-content/uploads/2024/08/Ideal-Smoking-Cessation-Policy_Final_0.pdf

Cole EJ, et al. Stanford Accelerated Intelligent Neuromodulation Therapy for treatment-resistant depression. Am J Psychiatry. 2020 Aug 1;177(8):716-726.

Cole EJ, et al. Stanford Neuromodulation therapy (SNT): a double-blind randomized controlled trial. Am J Psychiatry. 2022 Feb;179(2):132-141. Epub 2021 Oct 29

Concerto C, et al. Transcranial magnetic stimulation for the treatment of gambling disorder: A systematic review. J Integr Neurosci. 2023;22(6):164.

Croarkin PE, et al. Left prefrontal transcranial magnetic stimulation for treatment-resistant depression in adolescents: a double-blind, randomized, sham-controlled trial. Neuropsychopharmacology. 2021 Jan;46(2):462-469.

d'Andrea G, et al. Investigating the role of maintenance TMS protocols for major depression: systematic review and future perspectives for personalized interventions. J Pers Med. 2023 Apr 21;13(4):697. PMID: 37109083.

Dalhuisen I, et al. rTMS as a next step in antidepressant nonresponders: a randomized comparison with current antidepressant treatment approaches. Am J Psychiatry. 2024 Sep 1;181(9):806-814.

Di Lazzaro V, et al. Transcranial static magnetic stimulation for amyotrophic lateral sclerosis: a bicentric, randomised, double-blind placebo-controlled phase 2 trial. Lancet Reg Health Eur. 2024 Jul 30;45:101019. PMID: 39185360

Dragon K, et al. Four weeks standard vs. one week accelerated intermittent Theta Burst Stimulation for the treatment of depression - A retrospective analysis. Behav Brain Res. 2025 Feb 28;479:115361.

Fang J, et al. Repetitive transcranial magnetic stimulation for the treatment of amyotrophic lateral sclerosis or motor neuron disease. Cochrane Database Syst Rev. 2013 May 31;5(5):CD008554.

Fitzgerald PB, et al. A pilot investigation of an intensive theta burst stimulation protocol for patients with treatment resistant depression. Brain Stimul. Jan-Feb 2020;13(1):137-144.

Fitzgerald PB, et al. Accelerated repetitive transcranial magnetic stimulation in the treatment of depression. Neuropsychopharmacology. 2018 Jun;43(7):1565-1572.

Fitzgerald PB, et al. An open label trial of clustered maintenance rTMS for patients with refractory

depression. Brain Stim. 2013 May;6(3):292-7.

Fitzsimmons SMDD, et al. Repetitive transcranial magnetic stimulation for obsessive-compulsive disorder: A systematic review and pairwise/network meta-analysis. J Affect Disord. 2022 Apr 1;302:302-312.

Fitzsimmons SMDD, et al. Transcranial magnetic stimulation-induced plasticity improving cognitive control in obsessive-compulsive disorder, part I: clinical and neuroimaging outcomes from a randomized trial. Biol Psychiatry. 2025 Apr 1;97(7):678-687. Epub 2024 Jul 30.

Garzon JF, et al. A multisite, 6-month, open-label study of maintenance transcranial magnetic stimulation for adolescents with treatment-resistant depression. J Child Adolesc Psychopharmacol. 2025 Mar;35(2):99-108. doi: 10.1089/cap.2024.0067. Epub 2024 Dec 26.

Gao F, et al. Repetitive transcranial magnetic stimulation for pain after spinal cord injury: a systematic review and meta-analysis. J Neurosurg Sci. 2017 Oct;61(5):514-522.

Geoly AD, et al. Durability of clinical benefit with Stanford Neuromodulation Therapy (SNT) in treatment-resistant depression. Brain Stimul. 2025 May-Jun;18(3):875-881.

George MS, et al. Daily left prefrontal transcranial magnetic stimulation therapy for major depressive disorder: a sham- controlled randomized trial. Arch Gen Psychiatry. 2010 May;67(5):507-16.

Guan HY, et al. High-frequency neuronavigated rTMS effect on clinical symptoms and cognitive dysfunction: a pilot double-blind, randomized controlled study in veterans with schizophrenia. Transl Psychiatry. 2020 Feb 25;10(1):79.

He H, et al. Repetitive transcranial magnetic stimulation for treating the symptoms of schizophrenia: A PRISMA compliant meta-analysis. Clin Neurophysiol. 2017 May;128(5):716-724.

Hua JPY, et al. Cerebellar stimulation in schizophrenia: A systematic review of the evidence and an overview of the methods. Front Psychiatry. 2022;13:1069488.

Janicak PG, et al. Durability of clinical benefit with transcranial magnetic stimulation (TMS) in the treatment of pharmacoresistant major depression: assessment of relapse during a 6-month, multisite, open-label study. Brain Stimul. 2010 Oct;3(4):187-99.

Johnstone S, et al. Neuromodulation to treat substance use disorders in people with schizophrenia and other psychoses: A systematic review. Front Psychiatry. 2022;13:793938.

Kim J, et al. Effects of cranial electrotherapy stimulation with novel in-ear electrodes on anxiety and resting-state brain activity: A randomized double-blind placebo-controlled trial. J Affect Disord. 2021 Dec 1;295:856-864.

Knijnik LM, et al. Repetitive transcranial magnetic stimulation for fibromyalgia: systematic review and meta-analysis. Pain Pract. 2016 March;16(3):294-304.

Krone LB, et al. Brain stimulation techniques as novel treatment options for insomnia: A systematic review. J Sleep Res. 2023 Dec;32(6):e13927.

Kumar N, et al. A randomized, double blind, sham-controlled trial of repetitive transcranial magnetic

stimulation (rTMS) in the treatment of negative symptoms in schizophrenia. Brain Stimul 2020 May-Jun;13(3):840-849.

Lam RW, et al. Repetitive transcranial magnetic stimulation for treatment-resistant depression: A systematic review and meta-analysis. Can J Psychiatry. 2008;53(9):621-631.

Lan L, et al. The efficacy of transcranial magnetic stimulation on migraine: a meta-analysis of randomized controlled trails. J Headache Pain. 2017 Aug 22;18(1):86.

Levkovitz Y, et al. Efficacy and safety of deep transcranial magnetic stimulation for major depression: a prospective multicenter randomized controlled trial. World Psychiatry. 2015;14:64–73.

Li CT, et al. Effects of prefrontal theta-burst stimulation on brain function in treatment-resistant depression: A randomized sham-controlled neuroimaging study. Brain Stimul. 2018 Sep-Oct;11(5):1054-1062.

Li X, et al. Two weeks of image-guided left dorsolateral prefrontal cortex repetitive transcranial magnetic stimulation improves smoking cessation: A double-blind, sham-controlled, randomized clinical trial. Brain Stimul. 2020 Sep-Oct;13(5):1271-1279.

Lipton RB, et al. Single-pulse transcranial magnetic stimulation for acute treatment of migraine with aura: a randomised, double-blind, parallel-group, sham-controlled trial. Lancet Neurol. 2010 Apr;9(4):373-80.

Liu SY, et al. Efficacy of cranial electrotherapy stimulation for treating primary and secondary depression in adults: A meta-analysis of randomized controlled trials. J Affect Disord. 2025 Aug 1;382:488-497.

Lyon D, et al. Randomized sham-controlled trial of cranial microcurrent stimulation for symptoms of depression, anxiety, pain, fatigue and sleep disturbances in women receiving chemotherapy for early-stage breast cancer. Springerplus. 2015 Jul 23;4:369.

Majumder P, et al. The safety and efficacy of repetitive transcranial magnetic stimulation in the treatment of major depression among children and adolescents: a systematic review. Cureus. 2021 Apr 19;13(4):e14564.

Mallik G, et al. Safety and efficacy of continuous theta burst "intensive" stimulation in acute-phase bipolar depression. J of ECT. 2023 Mar;39(1):28-33.

Mantovani A, et al. Long-term efficacy of repeated daily prefrontal transcranial magnetic stimulation (TMS) in treatment-resistant depression. Depress Anxiety. 2012 Oct;29(10):883-90.

Matheson SL, et al. Quality assessment, and comparison of evidence for electroconvulsive therapy and repetitive transcranial magnetic stimulation for schizophrenia: a systematic meta-review. Schizophr Res. 2010 May;118(1-3):201-10.

McClintock SM, et al. Consensus recommendations for the clinical application of repetitive transcranial magnetic stimulation (rTMS) in the treatment of depression. J Clin Psychiatry. 2018 Jan/Feb;79(1).

McLoughlin DM, et al. The clinical effectiveness and cost of repetitive transcranial magnetic

stimulation versus electroconvulsive therapy in severe depression: a multicentre pragmatic randomized controlled trial and economic analysis. Health Technol Assess. 2007 Jul;11(24):1-54.

Mischoulon D, et al. Efficacy and safety of a form of cranial electrical stimulation (CES) as an add-on intervention for treatment-resistant major depressive disorder: A three-week double blind pilot study. J Psychiatr Res. 2015 Nov;70:98-105.

Morriss R, et al. Clinical effectiveness of active Alpha-Stim AID versus sham Alpha-Stim AID in major depression in primary care in England (Alpha-Stim-D): a multicentre, parallel group, double-blind, randomised controlled trial. Lancet Psychiatry. 2023 Mar;10(3):172-183.

National Institute for Health and Clinical Excellence (NICE) [Internet]. Repetitive transcranial magnetic stimulation for depression. Interventional Procedure Guidance [IPG 542]. 2015 Dec [accessed 2025 Dec 15]. Available from: https://www.nice.org.uk/guidance/ipg542

National Institute for Health and Clinical Excellence (NICE) [Internet]. Transcranial magnetic stimulation for obsessive-compulsive disorder. Interventional Procedure Guidance [IPG676] 2020 Aug [accessed 2025 Dec 15]. Available from: https://www.nice.org.uk/guidance/ipg676

O'Connell NE, et al. Non-invasive brain stimulation techniques for chronic pain. Cochrane Database Syst Rev 2018 Apr 13;4:CD008208.

Ontario Health. Repetitive transcranial magnetic stimulation for people with treatment-resistant depression: a health technology assessment. Ont Health Technol Assess Ser. 2021 May; 21(4):1-232.

O'Reardon JP, et al. Efficacy and safety of transcranial magnetic stimulation in the acute treatment of major depression: a multisite randomized controlled trial. Biol Psychiatry. 2007 Dec 1;62(11):1208-16.

Ozer U, et al. Efficacy of accelerated deep transcranial magnetic stimulation with double cone coil in obsessive-compulsive disorder: A double-blind, placebo-controlled study. J Psychiatr Res. 2024 Mar;171:325-331. Erratum in: J Psychiatr Res. 2025 Jan;181:647.

Papakostas GI, et al. Comparative effectiveness research trial for antidepressant incomplete and non-responders with treatment resistant depression (ASCERTAIN-TRD) a randomized clinical trial. Mol Psychiatry. 2024 Aug;29(8):2287-2295.

Peng Z, et al. Effectiveness of repetitive transcranial magnetic stimulation for chronic tinnitus: a systematic review. Otolaryngol Head Neck Surg. 2012 Nov;147(5):817-25.

Prato M, et al. Accelerated repetitive Transcranial Magnetic Stimulation (aTMS) vs. standard repetitive Transcranial Magnetic Stimulation (rTMS) in the treatment of Major Depressive Episodes: A randomized, single-blind, controlled trial. TMS Journal. 2025 Aug. Volume 4:100177

Price L, et al. A meta-analysis of cranial electrotherapy stimulation in the treatment of depression. J Psychiatr Res. 2021 Mar;135:119-134. Epub 2020 Dec 21.

Qiu H, et al. Efficacy and safety of repetitive transcranial magnetic stimulation in children and adolescents with depression: A systematic review and preliminary meta-analysis. J Affect Disord. 2023 Jan 1;320:305-312.

Ramakrishnan D, et al. An evaluation of treatment response and remission definitions in adult obsessive-compulsive disorder: A systematic review and individual-patient data meta-analysis. J Psychiatr Res. 2024 May;173:387-397.

Roth Y, et al. Real world efficacy and safety of various accelerated deep TMS protocols for major depression. Psychiatry Res. 2023 Oct;328:115482

Saltychev M and Juhola J. Effectiveness of high-frequency repetitive transcranial magnetic stimulation(rTMS) in migraine - a systematic review and meta-analysis. Am J Phys Med Rehabil. 2022 Nov 1;101(11)101-1006.

Saltychev M and Laimi K. Effectiveness of repetitive transcranial magnetic stimulation in patients with fibromyalgia: a meta-analysis. Int J Rehabil Res. 2017 March;40(1):11-18.

Senova A, et al. Durability of antidepressant response to repetitive transcranial magnetic stimulation: Systematic review and meta-analysis. Brain Simul. 2019;12(1):119-128.

Shen Y, et al. Repetitive transcranial magnetic stimulation, and transcranial direct current stimulation as treatment of poststroke depression: a systematic review and meta-analysis. Neurologist. 2022 Jul 1;27(4):177-182.

Shevorykin A, et al. Transcranial magnetic stimulation for long-term smoking cessation: preliminary examination of delay discounting as a therapeutic target and the effects of intensity and duration. Front Hum Neurosci. 2022 Jul 5;16:920383.

Short et al. Ten sessions of adjunctive left prefrontal rTMS significantly reduces fibromyalgia pain: a randomized, controlled pilot study. Pain. 2011 Nov;152(11)2477-2484.

Sigrist C, et al. Transcranial magnetic stimulation in the treatment of adolescent depression: a systematic review and meta-analysis of aggregated and individual-patient data from uncontrolled studies. Eur Child Adolesc Psychiatry. 2022 Oct;31(10):1501-1525.

Sonmez AI, et al. Accelerated TMS for depression: a systematic review and meta-analysis. Psychiatry Res. 2019 Mar;273:770-781. Epub 2018 Dec 7

Steuber ER and McGuire JF. A meta-analysis of transcranial magnetic stimulation in obsessive-compulsive disorder. Biol Psychiatry Cogn Neurosci Neuroimaging. 2023 Nov;8(11):1145-1155.

Sun CH, et al. Adjunctive repetitive transcranial magnetic stimulation for adolescents with first-episode major depressive disorder: a meta-analysis. Front Psychiatry. 2023 Aug 1;14:1200738.

Trapp NT, et al.; National Network of Depression Centers Neuromodulation Task Group. Consensus review and considerations on TMS to treat depression: A comprehensive update endorsed by the National Network of Depression Centers, the Clinical TMS Society, and the International Federation of Clinical Neurophysiology. Clin Neurophysiol. 2025 Feb;170:206-233. Epub 2024 Dec 19.

Trevizol AP, et al. Effect of repetitive transcranial magnetic stimulation on anxiety symptoms in patients with major depression: An analysis from the THREE-D trial. Depress Anxiety. 2021 Mar;38(3):262-271. Epub 2020 Dec 11.

VA/DoD Clinical Practice Guideline [Internet]. Management of bipolar disorder (BP). 2023 May [accessed 2025 Dec 15]. Available from: https://www.healthquality.va.gov/guidelines/mh/bd/index.asp

VA/DoD Clinical Practice Guideline [Internet]. Management of major depressive disorder. 2022 Feb [accessed 2025 Dec 15] Available from: https://www.healthquality.va.gov/guidelines/MH/mdd/index.asp

VA/DoD Clinical Practice Guideline [Internet]. Management of post-traumatic stress disorder and acute distress disorder. 2023 Jun [accessed 2025 Dec 15]. Available from https://www.healthquality.va.gov/guidelines/MH/ptsd/

Voigt JD, et al. Theta burst stimulation for the acute treatment of major depressive disorder: A systematic review and meta-analysis. Translational Psychiatry. 2021;11(330):1-12.

Walton D, et al. Transcranial magnetic stimulation for the treatment of epilepsy. Cochrane database Syst Rev 2021 Apr 22;(4):CD011025.

Wilson S, et al. Systematic review of preservation TMS that includes continuation, maintenance, relapse-prevention, and rescue TMS. J Affect Disord. 2022 Jan;296:79-88.

Xie YJ, et al. Effect of repetitive transcranial magnetic stimulation on gait and freezing of gait in Parkinson disease: a systematic review and meta-analysis. Arch Phys Med Rehabil. 2020 Jan;101(1):130-140.

Yamazaki R, et al. Maintenance repetitive transcranial magnetic stimulation (rTMS) therapy for treatment-resistant depression: a study protocol of a multisite, prospective, non-randomized longitudinal study. Psychiatry. 2023 Jun;23:437.

Zhang W, et al. Efficacy of repetitive transcranial magnetic stimulation in Parkinson's disease: A systematic review and meta-analysis of randomised controlled trials. EClinicalMedicine. 2022 Jul 29;52:101589.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Transcranial Magnetic Stimulation (LCD) L33398 [accessed 2025 Dec 9]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid

guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.

- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 01/19 **Revised**: 10/21, 12/21, 10/23, 10/24, 12/24, 6/26 **Reviewed**: 01/21, 12/22, 12/23	
Date	**Summary of Changes**
6/2026	• Transitioned Transcranial Magnetic Stimulation (TMS) policy, 1370/20.000496 to Lifetime HealthCare Companies policy template.
12/2024	• Updated Medicare product variation to "subject to all terms and conditions noted above in the policy".
10/2024	• Added criteria for repeat TMS treatment: must have a 3-month gap in treatment. • Added verbiage that maintenance/continuation TMS treatment is not covered.
10/1/2023	• Added NPPs to policy as providers that can perform TMS, as per CMS.
1/1/2022	• Updated link in resources for source #4. • Updated criteria used to make medical necessity determinations • Criteria for Medicare is listed independently.

MEDICAL POLICY

Medical Policy Title	**Transendoscopic Therapies for Gastroesophageal Reflux Disease (GERD)**
Policy Number	**7.01.45**
Current Effective Date	**September 1, 2026**
Next Review Date	**March 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. The following transendoscopic procedures are considered **investigational** for the treatment of gastroesophageal reflux disease (GERD):

A. Thermal energy-based antireflux therapies applied to the gastroesophageal junction (e.g., Stretta procedure, anti-reflux mucosal ablation [ARMA]);

B. Endoscopic gastroplasty;

C. Endoscopic gastroplication (e.g., GERDx-System, Apollo OverStitch, EndoCinch, Syntheon ARD Plicator);

D. Transoral incisionless fundoplication (TIF) (e.g., EsophyX, MUSE);

E. Injection or implantation of biocompatible bulking agents (e.g., polymethylmethacrylate [PMMA] or plexiglas beads, Durasphere).

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Gastroesophageal reflux disease (GERD) is a prevalent condition characterized by classic symptoms such as heartburn and regurgitation, as well as other manifestations including chest discomfort, dysphagia, and chronic cough or throat clearing. While many individuals experience episodic reflux symptoms, a subset develops chronic GERD that increases the risk of complications such as erosive esophagitis, dysphagia, Barrett esophagus, and asthma.

The pathophysiology of GERD is multifactorial. Excessive acid exposure to esophageal mucosa may

occur due to dysfunction of the lower esophageal sphincter, impaired diaphragmatic support of the gastroesophageal junction, or abnormalities in esophageal clearance mechanisms. Delayed acid clearance increases the duration of exposure and enhances the potential for mucosal injury.

Current guideline-based management emphasizes a stepwise approach beginning with lifestyle modification (e.g., weight loss, smoking cessation, head of bed elevation, elimination of food triggers) and pharmacologic therapy such as antacids and proton pump inhibitors (PPIs).

For patients who continue to experience symptoms despite optimized medical therapy, or for whom procedural intervention is clinically appropriate, antireflux surgical and transesophageal endoscopic therapies may be considered. Nissen fundoplication, the most commonly performed antireflux procedure, reinforces the lower esophageal sphincter by wrapping a portion of the gastric fundus around the distal esophagus and, when indicated, concurrently repairing an associated hiatal hernia to restore normal anatomy.

Transesophageal endoscopic therapies have emerged as minimally invasive alternatives to long-term pharmacologic management or laparoscopic. These procedures, considered forms of natural orifice transluminal endoscopic surgery (NOTES), generally fall into three categories:

- Energy-based therapies. The Stretta procedure delivers controlled RF energy to the lower-esophageal sphincter (LES)/gastroesophageal junction (GEJ) and appears to modulate neuromuscular function, reduce transient LES relaxations, and decrease GEJ compliance. The precise mechanism remains uncertain. Anti-reflux mucosal ablation (ARMA) uses thermal mucosal ablation (e.g., electrocautery in spray coagulation mode) of the gastric cardia to induce fibrosis and tighten the GEJ.
- Endoluminal/endoscopic GEJ-reshaping procedures (e.g., mechanical plication, mucosal resection/remodeling, hybrid techniques) are designed to recreate a functional valve and reinforce the antireflux by folding or fastening the fundus or by inducing mucosal fibrosis/scar remodeling. Devices examples include Medigus Ultrasonic Surgical Endostapler (MUSE), GERDx-System, StomaphyX, Apollo Overstitch, Captivator EMR Device).
- Transoral incisionless fundoplication (TIF), also referred to as endoluminal fundoplication (ELF), reconstructs the gastroesophageal valve and reinforce the antireflux barrier using a specialized device passed transorally under endoscopic visualization. Gastric fundus tissue is drawn into a shaping mold and secured with polypropylene fasteners to create a 3–5 cm partial fundoplication without external incisions.
- Injection or implantation of a prosthetic or bulking agent is used to increase tissue bulk at the LES and reduce reflux. These materials are intended to augment the antireflux barrier by improving closure of the sphincter.

SUPPORTIVE LITERATURE

The evidence is insufficient to determine that transesophageal endoscopic therapies for the treatment of GERD (e.g., application of radiofrequency energy, gastroplication, TIF, and injection/implantation of prosthetic devices or bulking agents) results in an improvement in the net health outcome. Large-

scale, long-term controlled studies of these transendoscopic techniques are needed to establish the safety and efficacy of these procedures.

Meta-Analyses Comparing Multiple Antireflux Procedures

Yao et al (2024) conducted a systematic review and network meta-analysis to assess the efficacy of various antireflux interventions when compared to a control group of either PPIs or sham. A total of 19 randomized controlled trials (RCTs) (n=1181 subjects) met inclusion criteria. Four RCTs compared endoscopic band ligation (EBL; n=306 cases); 6 RCTs compared Stretta (235 cases); 5 RCTs compared TIF (340 cases), 2 RCTs compared endoscopic full-thickness plication (EFTP) (214 cases), and 2 RCTs compared EndoCinch (86 cases). This network meta-analysis found that TIF was significantly inferior to PPIs, EFTP, and EndoCinch in decreasing acid exposure. EBL was not inferior to TIF in improving GERD symptoms. The effect of EBL in increasing the LES pressure and improving acid exposure could not be concluded given that no relevant data were provided in the 4 RCTs involved. EBL and TIF may achieve equivalent efficacy in improving the Health-Related Quality of Life (HRQL) score and decreasing the incidence of esophagitis and PPIs utility in patients with GERD, and both may be superior to control and other types of endoscopic interventions. TIF may significantly increase the LES pressure and was superior to Stretta and EndoCinch. The mechanism of Stretta in GERD therapy remains a mystery, has not yet been fully clarified, and more studies are required. The authors concluded that given the limited number of included RCTs on different types of endoscopic treatments, indirect comparison, and inherent heterogeneity, the analysis results should be interpreted with caution. More well-designed and prospective multicenter RCTs with long-term follow-up are required to evaluate the long-term efficacy and safety of different endoscopic minimally invasive interventions in the treatment of GERD.

Tade et al (2025) conducted a meta-analysis of randomized and cohort studies (1980–2024) including adults with GERD who underwent fundoplication (Nissen, Toupet), magnetic sphincter augmentation (MSA), or transoral incisionless fundoplication (TIF). The analysis pooled 9,516 patients with available pre- and post-operative acid exposure time (AET), DeMeester score, and/or symptom relief scores (e.g., GERD-HRQL); the median follow-up was 12 months. Across procedures, AET, DeMeester scores, and symptom relief improved significantly. In multilevel meta-regression, TIF showed significantly less improvement than Nissen in AET ($p = 0.045$) and DeMeester ($p = 0.023$), while MSA and Toupet demonstrated significantly better symptom relief than Nissen (MSA $p = 0.044$; Toupet $p = 0.034$). The authors noted study-level heterogeneity and limitations, including incomplete data on hiatal hernia characteristics/repair techniques and procedural variations, and they did not meta-analyze postoperative complications (e.g., dysphagia, bloating) as primary outcomes. Overall, Nissen fundoplication demonstrated significantly better improvement with acid exposure and DeMeester score compared to MSA and TIF. However, symptom relief scores are significantly improved with Toupet fundoplication and MSA compared to other surgical treatment options.

Endoscopic Energy-Based Therapies

Kalapala et al (2017) published interim results from a small RCT of 20 patients randomized to PPI plus Stretta or PPI alone, with 3 months of follow-up. While short-term outcomes such as GERD symptoms and cessation of PPIs appeared improved for the Stretta group, the study sample was

small, and power calculations were not conducted.

Ma et al (2020) reported on a retrospective comparison of laparoscopic Toupet fundoplication with the Stretta procedure. The two groups were comparable at baseline in demographic characteristics, body mass index, GERD family history, and comorbid hypertension, coronary disease, and diabetes. Two patients in each group were lost to follow-up and excluded from the final analyses. At 12 months, there were no statistically significant differences between the laparoscopic Toupet fundoplication and Stretta groups in GERD relapse. However, compared to laparoscopic Toupet fundoplication, the Stretta group had a high DeMeester score (8.8 vs. 7.3; $p<.05$) and less LES pressure. Important limitations of this study are its single-center design and short follow-up time.

Zerbib et al (2020) published a double-blind RCT that compared Stretta plus proton pump inhibitor (PPI) therapy (n=29) to sham plus PPI therapy (n=33) in individuals with PPI-refractory heartburn from eight French centers. The primary endpoint was clinical success at week 24, defined as an intake of fewer than 7 PPI doses over the previous 2 weeks and adequate subjective patient-reported symptom control. Fewer patients achieved the primary endpoint in the Stretta group, but the difference was not statistically significant. Severe adverse events were more frequent in the Stretta group (7 vs. 2) and included epigastric pain (n=3), delayed gastric emptying, vomiting, headache, and 1 leiomyoma. Limitations of this RCT include that pH-impedance monitoring was not performed either at enrollment or during follow-up. Thus, baseline status of GERD diagnosis is unclear, and the physiologic effects of Stretta are unknown.

Xie et al (2021) published a systematic review and network meta-analysis of ten RCTs (n=516 participants) that evaluated the comparative effects of Stretta, TIF, and PPIs in patients with GERD. Of the included RCTs, five compared Stretta to control (PPI or sham + PPI) and five compared TIF to control (PPI or sham + PPI). Results of the network meta-analysis revealed that improvements in the health-related quality of life score induced by Stretta were not significantly different than the improvements seen with TIF; however, both Stretta and TIF were significantly superior to PPIs. Additionally, both Stretta and TIF were significantly better than PPIs at improving heartburn scores. With regard to reduction in PPI use and esophagitis incidence, no significant differences between TIF and Stretta were observed. This network meta-analysis had several limitations including a lack of assessment of long-term efficacy, the small number of studies, and lack of RCTs directly comparing Stretta and TIF, some comparisons were significantly affected by heterogeneity, and the evidence quality of each outcome ranged from moderate to very low.

Endoluminal/Endoscopic GEJ-Reshaping Procedures

Weitzendorfer et al (2018) conducted a prospective single-center one-arm trial on the clinical and functional outcomes of endoscopic full-thickness plication with GERDx-system. The study included 40 adult patients with at least one typical reflux symptom despite treatment with a PPI for at least 6 months, pathologic esophageal acid exposure, endoscopic Hill grade II–III, a hiatal hernia measuring < 2 cm and excluded individuals with Barrett's esophagus or esophageal motility disorders. Outcomes measured Evaluation of Gastrointestinal Quality of Life Index (GIQLI), symptom scores, esophageal manometry, and impedance-pH monitoring which were performed at baseline and at three months after surgery. Although 30 participants (75%) reported symptomatic improvement, the authors noted

grade A esophagitis persisted or recurred in about one-third of patients. Only 19 patients (63.3%) were off medication after application, which the authors report is similar to other endoscopic procedures like MUSE and Esophyx. The study was limited by the lack of randomization, small sample size, and the necessity of high operator expertise needed to achieve a good procedure outcome. Long-term outcomes are required to expand our knowledge of the effects of this procedure.

Kalapala et al (2022) published results of a randomized, sham-controlled, single-blinded clinical trial using a new endoscopic full-thickness fundoplication device, the GERD-X. A total of 70 individuals with PPI-dependent GERD were randomized to either GERD-X treatment or a sham procedure. The primary end point was ≥ 50% improvement in GERD-HRQL score at 3 months. This outcome was more frequently achieved in the GERD-X group vs. sham (65.7% vs 2.9%; p<0.001). In the GERD-X group, 62.8% of subjects were off-PPI at 12 months compared with 11.4% in the sham group (p<0.001). Overall, the procedure using the GERD-X device was found to be effective at reducing GERD symptoms and improving quality of life. However, in this small, short-term study, reflux was not assessed objectively at the end of 12-month follow-up in all subjects. The authors concluded that large, prospective trials with long-term follow-up are required to conclude the benefits of this procedure after 1 year.

Liu et al (2019) evaluated the short-term efficacy of clip band ligation anti-reflux therapy (C-BLART), a new alternative endoscopic treatment for controlling GERD symptoms, esophageal acid exposure, esophagitis, and quality of life. Patients with refractory GERD were recruited for a nonrandomized concurrent comparison, with 60 patients in the C-BLART with tailored PPI use group and 43 patients in the BID proton pump inhibitor (PPI) group. Crossover from the BID PPI group to the C-BLART with tailored PPI use group was allowed after 6 months. The LES pressure and GERD-Q score improved more in the C-BLART with tailored PPI use group ($P < 0.001$) after 6 months, with no significant difference in the decrease in esophagitis compared with the baseline endoscopic results ($P = 0.268$). Treatment with PPIs had been halted in 43% of the patients at 6 months after C-BLART. At 12 months after C-BLART, the DeMeester score showed a significant improvement compared with the baseline measurements ($P = 0.025$). The GERD-Q score and LES pressure did not significantly improve compared with the baseline values ($P = 0.102$, $P = 0.184$) in C-BLART with tailored PPI use group. At 6 to 12 months, $n = 6$ (10%) patients had undergone laparoscopic fundoplication to control their symptoms in all the patients after C-BLART. The authors concluded that C-BLART is a novel treatment for controlling refractory GERD symptoms, esophageal acid exposure, and LES pressure according to this short-term analysis, safely performed endoscopically to create an anti-reflux barrier with ligated bands. Despite improvements in DeMeester score, LES pressure, and GERD-Q scores in the C-BLART with tailored PPI use group, many patients continue to demonstrate objective evidence of GERD.

Antireflux Mucosal Interventions

Al-Obaidi (2025) conducted a systematic review and meta-analysis that evaluated the efficacy of antireflux mucosal ablation (ARMA) and antireflux mucosectomy (ARMS). The meta-analysis included studies reporting pre- and post-procedure esophageal 24-hour pH monitoring following ARMA and ARMS. Based on pooled data from three studies, ARMA demonstrated a significant post-procedure decrease in median acid exposure time (AET) with a standardized mean difference of -20.74 (p <

0.0001). Based on six studies, ARMS showed a significant reduction in DeMeester score (SMD: -2.79, $p < 0.0001$). The overall clinical success rate, defined as significant symptom improvement or reduced reliance on proton pump inhibitors, was 87% for ARMA and 78% for ARMS. The authors concluded that both procedures displayed promising efficacy in improving GERD-related outcomes, though they noted high heterogeneity suggesting further research is needed to identify patient-specific factors influencing treatment response.

Transoral Incisionless Fundoplication (TIF)

Current evidence is insufficient to determine the effect of this intervention on the net health outcome in patients whose symptoms are adequately controlled by PPIs.

Trad et al (2015; 2017; 2018) conducted TEMPO, prospective, randomized, multicenter trial comparing TIF 2.0 (n=40) with maximal-dose PPI therapy (n=23), with the primary endpoint of symptom elimination. At 6 months (pre-crossover), TIF eliminated troublesome regurgitation significantly more often than PPIs (97% vs 50%, $p = 0.006$), whereas pH normalization rates were not significant between groups (54% off PPI after TIF vs 52% on PPI in the control arm; $p = 0.914$). By the 3-year follow-up, all patients in the control group had crossed over to TIF and were included in the follow-up. Among 63 TIF-treated patients, 83% had available data on PPI use, with 71% reporting cessation, and 77% had evaluable symptom and pH data, showing pH normalization in 40% and resolution of troublesome regurgitation in 90%. At 5 years, follow-up data were available for 44 patients, of whom 86% continued to show elimination of troublesome regurgitation, 34%–43% were completely off PPIs, and GERD-HRQL scores remained improved with high satisfaction. No serious adverse events were reported, and 3 reoperations occurred over 5 years. Overall, the long-term results suggest that TIF provides durable improvement in regurgitation symptoms with moderate rates of PPI discontinuation, supporting its use in selected GERD patients seeking a minimally invasive alternative to medical therapy.

Testoni PA et al (2015 and 2019) published sequential prospective single-center cohorts evaluating the long-term durability of TIF using the EsophyX device. The 2015 study reported outcomes in 50 patients (51 procedures) followed for up to 6 years, with technical success in 48/50 and severe complications in 2/51 procedures. Patients experienced significant early improvement in GERD-HRQL, regurgitation scores, and PPI dependence. The subsequent 2019 study extended follow-up and demonstrated that the improvements in GERD-HRQL observed at 2 years were maintained without substantial decline through the 10-year period; however, at 10 years, only 14 patients had evaluable follow-up, which limits generalizability of the apparent durability. The proportions of patients who discontinued or halved PPI therapy were 86.7%, 84.4%, 73.5%, 83.3%, and 91.7% at 2, 3, 5, 7, and 10 years, respectively. Non-responders (n=7) ultimately underwent surgical fundoplication, and some patient attrition occurred over time. These findings suggest that symptom control and reduced PPI use can be maintained long-term (6-10 years) after EsophyX-based TIF in selected patients; however, the single-arm observational design, modest sample size, and loss to follow-up limit generalizability.

Richter et al (2018) performed a systematic review and network meta-analysis of RCTs completed through May 2017 to compare the relative efficacies of TIF and laparoscopic Nissen fundoplication

(LNF) in GERD. Across seven trials (n=1,128 patients), LNF demonstrated the highest probability of improving physiologic GERD parameters, including increased LES pressure and reduced esophageal acid exposure. TIF ranked below LNF and PPIs on most objective measures, and the authors concluded that LNF is superior to TIF and PPIs for improving physiologic parameters of chronic GERD, including increased LES pressure and decreased percent time pH. TIF was not recommended as a long-term alternative to PPI or LNF treatment of GERD, as long-term efficacy has not been demonstrated.

Chimukangara et al (2019) performed a single-center, retrospective cohort study evaluating long-term outcomes in 57 patients who underwent TIF (EsophyX) between 2007 and 2014 at a large academic medical center. All patients had symptomatic GERD and were taking a PPI at least daily. Patients were excluded for hiatal hernia > 2 cm, LA grade C or D esophagitis, or biopsy-proven Barrett's esophagus. Reflux symptoms and GERD-HRQL were assessed at baseline, short-term (median 12 months, n=36), and long-term (median 97 months, n=23) follow-up. Twelve patients (21%) underwent subsequent laparoscopic antireflux surgery during follow-up, including five within the first year. GERD-HRQL improved from 24 at baseline to 7 at short-term and 10 at long-term ($p < 0.01$ for both). Dissatisfaction with symptom control decreased from 100% at baseline to 26% at long-term. While most patients were on twice-daily PPI therapy pre-TIF, 73% of those who resumed PPIs long-term were on daily PPI therapy (20 mg or 40 mg). The study is limited by its retrospective design, small sample size, single-institution setting, and lack of a matched LARS comparison group. The authors concluded that TIF can provide durable improvements in disease-specific quality of life for some patients with GERD, although many resume antisecretory medications long-term, and most report ongoing satisfaction with symptom management.

Testoni SGG et al (2021) published a systematic review and meta-analysis examining long-term outcomes (≥ 3 years) after TIF performed with the EsophyX device, with outcomes including patient satisfaction, QoL, and PPI use. Among the 8 included studies (n=418; only one open-label RCT) the mean follow-up was 5.3 years, and many patients reported symptom improvement and reduced PPI use, with pooled satisfaction increasing from 12.3% pre-procedure to 70.6% post-procedure, 53.8% completely off PPIs and 75.8% off or on only occasional PPIs at long-term follow-up, mean GERD-HRQL improving from 26.1 to 5.9 (off PPIs), and normalization rates of 73% for heartburn and 86% for regurgitation. The analysis was limited by marked heterogeneity and the predominance of non-controlled designs (only one open-label RCT). The authors conclude that TIF appears to be a safe long-term option for selected patients who decline or cannot tolerate prolonged PPI therapy or surgery.

Testoni SGG et al (2022) conducted a prospective, single-center observational study evaluating the clinical, functional, and endoscopic effects of TIF performed with the MUSE device in 46 adults with chronic (≥ 6 months) GERD symptoms, partial or complete response to PPI therapy, non-erosive reflux disease (NERD) or hypersensitive esophagus, Barrett's esophagus < 3 cm, and BMI < 40 kg/m^2. TIF was successfully completed in 45/46 cases, with two perforations requiring surgery (4.4%) and one additional patient undergoing Nissen fundoplication within 6 months for lack of efficacy, after which these patients were excluded from follow-up analyses. The study showed significant symptom improvement with PPI cessation in 64.3%, 62.9%, and 74.2% of patients at 1,

2, and 3 years (corresponding ITT rates 58.7%, 56.4%, 65.7%), and ≥ 50% reductions in GERD-HRQL and Reflux Symptom Index (RSI) scores were sustained through 3 years; however, esophagitis persisted in about one-third of patients at 1 year, and improvements in pH-impedance observed at 6 months were not maintained at 1 year, although high-resolution manometry (HRM) at 6 months showed increases in LES length and peristaltic waves. The authors note limitations including small sample size, inclusion limited to mild (grade A) esophagitis, lack of a control group, and the need for larger randomized trials with longer-term follow-up.

Canto et al (2025) conducted a prospective, multicenter cohort registry study across nine academic and community centers enrolling adults with confirmed GERD, body mass index <35 kg/m², and hiatal hernia < 2 cm who underwent TIF 2.0. Primary outcomes were safety and clinical success (defined as response in 1 subjective and at least 1 of 3 objective secondary endpoints), and secondary outcomes included symptom improvement, esophageal acid exposure time (AET), esophagitis healing, proton pump inhibitor (PPI) use, and satisfaction. Patients completed surveys and postprocedure adverse assessments at 1-, 6-, and 12-months. Of 85 patients treated, 81 were included in the analysis. Clinical success was achieved in 94%, GERD-Health-Related Quality of Life improved in 89%, Reflux Symptom Index normalized in 85% of those with elevated baseline, patient satisfaction increased from 8% to 79% (P<.0001), and daily PPI use decreased from 81% at baseline to 80% on no or occasional PPI after TIF 2.0 (P<.0001). AET normalized in 72% overall and was more likely when an optimized TIF 2.0 valve (> 300° circumference and > 3-centimeter length) was achieved (94% vs 57%; P=.007). No TIF 2.0-related serious adverse events were reported. The authors conclude that TIF 2.0 is a safe and effective outpatient endoscopic option for appropriately selected patients with GERD. Larger prospective studies of long-term outcomes, particularly for concomitant hiatal hernia repair with TIF (cTIF), are needed to compare safety, effectiveness, and durability with surgical antireflux approaches.

Prosthetic or Bulking Agents

High-quality data from large RCTs are needed to compare bulking procedures with both sham controls and with the currently accepted treatments for GERD (i.e., drug therapy, laparoscopic fundoplication) to determine the effects on health outcomes.

The available evidence for Durasphere consists of a single case series. One open-label pilot study by Ganz et al (2009) assessed ten patients diagnosed with GERD and injected with Durasphere (Carbon Medical Technologies). At 12 months, seven patients (70%) discontinued all antacid medication completely. No erosion, ulceration, or sloughing of the material was noted at any injection site.

The available evidence for polymethylmethacrylate beads consists of a single case series that evaluated transesophageal submucosal implantation of polymethylmethacrylate beads in ten patients with GERD who were either refractory to or dependent on PPIs (Feretis 2001). While a significant decrease in symptom scores was noted at posttreatment follow-up (time not specified), the small number of patients and lack of long-term follow-up precluded scientific analysis.

PROFESSIONAL GUIDELINE(S)

In 2025, the American Society for Gastrointestinal Endoscopy (ASGE; Desai) published updated

guidelines on the diagnosis and management of gastroesophageal reflux disease (GERD). In patients with GERD symptoms, the ASGE made a strong recommendation for lifestyle modification (e.g., dietary changes, weight loss when indicated, head-of-bed elevation), and medical management with PPIs at the lowest dose for the shortest duration. Recommendations for endoscopic therapies include:

- Conditional recommendation: Transoral incisionless fundoplication (TIF) may be considered as an alternative to chronic medical management for patients with confirmed GERD, small hiatal hernia (≤ 2 cm), Hill grade I or II, and any of the listed criteria (including GERD ≥ 6 months, chronic PPI use ≥ 6 months, refractory GERD, regurgitation-predominant GERD patient preference for avoidance of long-term PPI use).
    - Overall, the certainty in the evidence was moderate to very low. TIF 2.0 showed short-term improvement with durable symptom remission up to 5 years with relatively low serious adverse event rates.
- Conditional recommendation: Combined hiatal hernia repair with TIF (cTIF) may be considered for patients with large hiatal hernia (> 2 cm) and Hill grade III or IV, in a multidisciplinary review.
    - Overall, the certainty of the evidence was very low. The panel considered the evidence as important but inadequate. Evidence for surgical therapies has been established and whether cTIF is comparable is not yet established with high-quality data.
- Best practice advice: Radiofrequency energy to the lower esophageal sphincter (e.g., Stretta) may be considered when other alternatives (e.g., endoscopic, or surgical fundoplication) are not available or feasible.
    - Overall, the certainty in the evidence was low to very low. The panel acknowledged that evidence on Stretta has been affected by differing results from RCTs and cohort studies. Existing challenges include lack of durable benefit, no effect on PPIs, no effect on acid exposure, higher adverse events, better available treatments. Stretta is only applicable for GERD patients with small hiatal hernias (≤ 2 cm) and Hill grade I or I.
- No recommendation for or against the following novel endoscopic antireflux therapies due to insufficient controlled long-term data: endoscopic full-thickness fundoplication (EFTP) using device GERDxTM, MUSE, antireflux mucosectomy (ARMS), antireflux mucosal ablation (ARMA).

Slater et al (2023) published a multi-society consensus guideline with recommendations on the treatment of GERD. The panel suggests that adult patients with GERD may benefit from:

- Either MSA or Nissen fundoplication based on surgeon and patient shared decision making. (Conditional recommendation, very low certainty of evidence).
    - The panel judged that the desirable and undesirable effects were balanced and thus favored neither MSA nor Nissen fundoplication.
- Fundoplication over TIF 2.0 (Expert Opinion recommendation; Grade recommendation was unable to be determined due to lack of evidence).

  - The low level of worldwide adoption of endoscopic treatment with TIF 2.0 is correlated with lack of sufficient comparative trials.
- TIF 2.0 over continued PPI (Conditional recommendation, moderate certainty of evidence).
  - TIF 2.0 is an intervention for those who want to avoid both traditional surgery and lifelong medication. Additional long-term prospective comparative studies of TIF (and especially combined laparoscopic hiatal hernia repair and endoscopic TIF) versus fundoplication (partial fundoplication in particular) are needed.
- Fundoplication over Stretta (Conditional recommendation, very low certainty of evidence).
- Stretta over PPI (Conditional recommendation, low certainty of evidence).
- Partial fundoplication compared to complete fundoplication. (Conditional recommendation, moderate certainty of evidence).

In 2022, the American Gastroenterological Association (AGA) issued a clinical practice update on the personalized approach to the evaluation and management of GERD (Yadlapati 2022). The guideline states "transoral incisionless fundoplication is an effective endoscopic option in carefully selected patients" with proven GERD. The guideline further stated that TIF has "demonstrable value in patients with regurgitation-predominant GERD" and that "further research into risks/benefits, durability, effectiveness, and treatment outcomes will enhance optimal utilization" as part of a personalized approach to treatment.

In 2022, the American College of Gastroenterology (ACG) issued guidelines on the diagnosis and management of GERD include the following recommendations for surgical and endoscopic options for GERD (Katz 2022):

- Recommend consideration of magnetic sphincter augmentation (MSA) as an alternative to laparoscopic fundoplication for patients with regurgitation who fail medical management. (Strong, moderate level of evidence)
- Suggest consideration of Roux-en-Y gastric bypass (RYGB) as an option to treat GERD in obese patients who are candidates for this procedure and who are willing to accept its risks and requirements for lifestyle alterations. (Conditional, low level of evidence)
- No recommendation for radiofrequency energy (Stretta) as an alternative to medical or surgical antireflux therapies since data on the efficacy is inconsistent and highly variable. (Conditional, low level of evidence)
- Suggest consideration of TIF for patients with troublesome regurgitation or heartburn who do not wish to undergo antireflux surgery and who do not have severe reflux esophagitis or hiatal hernias > 2 cm. (Conditional, low level of evidence)

Gawron et al (2020) published recommendations from an expert U.S. panel, facilitated by the American Foregut Society, for adults with objectively confirmed GERD. The panel concluded that optimization of medical therapy with continued PPI and tapering to the lowest effective dose is appropriate for complete responders without a significant hernia. For PPI non-responders, invasive

therapy should be pursued only when objective evidence of abnormal reflux is present (e.g., positive impedance-pH on PPI), recommending:

- Laparoscopic fundoplication (LF) and magnetic sphincter augmentation (MSA) are appropriate options for complete or partial PPI responders regardless of whether a clinically significant hiatal hernia is present.
- Transoral incisionless fundoplication (TIF) is considered appropriate for complete or partial responders without a clinically significant hiatal hernia.
- Radiofrequency energy delivery is not appropriate for complete or partial responders.

National Institute for Health and Care Excellence (NICE) issued the following interventional practice guidelines (IPG) for the treatment of GERD:

- In 2023 (IPG753), NICE concluded that the evidence on the safety of endoluminal gastroplication for gastroesophageal reflux disease is adequate; however, evidence on its efficacy is inadequate in quality, particularly in terms of patient selection and long-term outcomes. Therefore, this procedure should be used only in research.
- In 2013 (IPG461), NICE concluded that the evidence on the safety of endoscopic radiofrequency ablation for gastro-esophageal reflux disease is adequate in the short and medium term, but there is uncertainty about longer-term outcomes. There is evidence of symptomatic relief, but objective evidence on reduction of reflux is inconclusive.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates devices for transendoscopic procedures as medical devices. All devices require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed 2026 Jan 27]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: https://www.fda.gov/medical-devices/medical-device-safety/medical-device-recalls-and-early-alerts [accessed 2026 Jan 27]

Radiofrequency Thermal Energy

In 2000, the Stretta System was cleared for marketing by the FDA through the 510(k) process for general use in the electrosurgical coagulation of tissue and was specifically intended for use in the treatment of GERD. In 2010, Mederi Therapeutics began manufacturing the Stretta device. Mederi was acquired by Respiratory Technology Corporation in 2018.

Endoluminal Endoscopic GEJ-Reshaping

The Medigus Ultrasonic Surgical Endostapler (MUSE), formerly the SRS Endoscopic Stapling System, was cleared for marketing by the FDA through the 510(k) process in 2012 (K120299) and 2014 (K132151). MUSE is intended for endoscopic placement of surgical staples in the soft tissue of the

esophagus and stomach to create anterior partial fundoplication for the treatment of symptomatic chronic GERD in patients who require and respond to pharmacologic therapy.

The EsophyX (EndoGastric Solutions) is a transesophageal (or transoral) incisionless fundoplication (TIF) device that was originally cleared for marketing by the FDA through the 510(k) process in 2007 and has subsequently undergone 2 evolutions: Generation 2=EsophyX2 iterations (E2-Plus, HD) and Generation 3=Z iterations (EZ/ZR, Z+). In 2007, EsophyX (EndoGastric Solutions) was cleared for marketing by the FDA through the 510(k) process for full-thickness plication. In 2016, EsophyX Z Device with SerosaFuse Fasteners was cleared for marketing by the FDA through the 510(k) process (K160960) for use in transoral tissue approximation, full-thickness plication, ligation in the gastrointestinal tract, narrowing the gastroesophageal junction, and reduction of hiatal hernias of 2 cm or less in patients with symptomatic chronic GERD. In June 2017, EsophyX2 HD and the third-generation EsophyX Z Devices with SerosaFuse fasteners and accessories were cleared for marketing by the FDA through the 510(k) process (K171307) for expanded indications, including patients who require and respond to pharmacologic therapy and patients with hiatal hernias larger than 2 cm when a laparoscopic hiatal hernia repair reduces a hernia to 2 cm or less. An additional FDA 510(k) clearance (K172811) occurred in October 2017 for new product specification iterations of EsophyX2 HD and EsophyX Z Devices. This clearance allows for "a moderate increase in the upper limit of the temporary Tissue Mold clamping pressure occurring during each fastener deployment." A 2024 FDA 510(k) clearance (K240879) updated instructions for use and other device labeling.

The GERDx-System was cleared through the 510(k) process in 2024 (K233240) for endoscopic full-thickness plication in individuals with chronic GERD who require and respond to pharmacological therapy. The device was found substantially equivalent to the NDO Surgical Endoscopic Plication System (K071553), which was cleared in 2007 for the treatment of chronic GERD but was later removed from the market due to durability concerns and limited long-term clinical effectiveness. The GERDx-System incorporates technological refinements intended to improve safety and performance compared with its predicate device.

The Bard EndoCinch Suturing System received FDA 510(k) clearance on January 5, 2001 (K003956), and the NDO Surgical Endoscopic Plication System (Plicator) received FDA 510(k) clearance on April 17, 2003 (K023234) for the treatment of chronic GERD. Although both devices were cleared for marketing for the treatment of GERD, they are no longer available for clinical use in the United States. They were discontinued or withdrawn from the market due to limited efficacy, durability concerns, and lack of sustained commercial adoption.

Esophageal Bulking Agents

Durasphere and plexiglas (PMMA) do not currently have FDA approval for use in an anti-reflux application. The Gatekeeper System was withdrawn in late 2005, before FDA approval. Enteryx received FDA clearance 2003 and was recalled from market October 2005 based on a joint decision by the FDA and Boston Scientific. The recall was initiated by Boston Scientific, based upon growing data evidence of serious adverse effects.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
43192 (E/I*)	Esophagoscopy, rigid, transoral; with directed submucosal injection(s), any substance Excludes: Injection of sclerosis esophageal varices: Flexible, transoral (43204); Rigid, transoral (43192, 43499) (*E/I when used to report injection of a bulking agent or any other submucosal injection to treat GERD)
43201 (E/I*)	Esophagoscopy, flexible, transoral; with directed submucosal injection(s), any substance Excludes: Injection of sclerosis esophageal varices: Flexible, transoral (43204); Rigid, transoral (43192, 43499) (*E/I when used to report injection of a bulking agent or any other submucosal injection to treat GERD)
43210 (E/I*)	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed (*E/I when used to report any endoscopic treatment for GERD)
43236 (E/I*)	Esophagogastroduodenoscopy, flexible, transoral; with directed submucosal injection(s), any substance Excludes: Flexible, transoral; with control bleeding, any method (43255); Flexible, transoral; with injection sclerosis esophageal/gastric varices (43243); Injection sclerosis varices, esophageal/gastric (43243) (*E/I when used to report injection of a bulking agent or any other submucosal injection to treat GERD)
43257 (E/I)	Esophagogastroduodenoscopy, flexible, transoral; with delivery of thermal energy to the muscle of lower esophageal sphincter and/or gastric cardia, for treatment of gastroesophageal reflux disease (e.g., Stretta procedure)

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HCPCS Codes

Code	Description
Not Applicable	

ICD10 Codes

Code	Description
K21.0 - K21.9	Gastro-esophageal reflux disease (code range)
K44.0 - K44.9	Diaphragmatic hernia (code range)

REFERENCES

Al-Obaidi H, et al. The efficacy of antireflux mucosectomy (ARMS) and antireflux mucosal ablation (ARMA) for gastroesophageal reflux disease (GERD) by 24-h pH monitoring: systematic review and meta-analysis. Surg Endosc. 2025 Aug;39(8):4752-4764

American Society for Gastrointestinal Endoscopy (ASGE) Standards of Practice Committee; Desai M, et al. American Society for Gastrointestinal Endoscopy guideline on the diagnosis and management of GERD: summary and recommendations. Gastrointest Endosc. 2025 Feb;101(2):267-284. Epub 2024 Dec 17.

Canto MI, et al. Outcomes of transoral incisionless fundoplication (TIF 2.0): a prospective multicenter cohort study in academic and community gastroenterology and surgery practices (with video). Gastrointest Endosc. 2025 Jan;101(1):90-102.e1.

Chimukangara M, et al. Long-term reported outcomes of transoral incisionless fundoplication: an 8-year cohort study. Surg Endosc. 2019 Apr;33(4):1304-1309. Epub 2018 Aug 27.

Cohen LB, et al. Enteryx implantation for GERD: expanded multicenter trial results and interim post approval follow-up to 24 months. Gastrointest Endosc. 2005 May;61(6):650-8.

Fass R, et al. Systematic review, and meta-analysis of controlled and prospective cohort efficacy studies of endoscopic radiofrequency for treatment of gastroesophageal reflux disease. Surg Endosc. 2017 Dec;31(12):4865-4882.

Feretis C, et al. Endoscopic implantation of Plexiglas (PMMA) microspheres for the treatment of GERD. Gastrointest Endosc. 2001;53(4):423-426.

Ganz RA, et al. A new injectable agent for the treatment of GERD: results of the Durasphere pilot trial. Gastrointest Endosc. 2009;69(2):318-323.

Gawron AJ, et al. Surgical and endoscopic management options for patients with GERD based on proton pump inhibitor symptom response: recommendations from an expert U.S. panel. Gastrointest Endosc. 2020 Jul;92(1):78-87.e2.

Jaber F, et al. Concomitant hiatal hernia repair with transoral incisionless fundoplication for the treatment of refractory gastroesophageal reflux disease: a systematic review. Surg Endosc. 2024

Oct;38(10):5528-5540.

Janu P, et al. Laparoscopic hiatal hernia repair followed by transoral incisionless fundoplication with EsophyX device (HH + TIF): efficacy and safety in two community hospitals. Surg Innov. 2019 Dec; 26(6):675–686.

Kalapala R, et al. Endoscopic full-thickness plication for the treatment of PPI-dependent GERD: results from a randomised, sham controlled trial. Gut. 2022;71:686-694.

Kalapala R, et al. Treatment of gastroesophageal reflux disease using radiofrequency ablation (Stretta procedure): an interim analysis of a randomized trial. Indian J Gastroenterol. 2017 Sep;36(5): 337-342.

Katz PO, et al. ACG clinical guideline for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol 2022 Jan 01;117(1):27-56.

Liu S, et al. New treatment method for refractory gastroesophageal reflux disease (GERD): C-BLART (clip band ligation anti-reflux therapy)-a short-term study. Surg Endosc. 2020 Oct;34(10):4516-4524.

Ma L, et al. Stretta radiofrequency treatment vs Toupet fundoplication for gastroesophageal reflux disease: a comparative study. BMC Gastroenterol. 2020 May 27;20(1):162.

Maydeo A, et al. Endoscopic full-thickness plication for the treatment of gastroesophageal reflux after peroral endoscopic myotomy: a randomized sham-controlled study. Endoscopy. 2023;55(08):699-700.

National Institute for Health and Clinical Excellence (NICE) [Internet]. Endoluminal gastroplication for gastro-oesophageal reflux disease. Interventional procedures guidance [IPG753]. 2023 Mar 01 [accessed 2026 Feb 24]. Available from: https://www.nice.org.uk/guidance/ipg753

National Institute for Health and Clinical Excellence (NICE) [Internet]. Endoscopic radiofrequency ablation for gastro-oesophageal reflux disease. Interventional procedures guidance [IPG461]. 2013 Aug 28 [accessed 2026 Feb 24]. Available from: https://www.nice.org.uk/guidance/ipg461

Rausa E, et al. Efficacy of laparoscopic Toupet fundoplication compared to endoscopic and surgical procedures for GERD treatment: a randomized trials network meta-analysis. Langenbecks Arch Surg. 2023 Jan 21;408(1):52.

Richter JE, et al. Efficacy of laparoscopic nissen fundoplication vs transoral incisionless fundoplication or proton pump inhibitors in patients with gastroesophageal reflux disease: a systematic review and network meta-analysis. Gastroenterology. 2018 Apr;154(5):1298-1308.

Slater BJ, et al. Multi-society consensus conference and guideline on the treatment of gastroesophageal reflux disease (GERD). Surg Endosc. 2023 Feb;37(2):781-806. Also available from: https://www.sages.org/publications/guidelines/multi-society-consensus-conference-and-guideline-on-the-treatment-of-gerd/ [accessed 2026 Jan 27]

Testoni PA, et al. Long-term efficacy of transoral incisionless fundoplication with Esophyx (Tif 2.0) and factors affecting outcomes in GERD patients followed for up to 6 years: a prospective single-center study. Surg Endosc. 2015 Sep;29(9):2770-80.

Testoni SGG, et al. Long-term outcomes of transoral incisionless fundoplication for gastro-esophageal reflux disease: systematic-review and meta-analysis. Endosc Int Open. 2021 Feb;9(2):E239-E246.

Testoni PA, et al. Transoral incisionless fundoplication with EsophyX for gastroesophageal reflux disease: clinical efficacy is maintained up to 10 years. Endoscopy International Open. 2019;07: E647–E654.

Testoni SGG, et al. Transoral incisionless fundoplication with Medigus ultrasonic surgical endostapler (MUSE) for the treatment of gastro-esophageal reflux disease: outcomes up to 3 years. Surg Endosc. 2022 Jul;36(7):5023-5031.

Trad KS, et al. The TEMPO trial at 5 years: transoral fundoplication (TIF 2.0) is safe, durable, and cost-effective. Surgical Innovation 2018;25(2):149–157.

Trad KS, et al. Transoral fundoplication offers durable symptom control for chronic GERD: 3-year report from the TEMPO randomized trial with a crossover arm. Surg Endosc. 2017 Jun;31(6):2498-2508. Epub 2016 Sep 21.

Trad KS, et al. Transoral incisionless fundoplication effective in eliminating GERD symptoms in partial responders to proton pump inhibitor therapy at 6 months: the TEMPO Randomized Clinical Trial. Surg Innov. 2015 Feb;22(1):26-40.

Weitzendorfer M, et al. Clinical feasibility of a new full-thickness endoscopic plication device (GERDx) for patients with GERD: results of a prospective trial. Surg Endosc. 2018 May;32(5):2541-2549.

Xie P, et al. Efficacy of different endoscopic treatments in patients with gastroesophageal reflux disease: a systematic review and network meta-analysis. Surg Endosc. 2021 Apr;35(4):1500-1510.

Yadlapati P, et al. AGA clinical practice update on the personalized approach to the evaluation and management of GERD: expert review. Clin Gastroenterol Hepatol. 2022 May;20(5):984-994.e1.

Yao L, et al. Efficacy of different endoscopic treatments for gastroesophageal reflux disease: a systematic review and network meta-analysis. J Gastrointest Surg. 2024 Jul;28(7):1051-1061.

Zerbib F, et al. Randomised clinical trial: oesophageal radiofrequency energy delivery versus sham for PPI-refractory heartburn. Aliment Pharmacol Ther. 2020 Aug;52(4):637-645.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Select Minimally Invasive GERD Procedures (LCD L35080) [accessed 2026 Feb 24]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a

specific service, medical policy criteria apply to the benefit.

- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 5/26 **Revised**: **Reviewed**:	
Date	**Summary of Changes**
9/1/2026	• New: Service was previously referenced on Non-Covered Technology policy 1370/20.000444.

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: TRANSITIONAL CARE – NEW ENROLLEE

POLICY EFFECTIVE DATE:	6/14/2023
Policy Control #:	1370/20.000194
Next Annual Review:	July, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgement when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

DESCRIPTION

Care provided by a non-participating provider to a new enrollee of the Plan to ensure continuity of care and a smooth transition to a participating provider.

POSITION STATEMENT

CDPHP allows a new enrollee to continue an ongoing course of treatment with their current, non-participating health care provider during a transitional period of up to 60 days from the effective date of enrollment, when they are receiving services for **ONE** the following conditions:

- A life-threatening disease or condition defined as one that, according to the current diagnosis of the attending physician, has a high probability of death.
- A degenerative and disabling condition defined as any medically determinable physical or mental condition or disease which, according to the current diagnosis of the enrollee's attending physician requires specialized medical care over a prolonged period of time
- A new enrollee who is in the second or third trimester of pregnancy at the effective date of enrollment, in which case the transitional period includes the provision of post-partum services directly related to the delivery.

In addition, the provider must agree to all of the following:

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: TRANSITIONAL CARE – NEW ENROLLEE

- Accept the CDPHP reimbursement rates.
- Adhere to the CDPHP quality management requirements.
- Provide CDPHP with necessary medical information related to care rendered.
- Adhere to all the CDPHP policies and procedures in rendering care to the enrollee, including but not limited to the referral process, obtaining pre-authorizations when indicated, and providing a treatment plan for review and approval.
- Only render care for those services provided for in the enrollee's contract.
- Provider must sign a statement/letter indicating agreement to the above terms and conditions.

POLICY CONSIDERATIONS

Enrollees requiring transitional care will be assigned a case manager to assist both enrollee and provider with referral and authorization of services, and to ensure a smooth transfer of care to a participating provider.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy. • Child Health Plus defines postpartum period as a 12-month timeframe.
MEDICARE ADVANTAGE	New enrollees must transition all care to Medicare Advantage network providers upon effective date.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy. • Medicaid defines postpartum period as a 12-month timeframe. In the absence of a written agreement to the Plan's fee schedule, CDPHP will reimburse non-participating providers at the Medicaid fee-for-service rates to ensure continuity of care.

SOURCES

1. NYS Public Health Law, Article 44; §4403, http://public.leginfo.state.ny.us/lawssrch.cgi?NVLWO:

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

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POLICY NAME: TRANSITIONAL CARE – NEW ENROLLEE

2. Member Contract Language
3. Department of Health

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POLICY APPROVAL DATES

New:	10/98
Revised:	08/99, 02/00, 07/00, 09/02, 09/03, 04/05, 07/09, 07/10, 07/12, 07/16, 07/17, 07/18, 7/21, 7/23, 9/23, 7/24, 7/25
Reviewed:	07/04, 03/06, 02/07, 01/08, 07/08, 07/09, 7/11, 07/13, 07/14, 07/15, 07/19, 7/20, 7/22, 7/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
6/14/2023 *No change to effective date of policy	Under the Position Statement clarified that only one of the bullets needs to be met.
6/14/2023 *No change to effective date of policy	No changes to criteria. Clarified a degenerative and disabling condition.
6/14/2023	Under the CHP section, added new DOH update that extends the postpartum timeframe to 12 months.
3/1/2023	Under the Position Statement, clarified inclusion of a new enrollee in either their second or third trimester. Under the Medicaid section, added new DOH update that extends the postpartum timeframe to 12 months.
8/1/21	Removed statement regarding pre-existing conditions in the Policy Considerations section.

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: TRANSITIONAL CARE – NEW ENROLLEE

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: TRANSITIONAL CARE – PROVIDER LEAVES THE NETWORK

POLICY EFFECTIVE DATE:	6/14/2023
Policy Control #:	1370/20.000195
Next Annual Review:	July, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

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DESCRIPTION

Care rendered by an enrollee's health care practitioner who leaves the CDPHP participating network, for reasons other than imminent harm to patient care, a determination of fraud or a final disciplinary action by a state licensing board or other governmental agency that impairs the health care practitioner's ability to practice, to ensure continuity of care and a smooth transition to a participating practitioner.

POSITION STATEMENT

CDPHP allows an enrollee to continue an ongoing course of treatment with their current health care provider for a transitional period of up to 90 days, from either the date of notice or the effective date of termination, whichever is later **or**

If the enrollee is pregnant and undergoing a course of treatment for the pregnancy on the date the provider's contractual obligation to provide services to CDPHP enrollees terminates. In which case, the transitional period (which could extend longer than 90 days) includes the delivery and post-partum care directly related to the delivery.

In addition, the provider must:

- Accept the CDPHP reimbursement rates.
- Adhere to the CDPHP quality management requirements.

POLICY NAME: TRANSITIONAL CARE – PROVIDER LEAVES THE NETWORK

- Provide CDPHP with necessary medical information related to care rendered.
- Adhere to all the CDPHP policies/procedures in rendering care to the enrollee including but not limited to the referral process, obtaining pre-authorizations when indicated and providing a treatment plan for review and approval.
- Only render care for those services provided for in the enrollee's contract.

POLICY CONSIDERATIONS

Enrollees requiring transitional care will be offered the services of a case manager to assist with a smooth transfer of care to a new participating practitioner.

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy. • Child Health Plus defines postpartum period as a 12-month timeframe.
MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy. • Enrollees must transition all care to another Medicare Advantage network provider.
SELECT PLAN/HARP	Subject to all terms and conditions noted above in the policy. • Medicaid defines postpartum period as a 12-month timeframe. • In the absence of a written agreement to the Plan's fee schedule, CDPHP will reimburse non-participating providers at the Medicaid fee-for service rates to ensure continuity of care.

SOURCES

1. NY Public Health Law 4403(6)(e). http://public.leginfo.state.ny.us/lawssrch.cgi?NVLWO:
2. Member Contract Language
3. Department of Health Part 98 Regulation 10 NYCRR 98-1.13(o)

4. NY Insurance Law §§ 4306-c(c) and 4804(e)
5. 42 USCS §§ 300gg-113 and 300gg-138 (No Surprises Act)
6. NY Medicaid Managed Care Model Contract Section 15(b).

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POLICY APPROVAL DATES

New:	10/98
Revised:	08/99, 02/00, 09/02, 09/03, 04/05, 09/06, 07/12, 07/17, 01/18, 03/20, 5/22, 7/23, 9/23, 11/23
Reviewed:	07/04, 03/06, 09/07, 07/08, 07/09, 07/10, 07/11, 07/13, 07/14, 07/15, 07/16, 07/18, 07/19, 7/20, 7/21, 7/22, 7/24, 7/25, 7/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
6/14/2023* *No change to effective date for this update	Removed statement requiring the provider to sign an agreement letter.
6/14/2023	Under the CHP section, added new DOH update that extends the postpartum timeframe to 12 months.
3/1/2023	Under the Medicaid section, added new DOH update that extends the postpartum timeframe to 12 months.
6/1/2022 No change to effective date	Added additional regulatory language under the Position Statement regarding the providers termination.
6/1/2022	Regulatory requirement- removed statement that member must be in the second trimester of pregnancy.
7/1/2020	Medicare Advantage section updated to reflect a 90-day transitional period from the date the provider's contractual

POLICY NAME: TRANSITIONAL CARE – PROVIDER LEAVES THE NETWORK

	obligation to provide services to a member terminates.

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Policy/Procedure Name: Tregzi (allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq) **Control Number: 1350/20.000597**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Healthcare practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Tregzi (allogeneic regulatory T-cell immunotherapy with HSPC and T-cells-vldq) is an allogeneic regulatory T-cell based immunotherapy containing hematopoietic stem and progenitor cells (HSPCs) and T-cells indicated for the treatment of hematological malignancies while improving chronic graft-versus-host disease (cGVHD)-free survival in matched donor hematopoietic stem cell transplantation with myeloablative preparative regimen.[1] Administration of Tregzi involves four separate infusion bags for intravenous infusion: HSPCs, regulatory T-cells (Tregs), conventional T-cells (Tcons), and Tcon diluent. Its recommended dose is a single intravenous infusion of ≥ 1.0 × 106 HSPCs per kg, 1.3×10^6 to 3.5×10^6 Tregs per kg, and 1.3×10^6 to 3.5×10^6 Tcons per kg.

Chronic graft-versus-host disease is a major complication of allogeneic hematopoietic stem cell transplant (HSCT) that affects approximately 30% to 70% of HSCT recipients.[2] The condition is characterized by an immune-mediated response that leads to chronic inflammation and fibrosis of multiple organs.[2,3] Management of cGVHD involves treatment with immunosuppressants such as steroids and calcineurin inhibitors.

Approval of Tregzi was supported by the PRECISION-T Phase III Trial where 187 subjects between the ages of 18 and 65 years were enrolled and randomized to receive either Tregzi with single agent tacrolimus or a control arm comprised of a peripheral blood stem cell allograft with tacrolimus and methotrexate (Tac/MTX).[4,5] Subjects were diagnosed with either acute leukemia or myelodysplastic syndrome and received myeloablative conditioning. The primary endpoint evaluated survival free from moderate-to-severe cGVHD (cGFS). Patients treated with Tregzi at the one-year follow-up demonstrated 78% cGFS compared to 38.4% in the convention stem cell transplant plus Tac/MTX arm. Additional efficacy endpoints highlighted a 63.1% cGVHD and relapse-free survival at one year compared to 30.9%, respectively.

Warnings and precautions include a risk of graft failure, GVHD, infusion reactions, secondary malignancies and malignancies of donor origins, and transmission of infectious agents.[1] For further reduction in risk of developing GVHD, it is recommended that patients are treated with a single agent calcineurin inhibitor as prophylaxis. Adverse reactions were generally consistent with conventional hematopoietic stem cell transplants – some of the most common adverse reactions with incidence ≥ 20% were infections, gastrointestinal disorders (diarrhea, abdominal pain, vomiting, nausea), mucositis, and rash.[1,4]

Summary

Effective Date of Policy:	9/25/2026
Indications	Use in matched donor hematopoietic stem cell transplantation with myeloablative preparative regimen, for hematopoietic and immunologic reconstitution and to improve chronic graft-versus-host disease (cGVHD)-free survival, in the treatment of adults with hematological malignancies
HCPCS	J3590 (NOC)

Required Criteria for Approval - Medical

1. Must be prescribed by a hematologist, oncologist, or physician experienced in the treatment of hematologic malignancies **AND**
2. The patient must be eligible for an allogeneic hematopoietic (stem) cell transplant (HSCT) **AND**
3. The patient must receive therapy at an authorized treatment center **AND**
4. Must be at least 18 years of age **AND**
5. Must be diagnosed with one of the following:
    a. Acute myeloid, lymphoid, or mixed phenotype/undifferentiated leukemia in complete remission (CR) or in complete remission with incomplete hematologic recovery (CRi); See appendix for definitions of CR and CRi
    b. Myelodysplastic syndromes (MDS) with ≤ 10% blast burden in the bone marrow; **AND**
6. Consideration may be given to other hematological malignancies for which myeloablative allogeneic HSCT is an established treatment per NCCN guidelines
7. Provider must attest the patient will be treated with at least a single agent calcineurin inhibitor (such as tacrolimus) as prophylaxis to decrease the risk of graft versus host disease (GHVD) **AND**

8. Must have been screened and found seronegative for HIV-1 or -2 antibody, HTLV-1 or -2 antibody, Hepatitis B sAg, and Hepatitis C antibody **AND**
9. Must have a matched related or unrelated donor who is an 8/8 match for HLA-A, -B, -C, and DRB1 **AND**
10. Tregzi will not be authorized if the patient meets any of the following:
    a. Patient had a prior allogeneic hematopoietic stem cell transplant
    b. Hematopoietic cell transplantation-specific Comorbidity Index (HCT-CI) > 4
    c. Any uncontrolled autoimmune disease requiring active immunosuppressive treatment
    d. Current uncontrolled bacterial, viral, or fungal infection
11. Tregzi is indicated for one-time intravenous administration only and therefore will not be authorized for retreatment. Retreatment will be considered experimental/investigational when any FDA approved gene or cellular therapy, or any other gene or cellular therapy under investigation, has been previously administered
12. Tregzi is considered investigational for all other non-FDA approved indications
13. Approval will be for 6 months to allow one-time administration

Appendix

Definitions of Complete Remission (CR) and Complete Remission with Incomplete Hematologic Recovery (CRi)[6]

Definition of CR for AML and MPAL (meets all criteria, 1-5)

1. Bone marrow blasts < 5% by morphologic examination
2. ANC > 1.0×10^9/L (1,000/µL)
3. Absence of circulating blasts in the peripheral blood by morphologic examination
4. No evidence extramedullary disease
5. Platelet count > 100×10^9/L (100,000/µL)

CRi is defined as meeting all CR criteria except for residual neutropenia (< 1.0×10^9/L) and/or thrombocytopenia (< 100×10^9/L).

Definition of CR for ALL (meets all criteria, 1-6)

1. < 5% blasts in the bone marrow
2. Normal maturation of all cellular components in the bone marrow
3. No extramedullary disease (e.g., central nervous system, soft tissue disease)
4. ANC > 1,000/µL
5. Platelet count >100,000/µL
6. Transfusion independence

CRi is defined as meeting all CR criteria except for residual neutropenia (≤ 1.0×10^9/L) and/or thrombocytopenia (≤ 100×10^9/L).

Policy Guidelines

1. Utilization Management are contract dependent. Refer to specific contract/benefit language for exclusions.
    a. Coverage criteria may be dependent on the contract renewal date.
    b. Coverage of drugs listed in this policy are contract dependent.
    c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit
    d. Not all contracts/benefits cover all medical infusible drugs.
2. Clinical documentation must be submitted for each request (initial and recertification [if applicable]) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging and other objective or subjective measures of benefit. Requested dosing must remain consistent with FDA-approved dosing recommendations.
3. This policy does not apply to Medicare Part D and D-SNP pharmacy benefits. The drugs in this policy may apply to all other lines of business including Medicare Advantage.
4. Unless otherwise indicated within drug specific criteria, the drugs listed in this policy are administered by a healthcare professional and therefore are covered under the medical benefit.

5. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
6. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.
7. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
8. This policy is subject to ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.
9. For members with Medicare Advantage, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS permits a Medicare Advantage Organization (MAO) to establish its own coverage determinations in accordance with 42 CFR § 422.101(b)(6). Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan. Step therapy requirements may be imposed in addition to LCD/NCD requirements.
10. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html
11. The requested site of care may impact approval timeframe and is subject to review.
12. The following applies to all gene and cellular therapies unless otherwise specified within the drug-specific coverage criteria:
    a. Administration, Retreatment, and Treatment with Additional or Other Gene/Cellular Therapies
        i. One-Time Administration
            1. Most gene and cellular therapies, whether autologous, allogeneic ("off-the-shelf"), or in vivo gene-transfer therapies, are designed and studied as one-time treatments.
            2. Repeat dosing, reinfusion, or sequential therapy with other gene or cellular products has not been established as safe, effective, or clinically appropriate.
        ii. Retreatment/Repeat Administration
            1. Retreatment with the same gene or cellular therapy product is considered experimental and investigational because:
                a. Clinical trials evaluated these therapies as single-administration interventions
                b. Safety, efficacy, and durability of a second administration have not been established
                c. Risks of immune activation, insertional mutagenesis, or vector immunity may be increased with repeat dosing
        iii. Treatment with an Additional or Other Gene/Cellular Therapy
            1. Treatment with an additional or different gene or cellular therapy after prior exposure to any gene or cellular therapy is also considered experimental and investigational, unless supported by evidence demonstrating (a-c):
                a. Anticipated clinical benefit beyond available standard therapies
                b. Safety of sequential administration
                c. Justification for selecting a second gene/cellular intervention after a prior one
            2. This includes, but is not limited to:
                a. Switching between CAR-T products (e.g., CD19 → CD19 or CD19 → BCMA)
                b. Switching between autologous and allogeneic cellular therapies
                c. Sequential use of CAR-T, TCR-T, NK-cell therapies, or other genetically engineered cell therapies
                d. Receiving a gene therapy after previous gene or cellular therapy exposure

e. Receiving an in vivo gene therapy following any prior vector-based therapy

iv. Prior Gene/Cell Therapy Exposure

1. An individual is generally not eligible for additional gene or cellular therapy if they have previously received:
   a. Any autologous cellular therapy (e.g., CAR-T, TCR-T, TIL)
   b. Any allogeneic genetically modified cellular therapy
   c. Any in vivo gene therapy (e.g., AAV, lentiviral vector)
   d. Any ex vivo gene-modified cell product
   e. Are being considered for any other gene or cellular therapy without documented evidence supporting safety and anticipated benefit

References

1. Tregzi [package insert]. Sacramento, CA: Orca Biosystems Inc.; Revised 06/2026
2. Ye Y, Savani B, Malard F, et al. Chronic graft-versus-host disease. Nat Rev Dis Primers. 2026;12(1):37. doi:10.1038/s41572-026-00711-z
3. Flavin B. Chronic graft-vs-host disease: current understanding of disease and treatment landscape. J Manag Care Spec Pharm. 2022;28(12-b Suppl):S2-S12. doi:10.18553/jmcp.2022.28.12-b.s1
4. Meyer EH, Salhotra A, Gandhi AP, et al. Orca-T vs allogeneic hematopoietic stem cell transplantation (Precision-T): a multicenter, randomized phase 3 trial. Blood. 2026;147(11):1168-1177. doi:10.1182/blood.2025031313
5. ClinicalTrials.gov. Precision-T: A Randomized Study of Orca-T in Recipients Undergoing Allogeneic Transplantation for Hematologic Malignancies. ClinicalTrials.gov identifier: NCT05316701. Updated April 2024. Accessed August 25, 2026. https://clinicaltrials.gov/study/NCT05316701
6. U.S. Food and Drug Administration. Acute myeloid leukemia: developing drugs and biological products for treatment. Guidance for industry. FDA; October 2022. Accessed August 25, 2026. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/acute-myeloid-leukemia-developing-drugs-and-biological-products-treatment-0

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 9/25/2026

New: 9/2026

Revised	Reviewed

Revision Date	Changes Made

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MEDICAL POLICY

Medical Policy Title	**Tumor-Treatment Fields Therapy**
Policy Number	**6.01.45**
Current Effective Date	**November 1, 2026**
Next Review Date	**April 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Alternating electrical field therapy (tumor-treatment field (TTF) therapy) using Optune (Novocure, Portsmouth, New Hampshire) for treatment of recurrent supratentorial glioblastoma multiforme (GBM) is considered **medically appropriate**, when **ALL** the following criteria have been met:

   A. The patient has had a first or second recurrence of GBM;

   B. The patient has a Karnofsky Performance Status (KPS) of 60 or greater;

   C. The patient has not received prior treatment with Bevacizumab;

   D. The device is to be used as monotherapy after failure of standard medical therapy (e.g., chemotherapy, surgery, and/or radiation therapy);

   E. The patient is 22 years or older; **and**

   F. Documentation includes the following:

      1. The patient has histologically confirmed GBM (documentation of pathology required);

      2. The Optune (Novocure) will be initially allowed for up to six (6) months if the patient is compliant (18 hours or more per day) with the regimen;

      3. Continued use after six (6) months will require:

         a. Documentation that the patient has been compliant (18 hours or more per day); **and**

         b. Documentation that there has been no progression of tumor.

II. TTF therapy using Optune for treatment of newly diagnosed supratentorial GBM is considered **medically appropriate** when **ALL** the following criteria have been met:

   A. The device is to be used as an adjunct with the chemotherapy drug temozolomide (TMZ);

   B. The therapy follows standard treatments that include maximal debulking surgery and completion of radiation therapy, together with concomitant standard of care chemotherapy;

   C. The patient is 22 years or older; **and**

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D. Documentation includes the following:
    1. The patient has histologically confirmed GBM (documentation of pathology required);
    2. The Optune (Novocure) will be initially allowed for up to six (6) months if the patient is compliant (18 hours or more per day) with the regimen;
    3. Continued use after six (6) months will require:
        a. Documentation that the patient has been compliant (18 hours or more per day); **and**
        b. Documentation that there has been no progression of tumor.

III. TTF therapy is considered **investigational** for all other indications, including but not limited to:
    A. Mesothelioma;
    B. Metastatic non-small cell lung cancer (mNSCLC);
    C. Unresectable locally advanced pancreatic adenocarcinoma.

Device Repair

IV. Repair of a medically necessary Optune device or components not under warranty will be considered **medically appropriate** when the following criteria are met:
    A. Physician documentation includes **ALL** the following:
        1. date of device implantation/initiation;
        2. manufacturer warranty information, if applicable;
        3. attestation that the patient has been compliant with the use of device and will continue to benefit from the use of device;
    B. The device is no longer functioning adequately; and **BOTH** of the following criteria are met:
        1. inadequate function interferes with activities of daily living; **and**
        2. repair is expected to make the equipment fully functional (as defined by manufacturer).

V. Repair of equipment damaged due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

Device Replacement

VI. Replacement of a medically necessary Optune device or components not under warranty will be considered **medically appropriate** when **EITHER** of the following criteria are met:
    A. The device is no longer functioning adequately and has been determined to be non-repairable or the cost of the repair is in excess of the replacement cost; **or**
    B. There is documentation that a change in the patient's condition makes the present unit non-functional and improvement is expected with a replacement unit.

VII. The replacement of a properly functioning Optune device and its components or accessories is considered **not medically necessary**. This includes, but is not limited to, replacement desired due to advanced technology or in order to make the device more aesthetically pleasing;

VIII. The replacement of equipment damaged or lost due to patient neglect, theft, abuse, or when another available coverage source is an option (e.g., homeowners, rental, auto, liability insurance, etc.) is **ineligible for coverage**.

IX. Accessories or components for an Optune device that are considered not medically necessary or investigational by peer-reviewed literature will also be considered as **not medically necessary or investigational** by the Health Plan.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Glioblastoma multiforme (GBM), is the most common and aggressive primary intracranial tumor, with approximately 33% of patients surviving one year and less than 5% surviving more than five (5) years. Median survival with optimal therapy has been reported to be 10-to-15 months, with most tumors recurring within seven-to-nine months, despite multimodal treatment (e.g., repeat surgery, re-irradiation, and chemotherapy). Choice of chemotherapy for treatment in the case of recurrence varies, but may include alkylating agents (e.g., lomustine, carmustine, procarbazine), re-treatment with temozolomide, and, more recently, bevacizumab either alone or in combination with other agents. Overall survival after recurrence is relatively short, even with optimal therapy. New or novel treatments, such as TTF therapy, are being investigated to improve survival in patients with GBM.

TTF therapy is delivered via the Optune, which is a battery-powered, portable device that generates alternating low-intensity, intermediate electrical fields (100-300 kHz) by four (4) disposable electrode arrays (replaced one (1) to two (2) times per week) that are non-invasively attached to the patient's shaved scalp, placed in such a way as to encompass the tumor. The alternating low intensity electrical field is thought to disrupt cell division of the cancer cells, so that either cell division does not occur, or it is ineffective, resulting in death of the cancer cells without harming the normal healthy cells. The device is used by the patient at home on a continuous basis (18 hours per day) for the duration of treatment, which can last for several months. Patients can carry the device in a backpack or shoulder pack while conducting activities of daily living.

SUPPORTIVE LITERATURE

The United States Food and Drug Administration (FDA) approval of the Optune NovoTTF-100A

system, was based on a phase three (3), multi-national, prospective, randomized, controlled trial (RCT) (Stupp et al., 2012). Participating in the study were 237 patients with relapsed or progressive GBM, despite conventional radiotherapy, who were randomized in a 1:1 ratio to receive TTF therapy (delivered by the NovoTTF-100A System) only (n=120) or the best standard of care chemotherapy (active control) (n=117). Patient characteristics were balanced in both groups, with median age of 54 years and median Karnofsky Performance Status (KPS) score of 80%. More than 80% of participants had failed two or more prior chemotherapy regimens, and 20% had failed bevacizumab prior to study enrollment. Ninety-seven percent (116) of the 120 participants in the TTF group started treatment, and 93 participants (78%) completed one (1) cycle (four weeks) of therapy. Discontinuation of TTF therapy occurred in 27 participants (22%), due to noncompliance or the inability to manage the device. For each TTF treatment month, the median compliance was 86% (range, 41%-98%), which equaled a mean use of 20.6 hours per day. In the active control group, 113 (97%) of the 117 assigned participants received chemotherapy, and all but one individual completed a full treatment course. Twenty-one participants (18%) in the active control group did not return to the treatment site, and details on disease progression and toxicity were not available. This RCT did not reach its primary end point of improved survival compared with active chemotherapy. With a median follow-up of 39 months, 220 participants (93%) had died. Median survival was 6.6 months in the TTF group, compared with 6.0 months in the active control group (hazard ratio, 0.86; 95% confidence interval [CI], 0.66 to 1.12; p=0.27). For both groups, one-year survival was 20%. The survival rates for two- and three-year survival were 8% and 4%, respectively, for the TTF group versus 5% and 1%, respectively, for the active control group. Progression Free Survival (PFS) rate at six months was 21.4% in the TTF group, compared with 15.1% in the active control group (p=0.13). Limitations of the trial included a somewhat heterogeneous patient population, with participants included after progression of one or several lines of chemotherapy, as well as the use of different chemotherapy regimens in the control group. Another limitation was the absence of a placebo/supportive care arm. In the setting of advanced disease, the supportive care arm would have been useful to gauge the safety and efficacy of treatment for both groups of patients. Treatments used in the active control arm (best standard of care chemotherapy) in the recurrent disease setting have previously demonstrated limited efficacy, thus limiting the ability to determine the true treatment effect of TTF. Data from a trial of TTF versus placebo, or TTF plus standard chemotherapy, versus standard chemotherapy alone, would, therefore, provide a better assessment of treatment efficacy.

A subgroup analysis of patient data of this phase 3 trial (Wong et al 2014) evaluated the different characteristics of responders and non-responders in the TTF group, compared to the active control group. More patients in the TTF arm were considered responders (14 of 120, versus seven (7) of 117 in the chemotherapy arm). Median response time was longer for those in the TTF arm than the chemotherapy arm (7.3 months versus 5.6 months, p<0.001), and there was a strong correlation (Pearson's r) between response and overall survival in the TTF arm (p<0.001), but not in the chemotherapy arm (p=0.29). Compared with the chemotherapy arm, a higher proportion of responders in the TTF arm had a prior low-grade histology (36% vs 0%). These differences in treatment responder groups suggest that TTF therapy may differentially benefit certain types of GBM; however, the small numbers of responders in both groups limits generalizations that can be drawn from this analysis.

An analysis of the NovoTTF-100A Patient Registry Dataset (PRiDe) of 457 patients with recurrent GBM who were treated with NovoTTF therapy in the United States between October 2011 and November 2013, and a comparison to patient data in the Phase 3 trial, were performed (Mrugula et al 2014) to provide a larger data set of patients with recurrent GBM treated with TTF therapy. No new adverse events in the PRiDe group of patients were reported, compared to the Phase 3 trial group. However, median overall survival was longer in the TTF group in the PriDe group (9.6 months), compared to the TTF group in the Phase 3 trial (6.6 months) or to the active chemotherapy group in the Phase 3 trial (6.0 months). Median treatment time was almost double for the TTF PriDe group, compared to either the TTF or chemotherapy group in the Phase 3 trial. Favorable prognostic factors in the PriDe group included 75% or more daily compliance with the device, treatment with TTF at first recurrence, no prior treatment with bevacizumab, and Karnofsky Performance Score (KPS) 90 or greater. The authors suggested that there are subsets of patients who derive significant benefit from TTF therapy and that TTF therapy using the NovoTTF-100A device is safe and efficacious to treat recurrent GBM.

The FDA approval of the Optune device (formerly called the NovoTTF-100A system) for newly diagnosed GBM was based on the results from a clinical trial involving 695 patients who were newly diagnosed with GBM. The study compared those who used the device with temozolomide (TMZ) to those receiving TMZ alone (Stupp, 2015). Patients who used the device along with TMZ lived, on average, about seven (7) months with no disease progression, compared to four (4) months for those who had the drug alone. The device plus TMZ group survived for an average of 19.4 months after starting treatment, compared to 16.6 months for those who were treated with TMZ alone.

In 2019, through the humanitarian device exemption (HDE) process, the FDA approved the Optune Lua system (formerly called the NovoTTF-100L) for treatment of adult patients with unresectable, locally advanced or malignant pleural mesothelioma (MPM), to be used concurrently with pemetrexed and platinum-based chemotherapy (the current gold-standard of treatment). The decision was based on the results of the industry-designed and sponsored STELLAR trial (NCT02397928), which was summarized by Ceresoli et al. This was a prospective, single-arm, multi-center study of 80 participants treated between 2015 and 2018, who had inoperable, previously untreated MPM. The primary endpoint of the trial was overall survival, which was measured from time of diagnosis until date of death. Fifty patients (63%) were treated with a carboplatin and pemetrexed combination with TTF, and 30 patients (37%) received cisplatin and pemetrexed with TTF. Median overall survival was 18.2 months (95% CI 12.1-25.8) and comparable to other recent study results for median overall survival of chemotherapies for treatment of MPM. Even though the median overall survival, objective responses, and progression-free survival results did not appear to be impacted with TTF therapy, the similar outcomes reported in this study were achieved without an increase in systemic toxicity. Thirty-two patients did have severe adverse events during the trial period, which is also consistent with other trials of pemetrexed (anemia, neutropenia, and skin reaction being the most common). The majority of patients did have mild medical device reactions at the site of array adherence on the skin. This study's small sample size, lack of a control group, and lack of quality-of-life assessment did not provide enough information to draw conclusions on the efficacy of this therapy versus standard medical treatment. Further randomized clinical trials are needed.

Leal et al (2023) reported on a pivotal phase 3, open-label, randomized study (LUNAR). The study aimed to compare the addition of TTF therapy to standard systemic therapy with standard systemic therapy alone in patients with metastatic non-small-cell lung cancer. Between February 2017 and November 2021, 276 patients were enrolled and randomly assigned to receive TTFields therapy with standard therapy (n=137) or standard therapy alone (n=139). Their median age was 64 years, 178 (64%) were male and 98 (36%) were female, and 232 (84%) were current or former smokers. At baseline, the majority (156 [57%]) had non-squamous histology, 43 (16%) had liver metastasis, and ten (4%) had an ECOG performance score of 2. TTFields therapy (150 kHz) was delivered continuously to the thoracic region with the recommendation to achieve an average usage of at least 75% of each day (18 h/day) with the NovoTTF device system (device manufactured by Novocure). The primary endpoint was overall survival in patients receiving TTFields therapy with standard therapy compared with standard therapy alone. Key secondary endpoints were overall survival in subgroups receiving either docetaxel or an immune checkpoint inhibitor. Other secondary endpoints (reported here) were progression-free survival and overall response rate (both per radiological assessment); overall survival by squamous and non-squamous histology; measurement of patient-reported, health-related quality-of-life scores; and adverse events. Secondary endpoints of overall survival and progression-free survival in TTFields therapy-treated subgroups with average monthly device usage of more than 75% and 75% or less; progression free survival by squamous and non-squamous histology; overall survival and progression-free survival in subgroups who received nivolumab, pembrolizumab, or atezolizumab; and overall survival of patients who received TTFields therapy with docetaxel compared with patients treated with an immune checkpoint inhibitor alone will be reported elsewhere as part of more extensive analyses. Over the entire course of the study, a monthly average device usage of at least 18 h/day (75% of each day) was reached by 13 (19%) of 67 patients in the immune checkpoint inhibitor subgroup and 17 (26%) of 66 patients in the docetaxel subgroup. Overall survival was significantly longer with TTFields therapy and standard therapy versus standard therapy alone. Median overall survival was 13.2 months with TTFields therapy and standard therapy compared with 9.9 months with standard therapy alone, yielding an HR of 0.74 in favor of TTFields therapy. The one-year overall survival rate was 53% with TTFields therapy and standard therapy, and 42% with standard therapy alone. The overall response rate with TTFields therapy and standard therapy was 20.4% versus 17.3% with standard therapy alone. All complete responses (n=5) occurred in patients receiving an immune checkpoint inhibitor (four with TTFields therapy, one with immune checkpoint inhibitor alone). Study limitations include the open-label design and study being industry sponsored. Other limitations are that the study enrolled a low number of patients with brain metastases, potentially affecting the generalizability of these findings to that population. LUNAR was also initiated before the advent of standard genetic profiling by next-generation sequencing in non-small cell lung cancer, and thus little information about the relationship between TTFields therapy efficacy and tumor genetic subtype is available. Authors concluded that data from this study suggests that TTFields therapy is efficacious in metastatic non-small-cell lung cancer and should be considered as a treatment option to manage the disease. Additional studies are warranted to validate the benefit of TTFields therapy with standard systemic therapies in non-small-cell lung cancer.

In the pivotal phase III Panova-3 study, Babiker et al (2025) sought to confirm the safety and

efficacy of TTFields in patients with unresectable locally advanced pancreatic adencocarcinoma (LA-PAC). 571 patients with newly diagnosed LA-PAC were randomly assigned to receive gemcitabine and nab-paclitaxel by intravenous infusion once a day on days 1, 8, and 15 of a 28-day cycle with or without TTFields. The primary end point was overall survival (OS). Secondary end points included progression-free survival (PFS), local PFS, pain-free survival, and overall response rate (ORR). OS was significantly prolonged using TTFields with gemcitabine/nab-paclitaxel versus gemcitabine/nab-paclitaxel (median, 16.2 months versus 14.2 months. PFS, local PFS, and ORR were not improved. Pain-free survival was significantly prolonged with TTFields with gemcitabine/nab-paclitaxel (median, 15.2 months versus 9.1 months. Authors concluded that this study demonstrated significant OS, pain-free survival, and distant PFS benefits for TTFields with gemcitabine/nab-paclitaxel versus gemcitabine/ nab-paclitaxel. The study had several limitations including, but not limited to, industry sponsorship, small gain in OS, high dependence on treatment adherence and device burden, no improvement in PFS or ORR, open label study design and lack of independent confirmatory trials.

PROFESSIONAL GUIDELINE(S)

The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines for Central Nervous System Cancers V.3.2025 states that due to lack of clear efficacy data, the panel is divided regarding recommending alternating electric field therapy for the treatment and re-irradiation of recurrent glioblastoma. Concurrent treatment with adjuvant TMZ and alternating electric fields is a category 1 recommendation for newly diagnosed glioblastoma patients ≤ 70 years of age who have a good PS. This is also considered a reasonable treatment option for patients > 70 years of age with good PS and newly diagnosed glioblastoma who are treated with standard focal brain radiation and concurrent daily TMZ.

The NCCN Clinical Practice Guidelines for Malignant Pleural Mesothelioma V.2.2026 do not reference TTF therapy as a treatment for this indication.

The NCCN Clinical Practice Guidelines for Non-Small Cell Lung Cancer V.3.2026 do not refer to TTF therapy as a treatment for this indication.

In addition to malignant pleural mesothelioma, TTF is being investigated in non-small cell lung cancer, brain metastases from non-small cell lung cancer, pancreatic cancer, ovarian cancer, hepatocellular carcinoma and gastric adenocarcinoma. Future studies are warranted to determine the impact of TTF on the net health outcome.

The NCCN Clinical Practice Guidelines for Pancreatic Adenocarcinoma do not reference TTF therapy as a treatment for this indication.

REGULATORY STATUS

In April 2011, the NovoTTF-100A System (Novocure; assigned the generic name of TTF) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process. The FDA approved label reads as follows: "The NovoTTF-100A System is intended as a treatment for adult patients (22 years of age or older) with confirmed GBM, following confirmed recurrence in an upper region of the brain (supratentorial) after receiving chemotherapy. The device

is intended to be used as a stand-alone treatment and is intended as an alternative to standard medical therapy for recurrent GBM after surgical and radiation options have been exhausted."

In September 2014, FDA approved Novocure's request for a product name change from NovoTTF-110A System to Optune.

In October 2015, FDA expanded the indication for Optune in combination with temozolomide to include newly diagnosed GBM.

The device was granted priority review status in May 2015 because there was no legally marketed alternative device available for the treatment of newly diagnosed GBM, a life-threatening condition.

In July 2016, a smaller, lighter version of the Optune device, called the Optune System (NovoTTF-200A System), received FDA approval.

The FDA-approved label for newly diagnosed GBM reads as follows: "This device is indicated as treatment for adult patients (22 years of age or older) with histologically confirmed glioblastoma multiforme (GBM). Optune with temozolomide is indicated for the treatment of adult patients with newly diagnosed, supratentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant standard of care chemotherapy."

In May 2019, the FDA approved a modified version of the Optune System (NovoTTF-100A System), which is now called the Optune Lua System (NovoTTF™-100L System), for "treatment of adult patients with unresectable, locally advanced or metastatic, malignant pleural mesothelioma (MPM) to be used concurrently with pemetrexed and platinum-based chemotherapy. The indication was modified from that granted for the Humanitarian Device Exemption designation to more clearly identify the patient population the device is intended to treat and in which the safety and probable benefit of the device is supported by the available clinical data."

In September 2021, the FDA granted breakthrough designation to the NovoTTF-200T System for use together with atezolizumab and bevacizumab for the first-line treatment of patients with unresectable or metastatic liver cancer.

To date, all of the existing tumor treating fields products fall under the brand name Optune. In March 2020, the manufacturer of Optune products announced a plan to include a suffix after the brand name for newly approved indications to further delineate specific indications for individual products (e.g., Optune Lua). Optune was renamed Optune Gio in 2023.

In October 2024, the FDA approved Optune Lua as a device to be used together with PD-1/PD-L1 inhibitors or docetaxel. It is indicated for adult patients with metastatic non-small cell lung cancer (mNSCLC) who have progressed on or after a platinum-based regimen.

In February 2026, the FDA approved Optune Pax (Novocure) as a device to be used in combination with gemcitabine and nab-paclitaxel for patients with locally advanced pancreatic cancer.

The U.S. Food and Drug Administration (FDA) regulates Tumor Treating Field (TTF) Systems as medical devices. All TTF Systems including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices [accessed

2026 Feb 18]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Feb 18]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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HCPCS Codes

Code	Description
A4555	Electrode/transducer for use with electrical stimulation device used for cancer treatment, replacement only
E0766	Electrical stimulation device used for cancer treatment, includes all accessories, any type

ICD10 Codes

Code	Description
C45.0-C45.9	Mesothelioma (code range)
C71.0-C71.9	Malignant neoplasm of brain (code range)

REFERENCES

Babiker HM, et al. Tumor treating fields with gemcitabine and nab-paciltaxel for locally advanced pancreatic adenocarcinoma: randomized, open-label, pivotal phase III panova-2 study. J clin oncol. 2025 Jul 20;43(21):2350-2360.

Ballo MT, et al. Association of tumor treating fields therapy with survival in newly diagnosed glioblastoma: a systematic review and meta-analysis. J Neurooncol. 2023 Aug;164(1):1-9.

Ceresoli G, et al. Tumour treating fields in combination with pemetrezxed and cisplatin or carboplatin as first-line treatment for unresectable malignant pleural mesothelioma (STELLAR): a multicentre, single-arm phase 2 trial. Lancet Oncol. 2019 Dec;20(12):1702-1709.

Leal T, et al. Tumor treating fields therapy with standard systemic therapy versus standard systemic therapy alone in metastatic non-small-cell lung cancer following progression on or after platinum-based therapy (LUNAR): a randomized, open-label, pivotal phase 3 study. Lancet Oncol. 2023 Sep;24(9):1002-1017.

Mrugala MM, et al. Clinical practice experience with NovoTTF-100A system for glioblastoma: the patient registry dataset (PRiDe). Semin Oncol. 2014 Oct;41(Suppl 6):S4-13.

National Comprehensive Cancer Network (NCCN). [Internet]. Clinical practice guidelines for malignant pleural mesothelioma. V.22026 2025 Oct 3. [accessed 2026 Feb 18] Available from: https://www.nccn.org/professionals/physician_gls/pdf/meso_pleural.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines for non-small cell lung cancer. V3.2026.2025 Dec 24. [accessed 2026 Feb 18] Available from: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf

National Comprehensive Cancer Network (NCCN) [Internet]. Clinical practice guidelines in oncology. Central nervous system cancers. V.3.2025 2025 Dec 5. [accessed 2026 Feb 18] Available from:http://www.nccn.org/professionals/physician_gls/pdf/cns.pdf

National Institutes of Health (NIH) [Internet]. PDQ Malignant Mesothelioma Treatment (adult). 2023 May 17. [accessed 2025 Feb 20] Available from: Mhttps://www.cancer.gov/types/mesothelioma/hp/mesothelioma-treatment-pdq#_AboutThis_1

Rulseh AM, et al. Long-term survival of patients suffering from glioblastoma multiforme treated with tumor-treating fields. World J Surg Oncol. 2012;10:220.

Stupp R, et al. Effect of tumor-treating fields plus maintenance temozolomide vs maintenance temozolomide alone on survival in patients with glioblastoma. A randomized clinical trial. JAMA. 2017 Dec 19;318(23):2306-2316.

Stupp R, et al. Maintenance therapy with tumor-treating fields plus temozolomide vs temozolomide alone for glioblastoma: a randomized clinical trial. JAMA. 2015 Dec;314(23):2535-43.

Stupp R, et al. NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: a randomised phase III trial of a novel treatment modality. Eur J Cancer. 2012 Sep;48(14):2192-202.

Tailibert S, et al. Tumor treating fields: a new standard treatment for glioblastoma? Curr Opin Neurol. 2015 Dec;28(6):659-84.

Turner SG, et al. The effect of field strength on glioblastoma multiforme response in patients treated with the NovoTTF-100A system. World J Surg Oncol. 2014;12(1):162.

Villano JL, et al. Delayed response and survival from NovoTTF-100A in recurrent GBM. Medical Oncology. 2013;30(1):1-3.

Wong ET, et al. Response assessment of NovoTTF-100A versus best physician's choice chemotherapy in recurrent glioblastoma. Cancer Med. Jun 2014;3(3):592-602.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

LCD - Tumor Treatment Field Therapy (TTFT) (LCD L34823) [accessed 26 Feb 18]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 7/26

Revised:

Reviewed:

Date	Summary of Changes
11/1/2026	• New

Policy/Procedure Name: Tzield (Teplizumab) **Control Number: 1350/20.000464**

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Type 1 Diabetes Mellitus (T1DM) is one of the most common chronic childhood diseases. There is a bimodal distribution in regard to the onset-age of T1DM in children; one peak occurs at four to six years of age and a second peak occurs at 10 to 14 years of age. Although more common in children, 25% of T1DM cases are diagnosed in adults. Overall, approximately 1 million to 1.5 million Americans have T1DM. The disorder is caused by insulin deficiency following the destruction of the insulin-producing beta cells of the pancreas. This detail assists in the differentiation between T1DM and Type 2 Diabetes Mellitus (T2DM) since the latter is mostly characterized by insulin resistance as opposed to insulin deficiency.

The lifetime risk of developing T1DM is increased in close relatives of patients with the disorder. Offspring of an affected mother have a 1% to 4% increased risk, offspring of an affected father have a 3% to 8% increased risk, and offspring with both parents affected have up to a 30% increased risk. In patients that are genetically susceptible to T1DM, the exposure to environmental agents such as food or viruses can trigger the immune response that leads to the destruction of insulin-producing pancreatic beta cells. The initial diagnosis of T1DM is often made after three initial presentations: diabetic ketoacidosis (DKA), asymptomatic incidental discovery, or classic new onset of polydipsia, polyuria, weight loss with hyperglycemia, and ketonemia. T1DM can be further broken down into four stages of increasing disease progression. Details about these stages can be found in the "considerations" section of this policy.

Tzield (teplizumab) is a CD3-directed monoclonal antibody that is indicated to delay the onset of stage 3 T1DM in patients eight years of age and older with stage 2 T1DM. The efficacy of Tzield was evaluated in a prospective, randomized, placebo-controlled, double-blind, multicenter phase II clinical trial (An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes (NCT01030861). This study enrolled 76 participants between the ages of eight and 45 years of age. The median age was 14 in the treatment group and 13 in the placebo group. Participants included in the study did not have a diagnosis of T1DM but were classified as being high risk due to having a relative of varying degree with T1DM. Participants were randomized to receive intravenous infusions of either Tzield (n = 44) or placebo (n = 32) over 30 minutes followed by a 2-hour observation period for 14 consecutive days. This was conducted in an outpatient setting. The median follow-up period was 745 days and the duration of follow-up was > 3 years in 75% of the participants. The primary endpoint of the study was the elapsed time from randomization to the clinical diagnosis of diabetes, determined with the use of criteria from the American Diabetes Association. Scheduled oral glucose-tolerance tests (OGTT) were performed at three and six months after the infusions and every six months thereafter. OGTT results that indicated diabetes were confirmed, and the date of diagnosis was identified as the time of the first of the two diagnostic tests. The median time to T1DM diagnosis was 48.4 months in the treatment group and 24.4 months in the placebo group (HR = 0.41 [95% CI, 0.22 to 0.78, p = 0.006]). Overall, T1DM was diagnosed in 19 (43%) of the participants in the treatment group and in 23 (72%) of the participants in the placebo group. Significant adverse events that occurred during the study were lymphopenia (68% in the treatment group, 6% in the placebo group), infection with normal ANC (27% in the treatment group, 13% in the placebo group), and rash (30% in the treatment group, 0% in the placebo group). Of note, the nadir lymphocyte count occurred at day five in the treatment group and was resolved by day 45 in all participants except for one.

In June 2023, the American Diabetes Association released updates to the 2023 Standards of Care in Diabetes on the use of FDA approved therapies to delay the occurrence of T1DM. Section 2.6 states that when multiple islet autoantibodies are identified, referral to a specialized center for further evaluation and/or consideration of a clinical trial or approved therapy to potentially delay development of clinical diabetes should be considered.

Summary

Effective Date of Policy:	8/13/26
Indications	Delay the onset of stage 3 T1DM in patients eight years of age and older with stage 2 T1DM
ICD10 Diagnosis Codes	E10 (Diabetes Mellitus Type 1 diagnosis code)
HCPCS Code	J9381
Availability	2 mg/ml solution for injection
Duration	3 months to allow for 14-day treatment course

Required Criteria for Initial Approval		
All of the following conditions for the requested indication must be met in order to approve therapy:		
Specific Indication	**Inclusion Criteria**	**Recommended Dosing**

Delay the onset of stage 3 T1DM in patients eight years of age and older with stage 2 T1DM (FDA approval)
 	
ICD10: E10 (Diabetes Mellitus Type 1 diagnosis code)
	• Therapy is requested by an endocrinologist
	• Enrollee is 1 year of age or older
	• Must have a diagnosis of Stage 2 type 1 diabetes defined as (documentation must be submitted for the following):
	  ○ At least two of the following pancreatic islet autoantibodies must be confirmed
	  ▪ Glutamic acid decarboxylase 65 (GAD) autoantibodies
	  ▪ Insulin autoantibody (IAA)
	  ▪ Insulinoma-associated antigen 2 autoantibody (IA-2A)
	  ▪ Zinc transporter 8 autoantibody (ZnT8A)
	  ▪ Islet cell autoantibody (ICA)
	  ○ Dysglycemia without overt hyperglycemia as determined by oral glucose tolerance testing (OGTT), confirmed on two separate occasions within the previous 7 weeks. Note: Individuals < 18 years of age only require a single abnormal OGTT result within the previous 7 weeks.
	  ▪ Fasting blood glucose between 110 mg/dL and 125 mg/dL OR
	  ▪ 2-hour post-prandial glucose ≥ 140 mg/dL and < 200 mg/dL OR
	  ▪ 30-, 60-, or 90-minute value on OGTT ≥200 mg/dl
	• Prescriber must attest that the patient does not have clinical history that suggests type 2 diabetes AND
	• Tzield will not be covered for use in patients with Stage 3 Type 1 diabetes
	  ○ Although the phase 3 PROTECT trial met its primary endpoint, demonstrating significantly higher stimulated C-peptide levels in Tzield treated patients than placebo at week 78 (least-squares mean difference, 0.13 pmol/mL; 95% confidence interval [CI], 0.09 to 0.17; P<0.001), there was no significant difference observed in secondary endpoints. These secondary endpoints included mean daily insulin dose, the mean daily percentage of time in the target glucose range, the change from baseline in the mean hemoglobin A1c (HbA1c), and clinically important hypoglycemic events. Further studies are needed to confirm clinical benefit of Tzield in Stage 3 Type 1 diabetes. Of note, the confirmatory Phase 3 trial, βETA PRESERVE, has been initiated to assess HbA1c and prandial insulin use with Tzield compared to placebo in patients with recently diagnosed Stage 3 Type 1 diabetes.
	• Tzield will not be covered for any other non-FDA approved indication
	
	All other requests will be considered off-label/ investigational and will not be covered.
		• Tzield is administered by intravenous infusion (over a minimum of 30 minutes), using a body surface area-based dosing, once daily for 14 consecutive days.
		• See package insert for complete dosing and administration.

Continuation Criteria
• Coverage will be limited to a single cycle of 14 consecutive infusions, additional cycles of infusions will not be eligible for coverage. • Retreatment beyond a 14-day treatment course will be considered experimental/investigational and will not be authorized.

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.

Stages of T1DM

Stage 1	Beta cell autoimmunity (≥ 2 islet autoantibodies), normal blood glucose, and presymptomatic
Stage 2	Beta cell autoimmunity (≥ 2 islet autoantibodies), raised blood glucose, and presymptomatic
Stage 3	Beta cell autoimmunity (≥ 2 islet autoantibodies), raised blood glucose, and symptomatic
Stage 4	Longstanding disease

References

		Updated	Accessed
1	Herold, K. C., Bundy, B. N., & Long, S. A. (2019). An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes. *The New England Journal of Medicine*, 603-613.	08/2019	11/2022
2	Tzield (teplizumab) Clinical Trial (NCT01030861). Available at: https://www.clinicaltrials.gov/ct2/show/NCT01030861	8/2020	11/2022
3	Tzield [prescribing information], Provention Bio, Inc., Red Bank, NJ 07701.	12/2023	9/2024
4	Holt R I G, et al. The Management of Type 1 Diabetes in Adults. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care 2021; 44(11):2589-2625.	2021	11/2022
5	Nuha A. ElSayed, et al. American Diabetes Association; Addendum. 2. Classification and Diagnosis of Diabetes: *Standards of Care in Diabetes—2023*. Diabetes Care 2023;46(Suppl. 1):S19–S40. *Diabetes Care* 1 September 2023; 46 (9): 1715. https://doi.org/10.2337/dc23-ad08	6/2023	9/2023

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE CHOICES: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 8/13/2026

New: 12/14/2022

Revised	Reviewed
12/23, 9/25, 6/26, 8/26	12/24

Revision Date	Changes Made
12/22	New policy
12/23	Removed inclusion criteria: enrollee has a direct relative with a diagnosis of T1DM Clarified exclusion criteria: enrollee must not have any symptoms associated with stage 3 T1DM
9/25	Removed upper age limit of 45 years of age Updated language for dysglycemia Removed exclusion criteria Updated duration of authorization to 3 months
6/2026	Revised age for FDA expanded indication
8/2026	Updated language regarding Stage 3 Type 1 diabetes

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MEDICAL POLICY

Medical Policy Title	**Urine Drug Testing**
Policy Number	**2.02.50**
Current Effective Date	**June 1, 2026**
Next Review Date	**October 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

Presumptive Drug Testing for Pain Management

I. Presumptive (immunoassay) urine drug testing, in office or at point-of-care, for outpatient pain management, is considered **medically appropriate** for:

   A. Baseline screening before initiating treatment or at the time treatment is initiated when **ALL** of the following conditions are met:

      1. An adequate clinical assessment of patient history and risk of substance use disorder (SUD) is performed;
      2. Clinicians have knowledge of test interpretation; **and**
      3. There is a plan in place regarding how to use test findings clinically; **or**

   B. Subsequent monitoring of treatment at a frequency appropriate for the risk level of the individual patient (please refer to Policy Guidelines).

Presumptive Drug Testing for Substance Use Treatment

II. Presumptive (immunoassay) urine drug testing, in office or at point-of-care, for outpatient substance use treatment, is considered **medically appropriate** for:

   A. Baseline screening before initiating treatment or at the time treatment is initiated, one time per program entry when **ALL** of the following conditions are met:

      1. An adequate clinical assessment of patient history and risk of substance use disorder is performed;
      2. Clinicians have knowledge of test interpretation; **and**
      3. There is a plan in place regarding how to use test findings clinically; **or**

   B. Subsequent monitoring of treatment, either during a stabilization or maintenance phase at a frequency appropriate for the risk level of the individual patient (please refer to Policy Guidelines).

Definitive Drug Testing for Pain or Substance Use

III. Definitive urine drug testing, in outpatient pain management or substance use treatment, is considered **medically appropriate** in **ANY** of the following circumstances:

A. When presumptive urine drug testing is unable to identify the following:
    1. A specific substance or metabolite;
    2. Specific drugs in a large family of drugs;
    3. A specific substance or metabolite that is not detectable by qualitative urine drug testing (e.g., fentanyl, meperidine, synthetic cannabinoids);
    4. A negative qualitative urine drug test result (or to confirm a positive result) that is inconsistent with a patient's self-report, presentation, medical history, or current prescribed pain medication plan; **or**
    5. A non-prescribed medication or illicit use, to ensure the safe ongoing prescription of controlled substances;

B. When a definitive concentration of a drug is needed to guide management (e.g., discontinuance of THC use according to a treatment plan);

C. To rule out an error as the cause of a qualitative urine drug testing result;

D. When used as part of a differential assessment of medication efficacy, side effects, or drug-drug- interactions.

RELATED POLICIES

Corporate Medical Policy:

Out of Network Care, 1370/20.000145

POLICY GUIDELINE(S)

I. Testing frequency is dependent on the stability of the patient, the type of treatment, the treatment setting and the half-life of drugs in the matrix being tested.

II. Full informed consent is a requirement before urine drug testing. Patients should be informed of the specific drug testing protocol before treatment and should provide written agreement with the plan for monitoring. As stated in a joint U.S. Veterans Affairs/Department of Defense guideline, patients' refusal to consent to urine testing should be considered as one factor in the overall assessment of patients' ability to adhere to treatment.

III. Testing should be performed randomly or selectively based on patient history.

IV. Testing should not be performed as part of standard protocols (e.g., routine standing orders).

V. Testing should be supported by both an order for the test and rationale for the testing.

VI. The medical record should include documentation that the results were reviewed and will impact patient care.

VII. Presumptive urine drug testing for opioid pain management should be part of the pain management strategy and may be performed as follows:

    A. Prior to initiating opioid therapy.

B. Every three (3) months to assess effectiveness of the prescribed dose and decisions regarding tapering or increasing the dose are planned.

C. At least annually.

VIII. For end-of-life pain management with opioids, testing is indicated if there is any reason to consider diversion of the drug (lost scripts, lost pills, enormous escalation of utilization without member appearing to have consumed the specific amount of opioids).

IX. Frequency of presumptive urine drug testing for substance use disorder is based on the consecutive days of abstinence as follows:

A. 0 to 30 days consecutive abstinence: One (1) to three (3) presumptive urine drug tests per week. Requests for coverage of more than three (3) presumptive urine drug tests per week must be accompanied by clinical documentation to support additional testing.

B. 31 to 90 consecutive days of abstinence: One (1) to three (3) presumptive urine drug tests per week. Requests for coverage of more than three (3) presumptive urine drug tests per week must be accompanied by clinical documentation to support additional testing.

C. Greater than 90 consecutive days of abstinence: One (1) to three (3) presumptive urine drug tests per month.

1. Requests for coverage of more than three (3) physician-directed presumptive urine drug tests in one (1) month must be accompanied by clinical documentation to support additional testing. (e.g., Contingency management in SUD is over a 10-week to 12-week period.)

X. Definitive urine drug testing for opioid pain management may be performed to detect specific opioids that cannot be identified on standard immunoassays or in the event of unexpected urine drug test results.

XI. Frequency of definitive urine drug testing and the rationale for testing must be documented in the patient's medical record. Frequency is based on the following consecutive days of abstinence, as follows:

A. Zero (0) to 30 days consecutive days of abstinence: One (1) physician-directed testing profile per week. Requests for coverage of more frequent definitive urine drug tests in one (1) week must be accompanied by clinical documentation to support additional testing.

B. 31 to 90 consecutive days of abstinence: One (1) to three (3) physician-directed testing profile(s) per month. Requests for coverage of more than three (3) definitive urine drug tests in one month must be accompanied by clinical documentation to support additional testing.

C. Greater than 90 consecutive days of abstinence: One (1) to three (3) physician-directed testing profile(s) per three-month period. Requests for more than three (3) definitive urine drug tests in a three-month period must be accompanied by clinical documentation to support additional testing.

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XII. Frequency of urine drug testing for individuals on chronic opioid therapy depends on the risk of opioid misuse and/or the existence of an opioid disorder. Frequency of testing ranges from:

A. Low risk: One (1) to two (2) times per twelve (12) month period

B. Moderate risk: One (1) to two (2) times per six (6) month period

C. High risk: One (1) to three (3) times per three-month period for prescribed medications, non-prescribed medications that may pose a safety risk if mixed with prescribed medications, and illicit substances based on patient history, clinical presentation and/or community usage.

DESCRIPTION

Drug testing is a vital part of addiction assessment and treatment planning, especially when combined with other clinical tools like substance use history, physical and mental evaluations, withdrawal severity scores, and standardized lab assessments (ASAM, 2013). Skilled clinicians use drug testing to verify self-reports, confirm diagnoses, identify denial or minimization, enhance treatment motivation, monitor progress, and validate abstinence or adherence to prescribed medications. Contingency management, which rewards abstinence, is one example of an effective intervention. Urine drug testing is especially important during the intensive "primary treatment" phase, which includes psychosocial support, psychoeducation, psychotherapy, and cognitive-behavioral strategies. Random and frequent testing should be maintained throughout this phase. In the post-treatment monitoring phase, continued random testing remains central, supporting long-term recovery and abstinence. Testing should be unpredictable and more frequent early in treatment, with reduced frequency as abstinence stabilizes. Varying the testing panels and methods further strengthens its effectiveness.

<u>Categories of Urine Drug Testing</u>

- Presumptive Drug Testing (Screening) detects the presence or absence of drugs in urine when immediate results are needed for patient care. Common methods include immunoassays (IA) and thin layer chromatography (TLC). IAs, which can be lab-based or point-of-care (e.g., a physician's office), use antibodies to detect drugs through competitive binding. The amount of labeled drug that binds to the antibody is inversely related to the drug concentration in the sample.

  IA formats include cups, dipsticks, cassettes, or strips, read visually or with instruments. They vary in specificity—some detect individual drugs, others only drug classes—and may miss structurally similar substances. Cross-reactivity with other medications is possible but less common due to improved antibodies.

  The most common test, SAMHSA-5 panel tests for amphetamines, THC, cocaine, opiates (e.g., codeine, morphine), and PCP. Panels can be expanded to include benzodiazepines and synthetic/semi-synthetic opioids like oxycodone, buprenorphine, and methadone. Results are qualitative—positive (above threshold) or negative (below threshold)—and do not confirm drug absence. IA tests offer rapid results: minutes for onsite, 1–4 hours for lab-based.

- Definitive (Confirmatory) Testing identifies specific drugs and metabolites by analyzing their

molecular structures. It confirms results from screening evaluates and detects substances not identifiable by immunoassays (IAs). These lab-based tests quantify drug levels in urine and report exact concentrations.

Common methods include:

- Gas Chromatography-Mass Spectrometry (GC-MS): The gold standard for confirmatory testing. It separates and identifies compounds but typically requires prior specification of target drugs. Turnaround is several days.
- Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS): Faster and easier than GC-MS, it uses two mass spectrometers for enhanced detection without needing derivatization.
- Quantitative or confirmation testing can be performed as a reflex test which is performed after an initial test result to identify further diagnostic information.

Urine drug tests are vulnerable to tampering, including dilution (e.g., excessive water intake), commercial adulterants, and synthetic urine. Some tampering can be detected through visual inspection or onsite checks of temperature, creatinine, and specific gravity.

Accurate interpretation requires understanding drug metabolites and manufacturing byproducts. For example, trace hydrocodone in patients prescribed oxycodone may be acceptable due to manufacturing impurities.

Urine testing is commonly used at treatment initiation to assess current drug use. While routine universal screening may detect more misuse and reduce stigma, it can strain healthcare resources and affect trust. Selective testing based on risk assessment is an alternative. Protocols vary, some confirm all positive qualitative results with quantitative tests, while others confirm only unexpected results or those involving drugs with unreliable immunoassays.

SUPPORTIVE LITERATURE

Choucair et al (2024) studied the use of DART-MS/MS as a faster and more efficient alternative to traditional opioid detection methods in clinical laboratories. Current practices typically involve IA screening followed by LC-MS/MS confirmation, which, while accurate, are time-consuming and require extensive sample preparation. The researchers optimized DART-MS/MS by adjusting variables like temperature, extraction methods, and hydrolysis times, and evaluated its performance across 12 opioids. The method demonstrated high sensitivity and specificity for several opioids, including fentanyl, codeine, and hydrocodone, but was less effective for others like morphine and oxycodone. The study concludes that DART-MS/MS shows promise as a rapid, quantitative tool for opioid testing in urine, though further research is needed to broaden its clinical applications.

Magura et al (2023) investigated the comparative effectiveness of two drug testing methodologies—presumptive testing and direct-to-definitive testing—using two biological matrices: oral fluid and urine. A total of 1098 samples (urine and oral fluid) from individuals applying for methadone treatment were collected. All samples were evaluated via IA and LC-MS/MS. Presumptive testing, typically performed with IA, offers rapid screening but is susceptible to false positives and negatives due to limited specificity and cross-reactivity. Direct-to-definitive testing, using advanced techniques

like LC-MS/MS, provides highly accurate identification of drug compounds without the need for preliminary screening. The study analyzes a national sample of individuals misusing drugs to evaluate detection windows, analyte coverage, and diagnostic accuracy across both matrices. Urine testing is traditionally favored for its longer detection window and regulatory acceptance, while oral fluid testing is less invasive and better suited for detecting recent drug use. The findings aim to inform clinical and forensic toxicology practices by highlighting the trade-offs between speed, accuracy, and operational efficiency in drug testing protocols.

PROFESSIONAL GUIDELINE(S)

The American Society for Addiction Medicine (ASAM) updated its guidelines on Appropriate Use of Drug Testing in Clinical Addiction (2017). The guidelines include the following recommendations:

- Drug testing should be used widely in addiction treatment settings because evidence suggests that drug testing assists with monitoring adherence and abstinence in treatment and can improve patient outcomes and should be used in combination with a patient's self-reported information about substance use. Providers should understand that drug tests are designed to measure whether a substance has been used within a particular window of time and drug testing panels should be based on the patient's drug of choice, prescribed medications, and drugs commonly used in the patient's geographic location and peer group.
- Presumptive testing should be a routine part of initial and ongoing patient assessment, as it can provide more immediate (albeit less accurate) results. Definitive testing techniques should be used whenever a provider wants to detect specific substances not identified by presumptive methods, to quantify levels of the substance present, and to refine the accuracy of the results; and the results inform clinical decisions that have major clinical or non-clinical implications for the patient (e.g. treatment transition, changes in medication therapies, changes in legal status).
- For people in addiction treatment, frequency of testing should be dictated by patient acuity and level of care, and providers should look to tests' detection capabilities and windows of detection to determine the frequency of testing. Providers should understand that increasing the frequency of testing increases the likelihood of detection of substance use, but there is insufficient evidence that increasing the frequency of drug testing has an effect on substance use, itself.
- Drug testing should be scheduled more frequently (at least weekly) at the beginning of treatment, and the frequency should be decreased to monthly as recovery progresses and is stable.
- Testing should occur on a random schedule in outpatient services following weekends, holidays, and paydays, when feasible because the patient's opportunity for substance use is greater relative to residential treatment. Additional drug testing should be considered if a patient is experiencing stressful psychological events.

The ASAM published a public policy statement on the Ethical Use of Drug Testing in The Practice of Addiction Medicine in 2019. The statement included the following recommendations:

- Drug testing is recommended as a therapeutic tool in evidence-based addiction treatment. It

should not be used or presented as a punitive measure.

- Drug testing should be used only when clinically necessary. Tests should be selected based on an individualized clinical assessment of the patient and performed after informed consent whenever possible.
- Presumptive testing should be a routine part of initial and ongoing patient assessment.
- Definitive testing may be used when the results will alter the care plan or to detect specific substances not identified by presumptive methods and to refine the accuracy of the test results.
- It is inappropriate to order definitive testing for all analytes in every drug test conducted on a patient.
- Clinicians should ensure that drug test results remain confidential.
- Clinicians ordering drug tests should be aware of the costs of different testing methods and the financial burden that the patient and society may incur.
- If clinicians responsible for making clinical decisions based on drug test results do not have training in toxicology, collaboration should occur with a toxicologist or an individual with Medical Review Officer certification.
- Clinicians should maintain knowledge of state or federal rules or guidelines about drug testing that may apply to their practice.
- It is unethical for clinicians or addiction treatment programs to ask laboratories to change cutoff levels to improve that provider's quality metrics.
- It is unethical to provide or receive incentives for the use of drug testing independent of a clinical rationale.

The ASAM published a National Practice Guideline for the Treatment of Opioid Use Disorder (2020) which identifies the following:

- Urine drug testing can be used during assessment and diagnosis to validate patient self-reported information and to identify poly-substance use.
- Testing can be used to monitor patients for adherence to medication and for use of illicit and controlled substances during treatment.
- The frequency of drug testing is determined by a number of factors including the stability of the patient, type of treatment and treatment setting. The guideline also notes that no further clarification was found in the literature related to urine drug testing and this is considered a gap in literature.

The American Society of Interventional Pain Physicians (ASIPP) 2023 updated guidelines for opioids for chronic noncancer pain and made the following recommendations for urine drug testing:

- Urine drug monitoring (UDM) should be implemented at the initiation of opioid therapy and conducted periodically for monitoring therapeutic compliance as per available guidance referential to mode and frequency of testing. (Evidence Level: Moderate; Strength of

Recommendation: Strong).

- Tapering or weaning processes must be initiated slowly after appropriate criteria have been met and should entail slow tapering of the dosage across a specified period of time. Reinstitution of opioid therapy can be considered when such treatment is deemed medically necessary if the patient's behavior and pattern of drug use are shown to be stable, and if results of at least two consistent urine drug tests are negative (for opioids and/or illicit drugs). (Evidence Level: Moderate; Strength of Recommendation: Moderate).
- Adherence monitoring to assess and sustain appropriate use must be instituted at proper intervals, as based on risk stratification and indication(s) of other issues that may be regarded as negatively influencing therapeutic compliance. Evidence Level: Moderate; Strength of recommendation: Moderate

In 2014, the American College of Occupational and Environmental Medicine (ACOEM) updated its guidelines for Opioids for Treatment of Acute Subacute, Chronic, and Postoperative Pain chronic use of opioids and recommends:

- Baseline and random urine drug screening, qualitative and quantitative, for patients prescribed opioids for the treatment of subacute or chronic pain to evaluate presence or absence of the drug, its metabolites and other substance(s) use. In certain situations, other screenings (e.g., hair particularly for information regarding remote use or blood) (for acute toxicity) may be appropriate. (C; High Confidence).

The Centers for Disease and Control Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain (2016) recommends:

- When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually, to assess for prescribed medications, as well as other controlled prescription drugs and illicit drugs (recommendation category: B, evidence type 4).
- If clinicians suspect their patient might be sharing or selling opioids and not taking them, clinicians should consider urine drug testing to assist in determining whether opioids can be discontinued without causing withdrawal. A negative drug test for prescribed opioids might indicate the patient is not taking prescribed opioids, although clinicians should consider other possible reasons for this test result.
- Experts agreed that, prior to starting opioids for chronic pain, and periodically during opioid therapy, clinicians should use urine drug testing to assess for prescribed opioids, as well as other controlled substances and illicit drugs that increase the risk for overdose when combined with opioids, including nonprescribed opioids, benzodiazepines, and heroin.
- Most Experts agreed that urine drug testing at least annually for all patients was reasonable. Some experts noted that this interval might be too long in some cases and too short in others, and that the follow-up intervals should be left to the discretion of the clinician.
- In most situations, initial urine drug testing can be performed with a relatively inexpensive IA

panel for commonly prescribed opioids and illicit drugs. Patients who are prescribed less-commonly-used opioids might require specific testing for those agents. The use of confirmatory testing adds substantial costs and should be based on the need to detect specific opioids that cannot be identified on standard IAs or on the presence of unexpected urine drug test results.

- Clinicians should not test for substances for which results would not affect patient management or for which implications for patient management are unclear.
- Clinicians should be familiar with the drugs included in urine drug testing panels used in their practice and should understand how to interpret results for these drugs. Before ordering urine drug testing, clinicians should have a plan for responding to unexpected results.
- Clinicians should explain to patients that urine drug testing is intended to improve their safety, they should also explain expected results (e.g., presence of prescribed medication and absence of drugs, including illicit drugs, not reported by the patient).
- Clinicians should ask patients about use of prescribed and other drugs and ask whether there might be unexpected results. This will provide an opportunity for patients to provide information about changes in their use of prescribed opioids or other drugs.
- Clinicians should use unexpected results to improve patient safety (e.g., changing in pain management, tapering or discontinuing opioids, re-evaluating more frequently, offering naloxone, or referring for treatment for substance use disorder, all as appropriate). If tests for prescribed opioids are repeatedly negative, confirming that the patient is not taking the prescribed opioid, clinicians can discontinue the prescription without a taper.
- Clinicians should not dismiss patients from care based on a urine drug test result because this could constitute patient abandonment and could have adverse consequences for patient safety.

REGULATORY STATUS

Not Applicable

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
80305	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; capable of being read by direct optical observation only (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges]), includes sample validation when performed, per date of service
80306	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; read by instrument assisted direct optical observation (e.g., utilizing immunoassay [e.g., dipsticks, cups, cards, or cartridges), includes sample validation when performed, per date of service
80307	Drug test(s), presumptive, any number of drug classes, any number of devices or procedures; by instrument chemistry analyzers (e.g., utilizing immunoassay [e.g., EIA, ELISA, EMIT, FPIA, IA, KIMS, RIA]), chromatography (e.g., GC, HPLC), and mass spectrometry either with or without chromatography (e.g., DART, DESI, GC-MS, GCMS/MS, LC-MS, LC-MS/MS, LDTD, MALDI, TOF) includes sample validation when performed, per date of service
80320-80373	Definitive drug testing (code range)
80375	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 1-3 analytes
80376	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 4-6 analytes
80377	Drug(s) or substance(s), definitive, qualitative or quantitative, not otherwise specified; 7 or more analytes
83992	Phencyclidine (PCP)
0007U	Drug test(s), presumptive, with definitive confirmation of positive results, any number of drug classes, urine, includes specimen verification including DNA authentication in comparison to buccal DNA, per date of service (ToxProtect, Genotox Laboratories, Ltd)
0051U	Prescription drug monitoring, evaluation of drugs present by liquid chromatography tandem mass spectrometry (LC-MS/MS), urine or blood, 31 drug panel, reported as quantitative results, detected or not detected, per date of service (UCompliDx, Elite Medical Laboratory Solutions, LLC)

Code	Description
0082U	Drug test(s), definitive, 90 or more drugs or substances, definitive chromatography with mass spectrometry, and presumptive, any number of drug classes, by instrument chemistry analyzer (utilizing immunoassay), urine, report of presence or absence of each drug, drug metabolite or substance with description and severity of significant interactions per date of service (NextGen Precision™ Testing, Precision Diagnostics LBN Precision Toxicology, LLC)
0093U	Prescription drug monitoring, evaluation of 65 common drugs by LC-MS/MS, urine, each drug reported detected or not detected (ComplyRX, Claro Labs)
0117U	Pain management, analysis of 11 endogenous analytes (methylmalonic acid, xanthurenic acid, homocysteine, pyroglutamic acid, vanilmandelate, 5-hydroxyindoleacetic acid, hydroxymethylglutarate, ethylmalonate, 3-hydroxypropyl mercapturic acid (3-HPMA), quinolinic acid, kynurenic acid), LC-MS/MS, urine, algorithm reported as a pain-index score with likelihood of atypical biochemical function associated with pain (Foundation PI℠, Ethos Laboratories)
0227U	Drug assay, presumptive, 30 or more drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS) using multiple reaction monitoring (MRM), with drug or metabolite description, includes sample validation (Comprehensive Screen, Aspenti Health)
0328U	Drug assay, definitive, 120 or more drugs and metabolites, urine, quantitative liquid chromatography with tandem mass spectrometry (LC-MS/MS), includes specimen validity and algorithmic analysis describing drug or metabolite and presence or absence of risks for a significant patient-adverse event, per date of service (CareView360, Newstar Medical Laboratories LLC)
0603U	Drug assay, presumptive, 77 drugs or metabolites, urine, liquid chromatography with tandem mass spectrometry (LC-MS/MS), results reported as positive or negative

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HCPCS Codes

Code	Description
G0480	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 1-7 drug class(es), including metabolite(s) if performed
G0481	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 8-14 drug class(es), including metabolite(s) if performed
G0482	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 15-21 drug class(es), including metabolite(s) if performed

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Code	Description
G0483	Drug test(s), definitive, utilizing (1) drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including, but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem and excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase)), (2) stable isotope or other universally recognized internal standards in all samples (e.g., to control for matrix effects, interferences and variations in signal strength), and (3) method or drug-specific calibration and matrix-matched quality control material (e.g., to control for instrument variations and mass spectral drift); qualitative or quantitative, all sources, includes specimen validity testing, per day; 22 or more drug class(es), including metabolite(s) if performed
G0659	Drug test(s), definitive, utilizing drug identification methods able to identify individual drugs and distinguish between structural isomers (but not necessarily stereoisomers), including but not limited to, GC/MS (any type, single or tandem) and LC/MS (any type, single or tandem), excluding immunoassays (e.g., IA, EIA, ELISA, EMIT, FPIA) and enzymatic methods (e.g., alcohol dehydrogenase), performed without method or drug-specific calibration, without matrix-matched quality control material, or without use of stable isotope or other universally recognized internal standard(s) for each drug, drug metabolite or drug class per specimen; qualitative or quantitative, all sources, includes specimen validity testing, per day, any number of drug classes

ICD10 Codes

Code	Description
F11.10-F11.99	Opioid related disorders (code range)
F14.10-F14.99	Cocaine related disorders (code range)
F16.10-F16.99	Hallucinogen related disorders (code range)
F45.42	Pain disorder with related psychological factors
G89.21-G89.4	Chronic pain (code range)

REFERENCES

American Society of Addiction Medicine [Internet]. Appropriate use of drug testing in clinical addiction medicine. consensus statement 2017 Apr 5. [accessed 2025 Jul 29] Available from:

https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/guidelines/the-asam-appropriate-use-of-drug-testing-in-clinical-addiction-medicine-full-document.pdf?sfvrsn=700a7bc2_0

American Society of Addiction Medicine [Internet]. Public policy statement on the ethical use of drug testing in the practice of addiction medicine. 2019 Apr 3. [accessed 2025 Jul 29] Available from: https://www.asam.org/quality-care/clinical-guidelines

American Society of Addiction Medicine [Internet]. National practice guideline for the treatment of opioid use disorder/ 2020 focused update. 2019 Dec 18. [accessed 2025 Jul 29] Available from: https://www.asam.org/quality-care/clinical-guidelines/national-practice-guideline

Argoff CE, et al. Rational urine drug monitoring in patients receiving opioids for chronic pain: consensus recommendations. Pain Med. 2018 Jan 1;19(1):97-117.

Arthur J, et al. Random vs targeted urine drug testing among patients undergoing long-term opioid treatment for cancer pain. JAMA Oncol. 2020 Apr 1;6(4):580-581.

Arthur JA. Urine drug testing in cancer pain management. Oncologist. 2020 Feb; 25(2): 99–104.

Bharat C, et al. Agreement between self-reported illicit drug use and biological samples: a systematic review and meta-analysis. Addiction. 2023;118:1624-1648.

Chennapan K, et al. Medical screening of mental health patients in the emergency department: a systematic review. J Emerg Med. 2018 Oct 10;pii:S0736-4679(18)30930-2.

Choucair I, et al. Direct analysis in real time mass spectrometry (DART-MS/MS) for rapid urine opioid detection in a clinical setting. Clin Chim Acta. 2025 Jan 1;564:119939.

Chutuape MA, et al. Effects of urine testing frequency on outcome in a methadone take-home contingency program. Drug Alcohol Depend. 2001 Mar 1;62(1):69-76.

Dowell D, et al. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016 [Internet]. Recommendations and Reports 2016 Mar 18;65(1):1–49. [accessed 2025 Jul 29] Available from**:** https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

Hegmann KT, et al. American College of Occupational and Environmental Medicine. ACOEM practice guidelines: opioids for treatment of acute, subacute, chronic, and postoperative pain. J Occup Environ Med. 2014 Dec;56(12):e143-59.

Magura S, et al. Comparing presumptive with direct-to-definitive drug testing in oral fluid vs. urine for a U.S. national sample of individuals misusing drugs. Drug Alcohol Depend. 2023 Sep 1;250:110894.

Manchikanti L, et al. Does random urine drug testing reduce illicit drug use in chronic pain patients receiving opioids? Pain Physician. 2006;9(2):1230129.

Manchikanti L, et al. Comprehensive, evidence-based, consensus guidelines for prescription of opioids for chronic non-cancer pain from the American Society of Interventional Pain Physicians (ASIPP). Pain Physician. 2023 Dec;26(7S):S7-S126.

Moeller KE, et al. Clinical interpretation of urine drug tests: what clinicians need to know about urine

drug screens. Mayo Clin Proc. 2017 Ma7;92(5):774-796.

Starrels JL, et al. Systematic review; treatment agreements and urine drug testing to reduce opioid misuse in patients with chronic pain. Ann Intern Med. 2010 Jun 1;152(11):712-20.

Twillman RK, et al. Evaluation of trend of near-real-time urine drug test results for methamphetamine, cocaine, heroin, and fentanyl. JAMA Netw Open. 2020 Jan; 3(1): e1918514.

Yang YK, Snozek CLH. Value of Improving Result Interpretation in Direct-to-Definitive Urine Drug Panels. Clin Lab Med. 2025 Jun;45(2):233-246.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Urine Drug Testing (LCD L39611) [accessed 2025 Jul 29]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 7/19

Revised: 6/26

Reviewed: 7/20, 7/21, 7/22, 7/23, 7/24, 7/25

Date	Summary of Changes
6/2026	• Transitioned Urine Drug Testing policy, 1370/20.000502 to Lifetime HealthCare Companies policy template.

MEDICAL POLICY

Medical Policy Title	**Vagus Nerve Stimulation and Vagus Nerve Blocking Therapy**
Policy Number	**7.01.05**
Current Effective Date	**August 20, 2026**
Next Review Date	**August 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

This policy does not address transcutaneous vagus nerve stimulation. Refer to CMP 1.01.61 Non-Invasive Surface Electrical Stimulation for Pain and Rehabilitation.

POLICY STATEMENT(S)

I. An implantable vagus nerve stimulation (VNS) device is **medically appropriate** when used as a treatment for medically refractory seizures.

II. An implantable VNS device is **investigational** as a treatment for individuals with depression or any other non-epileptic conditions (e.g., heart failure, fibromyalgia, tinnitus, traumatic brain injury, essential tremor, headache, post-stroke).

III. Vagus nerve stimulation implants that allow detection and stimulation based on increased heart rate (e.g., AspireSR Model) are **investigational** for **ALL** indications.

IV. Vagus nerve blocking therapy is **investigational** as a treatment for individuals with morbid obesity.

RELATED POLICIES

Corporate Medical Policy

1.01.58 Cranial and Auricular Neuromodulation

1.01.59 Electromagnetic and Pulsed Field Stimulation

1.01.60 Implantable and Invasive Neuromodulation Systems

1.01.61 Non-invasive Surface Electrical Stimulation for Pain and Rehabilitation

1.01.62 Specialized Neuromodulation for Specific Conditions7.01.103 Responsive Neurostimulation for the Treatment of Refractory Focal Epilepsy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

Not Applicable

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

DESCRIPTION

Seizures have been defined as paroxysmal disorders of the central nervous system characterized by abnormal cerebral neuronal discharge, with or without loss of consciousness. Medically refractory seizures are defined as seizures that occur in spite of therapeutic levels of antiepileptic drugs or seizures that cannot be treated with therapeutic levels of antiepileptic drugs because of intolerable adverse effects of these drugs.

The goal of epilepsy surgery is to either remove the seizure-producing area of the brain or to limit the spread of seizure activity. Surgical results can be considered curative (stopping the seizures) or palliative (restricting the spread of the seizures). The type of surgery performed is dependent on the type of seizure and where the seizures begin in the brain. Curative procedures (e.g., temporal lobectomy, cortical excision, hemispherectomy) are performed when tests consistently point to a specific area of the brain where the seizures begin. Palliative procedures (e.g., corpus callosotomy, subpial transections) are performed when a seizure focus cannot be determined, or it overlaps brain areas critical for speech, movement, or vision.

The vagus nerve extends from the brain down the side of the neck to the large intestines, helping regulate key body systems such as the heart and digestion. A vagus nerve stimulator device (VNS) is a device used as an add-on therapy for individuals with epilepsy that is not well controlled by medication. It delivers mild electrical impulses to the vagus nerve targeting areas of the brain involved in seizure activity. VNS is especially important for individuals whose seizures do not respond to drug therapy, who are not candidates for epilepsy surgery, or for whom surgery has failed to significantly reduce sized frequency.

Surgery for implantation of a vagus nerve stimulator involves wrapping two spiral electrodes around the left vagus nerve within the carotid sheath. The electrodes are connected to an infraclavicular generator pack. The programmable stimulator may be programmed in advance, to stimulate at regular times or upon demand by the individual or caregiver by placing a magnet against the subclavicular implant site.

VNS is also being investigated for a variety of other non-epileptic conditions, including depression that has not responded to conventional treatment, bipolar disorder, obesity, autism, essential tremor, refractory anxiety, cluster headaches/migraines, bulimia, stroke, and Alzheimer's disease.

The vagus nerves play a significant role in food processing, in signaling the feeling of fullness, and in prolonging the absence of hunger through nervous control of multiple functions. Vagal blocking (VBLOC), therapy is being developed to induce intermittent intra-abdominal vagal blocking to treat obesity, using high-frequency electrical currents. The electrodes are positioned laparoscopically on the anterior and posterior vagal trunks near the esophagogastric junction (EGJ), without anatomic modification or tissue compression of the alimentary tract. Blocking vagus nerve signals may reduce appetite and create weight loss by limiting the expansion of the stomach*;* and by reducing the frequency and intensity of stomach contractions. Vagal blocking therapy may also reduce the absorption of calories by decreasing the secretion of digestive enzymes. When the blocking is paused, two-way neural signals resume, and the stomach and pancreas return to normal function.

Vagal blocking therapy's intermittent active therapeutic episodes are programmed for twelve hours per day, to prevent the body's natural tendency to circumvent the blocked neural signals and prolong the therapeutic effect during the individual's waking hours.

SUPPORTIVE LITERATURE

Vagus Nerve Stimulation for Focal Epilepsy

Panebianco et al (2022) updated the original 2015 review on the effectiveness of VNS as an add-on treatment for individuals with drug resistance focal epilepsy. The analysis included data from 439 participants and assessed treatment withdrawals, adverse effect, quality of life (QOL), cognition, mood, overall risk ratio for those who experience greater reduction in seizure frequency. The authors did not identify any new studies for this update thereby concluding the result are unchanged. VNS appears to be an effective treatment for individuals with intractable focal epilepsy. High level simulation was associated with greater reduction in seizure frequency compared to low level stimulation. Common side effects include voice alteration, hoarseness, pain, shortness of breath, cough, nausea, tingling sensations, headache, and infection at the surgical site. Shortness of breath, voice changes, and hoarseness occurred more frequently with high level stimulation. However, the evidence on both the effectiveness and side effects of the VNS therapy is limited and imprecise due to the small number of studies and participants, as well as gaps in trial designs and reporting. The certainty of evidence was rated as moderate to low meaning that future research is likely or very likely to impact confidence in these findings and may change the estimates.

Hamilton et al (2018) evaluated the efficacy of the AspireSR VNS, (including cardiac based seizure detection [CBSD]) by comparing outcomes in individuals receiving new AspireSR implants, and those individuals who underwent a battery replacement of AspireSR from an older VNS model. The results showed that the new implant group (AspireSR as first VNS) had a reduction in median seizures per year reduced from 192 to 64 and 59% experienced ≥50% reduction in seizures. A total of 41% saw greater than 80% reduction, 6% became seizure free during follow up, and 10% reported no anti-epileptic benefit. The battery replacement group (previously VNS to ApsireSR) showed a seizure reduction from 336 pre-VNS to 90 (post initial VNS) to 72 (post AspireSR). After the AspireSR upgrade, 71% achieved ≥50% additional reduction, and 74% required no change in stimulation duty cycle. Improvement was significantly greater from original VNS. Minimal surgical complications were reported, four cases of transient vocal cord paresis (2.6%), one lead migration (0.7%), and no infections or hemorrhage reported. Overall authors reported that AspireSR AutoStim feature (ictal tachycardia detection) provided significant value over traditional VNS.

VNS for Limb Dysfunction after Stroke

The evidence on VNS for treatment of upper-limb impairment due to stroke consists of 3 small RCTs and a systematic review that pooled their data. Two RCTs compared VNS plus rehabilitation to rehabilitation alone. Dawson et al (2016) conducted a randomized pilot trial of VNS in patients (n=21) with upper-limb dysfunction after ischemic stroke, which failed to show significant improvements for the VNS group on response and function outcomes. Dawson et al (2021) conducted a similar RCT with a larger patient population (n=106), which found a significant

difference in response and function outcomes. The third RCT compared VNS to sham (n=17) found that although VNS significantly improved response rate, there were 3 serious adverse events related to surgery (Kimberley et al 2019).

Ramos-Castaneda et al (2022) published a systematic review evaluating VNS on upper limb motor recovery after stroke, reporting that implanted VNS improved upper limb motor function based on Fugl-Meyer Assessment-Upper Extremity (FMA-UE) score when compared to control. This systematic review and meta-analysis concluded that VNS together with physical rehabilitation improves upper limb motor function in stroke patients; however, with several knowledge gaps and limitations, the authors acknowledge that more studies are needed to evaluate the efficacy.

Results from other pilot studies suggest that VNS might induce weight loss in obese patients and improve cognitive function in patients with Alzheimer's disease. However, these findings need to be validated in large, randomized, placebo-controlled trials with long-term outcomes reported.

VNS for Depression

Conway et al (2025) evaluated the safety and efficacy of the Food and Drug Administration (FDA) approved adjunctive VNS in adults with marked treatment resistant depression (TRD). The study consisted of a 12-month, double-blind multi center randomized sham-controlled trial that included 493 adults with TRD. Participants were randomized to either active VNS plus treatment as usual (Tau) or no-stimulation sham VNS therapy prior to device implantation and activation. The primary outcome was percentage of time in response from months 3 to 12, with response defined as a ≥50 % reduction from baseline on the Montgomery-Åsberg Depression Rating Scale (MADRS). Overall, 88.4% of participants completed the trial. The percentage of time in MADRS define response, did not significantly differ between the active and sham VNS groups. However, ratings from on-site clinicians (Clinical Global Inventory–Impression [CGI-I]), patients (Quick Inventory of Depressive Symptomology–Self Report [QIDS-SR]), and offsite masked raters (Quick Inventory of Depressive Symptomology–Clinician [QIDS-C]) revealed antidepressant benefits significantly favoring active VNS. Researchers concluded that although the primary outcome (percentage time in MADRS response) did not significantly differentiate VNS from sham, multiple secondary measures showed statistically and clinically significant improvements in patients receiving active VNS. Overall, the study supports VNS as a safe and moderately effective adjunctive treatment for patients with marked TRD especially when partial improvements are clinically meaningful.

Vagus Nerve Blocking Therapy

The current literature is insufficient to determine the overall safety and efficacy of treating obesity using vagal nerve blocking therapy. A randomized controlled clinical trial, EMPOWER, (MG Sarr et al 2012) found that VBLOC therapy to treat morbid obesity was safe overall; however, the weight loss was not any greater in the treatment group compared to the control group.

In the 2014 ReCharge trial, S Ikramuddin and colleagues conducted a randomized, double-blind, sham-controlled clinical trial to evaluate the effectiveness and safety of intermittent, reversible vagal nerve blockade therapy for obesity treatment. This study involved 239 participants who had a BMI of 40 to 45 or 35 to 40 and one or more obesity-related condition. It was conducted at ten sites in the

United States and Australia. Of the initial 239 participants, 157 patients received an active vagal nerve block device, and 75 received a sham device. All participants received weight management education. The coprimary efficacy objectives were to determine whether the vagal nerve block was superior in mean percentage excess weight loss to sham by a 10-point margin with at least 55% of patients in the vagal block group achieving a 20% loss and 45% achieving a 25% loss. The authors concluded that, among patients with morbid obesity, the use of vagal nerve block therapy compared with a sham control device did not meet either of the prespecified coprimary efficacy objectives, although weight loss in the vagal block group was statistically greater than in the sham device group. The treatment was well-tolerated, having met the primary safety objective.

The ReCharge trial 24-month outcomes were reported by Apovian et al (2017). At 24-months, participants (n=123) remaining in the trial had a mean excess weight loss (EWL) of 21%; mean total weight loss (TWL) of 8%; 58% had ≥ 5% TWL; and 34% had ≥ 10% TWL. Significant improvements ($p<0.05$) were seen in mean LDL, HDL, triglycerides, and systolic and diastolic blood pressures. Adverse events were reported as mild or moderate, with the most frequently reported related adverse events were heartburn and dyspepsia, neuroregulator site pain, nausea, belching, and dysphagia. Study limitations include short-term follow-up, missing data, lack of a blinded control group, and small study size.

PROFESSIONAL GUIDELINE(S)

The American Academy of Neurology reaffirmed their 2013 guidelines addressing vagus nerve stimulation for the treatment of epilepsy. The recommendations include the following guidance:

- VNS may be considered as adjunctive treatment for children with partial or generalized epilepsy (Level C, 14 Class III studies).
- VNS may be considered in patients with Lennox-Gastaut syndrome (LGS) (Level C, 4 Class III studies). The responder rate for patients with LGS does not appear to differ from that of the general population of patients with medication-resistant epilepsy.
- In adult patients receiving VNS for epilepsy, improvement in mood may be an additional benefit (Level C, 2 Class III studies).
- VNS may be considered progressively effective in patients over multiple years of exposure (Level C, 2 Class III studies).

The National Institute for Health and Carel Excellence (NICE) 2020 guidelines for implanted vagus nerve stimulation for treatment-resistant depression recommends the following guidance:

- Evidence suggests that animplanted VNS for treatment-resistant depression does not raise significant safety concerns though it is associated with common well known side effects. However, the evidence supporting its effectiveness is of limited quality. As a result, the use of this procedure should be restricted to a setting with appropriate clinical governance, informed consent processes, and provisions for audit or research.

The American Psychological Association (APA) clinical practice guideline addressing the treatment of depressive disorders in children, adolescents, adults, and older adults (2022) examined the efficacy

of psychological treatments, pharmacotherapy, and complementary and alternative medicine treatments.

- VNS may be an additional option for individuals who have not responded to at least four adequate trials of antidepressant treatment, including electroconvulsive therapy (ECT).
- VNS is approved for use in patients with treatment-resistant depression on the basis of its potential benefit with long-term treatment. There is no indication for the use of VNS in acute phase treatment of depression, as data showed no evidence for acute efficacy.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates vagus nerve stimulators as medical devices. All vagus nerve stimulators including related components require FDA approval before marketing and use in the United States to ensure they are safe and effective for human use. Refer to the FDA Medical Device website. Available from: https://www.fda.gov/medical-devices[accessed 2026 Jun 30]

The FDA lists the most serious type of medical device recalls as well as early alert communications about corrective actions being taken by companies that the FDA believes are likely to be the most serious type of recalls. Available from: Medical Device Recalls | FDA [accessed 2026 Jun 16]

The U.S. Food and Drug Administration (FDA) approved a vagus nerve stimulation device called the NeuroCybernetic Prosthesis system for treatment of seizures in July 1997. The data published in the medical literature are sufficient to conclude that vagal nerve stimulation improves health outcomes for individuals with partial onset seizures who are not candidates for surgery and whose seizures are refractory to other treatment. Studies have demonstrated that vagal nerve stimulation, as an adjunct to the optimal use of antiepileptic medications, in the treatment of medically refractory individuals with partial onset seizures reduces seizure frequency by approximately 25% after three months and, in most cases, the benefit treatment effect increases over time (up to a 50% reduction). Although FDA approval of this device is for individuals twelve years of age or older, studies on younger individuals have reported results similar to the adult trials, supporting the safety and efficacy of VNS in children with refractory seizures. Vagus nerve stimulation is carried out in centers experienced in the treatment of epilepsy.

The FDA approved Cyberonic's VNS Therapy System in July 2005 as an adjunctive long-term treatment of chronic or recurrent depression for individuals 18 years of age or older who are experiencing a major depressive episode and have not had an adequate response to at least four adequate antidepressant treatment regimens (medications and/or ECT). It is not intended as a first-line treatment, even for individuals with severe depression. In the D-01 depression case series, after 10-weeks of active VNS therapy, 30.5% of individuals had a 50% reduction in the depressive symptoms, based on the 28-item Hamilton Rating Scale for Depression (HRSD-28). In reports of longer-term outcomes, improvements in depressive symptoms continue out to one year, with 45% of patients having a 50% improvement in HRSD-28. These outcomes seem to stabilize out to two years, but there were substantial losses to follow-up (only 42 patients out of 60 available at two-year follow-up). The D-02 depression study was a double blind, randomized, placebo-controlled study (Rush et al 2005). Fifteen percent of patients in the active VNS group showed a 50% improvement on depressive

symptoms, whereas 10% of patients in the sham group showed a 50% improvement. A secondary outcome measurement, Inventory of Depressive Symptomology, self-rated (IDS-SR), showed a significant difference between the two groups, with 17.4% of patients in the VNS active group versus 7.5% of patients in the sham group demonstrating improvement. This randomized trial failed to achieve statistical significance with its primary endpoint. The available evidence does not permit conclusions about the usefulness of vagus nerve stimulation in the treatment of depression. Long-term data regarding the tolerability, as well as symptomatic and functional outcomes, of depressed patients receiving VNS are needed, to ascertain the effectiveness of this procedure for treating refractory depression.

In August 2021, the FDA approved a first-of-its-kind drug-free rehabilitation system intended to treat moderate to severe upper extremity motor deficits associated with chronic ischemic stroke using vagus nerve stimulation (VNS). The MicroTransponder Vivistim Paired VNS System (Vivistim System) is intended to be used to stimulate the vagus nerve during rehabilitation therapy in order to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment.

AspireSR Model 106 (Cyberonics) for Vagus Nerve Stimulation

The AspireSR Model 106 (Cyberonics, Inc.) received FDA premarket approval in February 2014. The newest modification to the vagus nerve stimulation (VNS) implant detects tachycardia heart rates, which may be associated with an impending seizure, and automatically delivers stimulation to the vagus nerve. Like its predecessors, the AspireSR can also deliver stimulation in the normal and magnet modes. However, when programmed for AutoStim mode, the AspireSR requires no patient interaction to trigger the delivery of electrical stimulation, as it is programmed to detect tachycardia and respond by delivering an extra automatic stimulation. The AutoStim mode should not be used in patients with significant arrhythmias being treated with pacemakers and/or an implantable defibrillator, beta-blockers, or any other treatment that may impact the intrinsic heart rate.

In November 2015, the FDA published a class 2 devices recall on all AspireSR Model 106 devices, due to a delay in the "Verify Heartbeat Detection" feature, which could decrease its battery life. In June 2017, Cyberonics recalled the M106 generators because of a manufacturing defect that could lower the longevity of the device. Instructions were sent to affected hospitals and physicians to monitor patients. In November 2017, Cyberonics recalled Model 3000 VNS Therapy Programmer, including models equipped with the Model 106 generator, due to a variety of problems that could lead to device failure or other complications, including delivery of more stimulation than intended or no stimulation. In January 2018, VNS Therapy Systems with the Model 106 generator were recalled because of a display warning issue.

Vagus Nerve Blocking Therapy

The FDA approved the Maestro Rechargeable System (Enteromedics) through the PMA process in January 2015. The device is indicated for use in adults aged 18 years and older who have a BMI of 40 to 45 kg/m2 or a BMI of 35 to 39.9 kg/m2 with one or more obesity-related comorbidities and have failed at least one supervised weight management program within the past five years. The Food and Drug Administration.[Internet]. Maestro Rechargeable System. Summary of Safety and

Effectiveness Data (SSED). Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf13/P130019b.pdf [accessed 2026 Jun 16]

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
0908T (E/I)	Open implantation of integrated neurostimulation system, vagus nerve, including analysis and programming, when performed
0909T (E/I)	Replacement of integrated neurostimulation system, vagus nerve, including analysis and programming, when performed
0910T (E/I)	Removal of integrated neurostimulation system, vagus nerve
0911T (E/I)	Electronic analysis of implanted integrated neurostimulation system, vagus nerve; without programming by physician or other qualified health care professional
0912T (E/I)	Electronic analysis of implanted integrated neurostimulation system, vagus nerve; with simple programming by physician or other qualified health care professional
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to single electrode array
61886	with connection to 2 or more electrode arrays
61888	Revision or removal of cranial neurostimulator pulse generator or receiver
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve
64568	Open implantation of cranial nerve (e.g., vagus nerve) neurostimulator electrode array and pulse generator
64569	Revision or replacement of cranial nerve (e.g., vagus nerve) neurostimulator electrode array, including connection to existing pulse generator
64570	Removal of cranial nerve neurostimulator (e.g., vagus nerve) electrode array and pulse generator
64999 (*E/I)	Unlisted procedure, nervous system (*E/I when billed as vagus nerve blocking (e.g., Maestro))
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and

Code	Description
	passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95976	with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
95977	with complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

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HCPCS Codes

Code	Description
C1767	Generator, neurostimulator (implantable), nonrechargeable
C1778	Lead, neurostimulator (implantable)
C1787	Patient programmer; neurostimulator
C1816	Receiver and/or transmitter, neurostimulator (implantable)
C1820	Generator, neurostimulator (implantable), with rechargeable battery and charging system
C1822	Generator, neurostimulator (implantable), high frequency with rechargeable battery and charging system
E0735 (E/I)	Noninvasive vagus nerve stimulator
L8679	Implantable neurostimulator pulse generator, any type
L8680	Implantable neurostimulator electrode, each
L8681	Patient programmer (external) for use with implantable programmable neurostimulator pulse generator, replacement only
L8682	Implantable neurostimulator radiofrequency receiver
L8683	Radiofrequency transmitter (external) for use with implantable neurostimulator radiofrequency receiver
L8685	Implantable neurostimulator pulse generator, single array, rechargeable, includes extension
L8686	Implantable neurostimulator pulse generator, single array, nonrechargeable, includes extension
L8687	Implantable neurostimulator pulse generator, dual array, rechargeable, includes extension
L8688	Implantable neurostimulator pulse generator, dual array, nonrechargeable, includes extension

Code	Description
L8689	External recharging system for battery (internal) for use with implantable neurostimulator, replacement only

ICD10 Codes

Code	Description
G40.001-G40.219	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset (code range)
G40.301-G40.319	Generalized idiopathic epilepsy and epileptic syndromes (code range)
G40.A01-G40.A19	Absence epileptic syndrome (code range)
G40.B01-G40.B19	Juvenile myoclonic epilepsy, not intractable (code range)
G40.401-G40.419	Other generalized epilepsy and epileptic syndromes (code range)
G40.501-G40.509	Epileptic seizures related to external causes (code range)
G40.801-G40.919	Other epilepsy and recurrent seizures (code range)
G93.45	Developmental and epileptic encephalopathy
Investigational Codes:	
All other ICD10 diagnosis codes are considered investigational.	

REFERENCES

American Academy of Neurology [Internet]. Update:Vagus nerve stimulation from the treatment of epilepsy. Practice Guidelines 2013. [reaffirmed 2025; accessed 2026 Jun 16]. Available from: https://www.aan.com/Guidelines/home/GuidelineDetail/618

American Psychological Association (APA) [Internet]. Practice guidelines for the treatment of patients with major depressive disorders. 2010 Oct. [accessed 2026 Jun 16]. Available from: https://psychiatryonline.org/books/guidelines

Apovian CM, et al. Two-year outcomes of vagal nerve blocking (vBloc) for the treatment of obesity in the ReCharge trial. Obes Surg. 2017 Jan;27(1):169-176.

Conway CR, et al. Vagus nerve stimulation in treatment-resistant depression: A one-year, randomized, sham-controlled trial. Brain Stimul. 2025 May-Jun;18(3):676-689.

Crutcher R, et al. Outcome and predictors of response to vagus nerve stimulation for drug-resistant epilepsy: a retrospective cohort study. Neurosurg Rev. 2025 Oct 3;48(1):676.

Dawson J, et al. Safety, feasibility, and efficacy of vagus nerve stimulation paired with upper-limb rehabilitation after ischemic stroke. Stroke. 2016 Jan;47(1):143-150. PMID 26645257.

Dawson J, et al. Vagus nerve stimulation paired with rehabilitation for upper limb motor function after ischaemic stroke (VNS-REHAB): a randomised, blinded, pivotal, device trial. Lance.t 2021;397:1545-1553.

Food and Drug Administration.[Internet]. MicroTransponder vivistim paired VNS system (Vivistim System). Summary of safety and effectiveness data (SSED). August 27, 2021. [accessed 2026 Jun 16]. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf21/P210007B.pdf

Hamilton P, et al. Clinical outcomes of VNS therapy with AspireSR (including cardiac-based seizure detection) at a large complex epilepsy and surgery centre. Seizure. 2018 May;58:120-126.

Ikramuddin S, et al. Effect of reversible intermittent intra-abdominal vagal nerve blockade on morbid obesity: the ReCharge randomized clinical trial. JAMA. 2014 Sep 3;312(9):915-22.

Kimberley TJ, et al. Vagus nerve stimulation paired with upper limb rehabilitation after chronic stroke. Stroke. 2018 Nov;49(11):2789-2792. PMID 30355189.

Lv H, et al. Vagus nerve stimulation for depression: a systematic review. Front Psychol. 2019 Jan 31;10:64.

Mandalaneni K, et al. Vagus nerve stimulator. 2023 Aug 7. In: StatePearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2026 Jan.

Morris GL, et al. Evidence-based guideline update: Vagus nerve stimulation for the treatment of epilepsy. report of the guideline development subcommittee of the American Academy of Neurology. Neurology J 2013 Oct 15;81(16)1453-1459. Reaffirmed on July 16, 2022.

Najib U, et al. Non-invasive vagus nerve stimulation for prevention of migraine: The multicenter, randomized, double-blind, sham-controlled PREMIUM II trial. Cephalalgia. 2022 Jun; 42(7):560-569.

National Institute for Health and Care Excellence (NICE) [Internet]. Implanted vagus nerve stimulation for treatment-resistant depression. [accessed 2026 Jun 16]. Available from: https://www.nice.org.uk/guidance/htg551

Panebianco M, et al. Vagus nerve stimulation for focal seizures. Cochrane Database Syst Rev. 2022 Jul 14;7(7):CD002896.

Ramos-Castaneda JA, et al. Efficacy and safety of vagus nerve stimulation on upper limb motor recovery after stroke. a systematic review and meta-analysis. Front Neurol. 2022 July;13:889953. PMID 35847207.

Rush AJ, et al. Vagus nerve stimulation for treatment-resistant depression: a randomized, controlled acute phase trial. Biol Psychiatry. 2005 Sep 1;58(5):347-54.

Sarr MG, et al. The EMPOWER study: randomized, prospective, double-blind, multicenter trial of vagal blockade to induce weight loss in morbid obesity. Obes Sur.g 2012 Nov;22(11):1771-82.

Stavrakis, S et al. Neuromodulation of inflammation to treat heart failure with preserved ejection fraction: a pilot randomized clinical trial. J Am Heart Assoc. 2022 Feb; 11(3):e023582.

Stavrakis S, et al. TREAT AF (transcutaneous electrical vagus nerve stimulation to suppress atrial fibrillation): a randomized clinical trial. JACC Clin Electrophysiol. 2020 Mar;6(3):282-291.

SEARCH TERMS

Not Applicable

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Vagus Nerve Stimulation (NCD 160.18) [accessed 2026 Jun 16]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 5/26

Revised:

Reviewed: 11/26

Date	Summary of Changes
6/1/2026	• New: Service was previously referenced on Non-Covered Technology policy 1370/20.000444.

RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: VENTRICULAR ASSIST DEVICE

POLICY EFFECTIVE DATE:	1/1/2026
Policy Control #:	1370/20.000473
Next Annual Review:	March, 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

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PROCEDURE CODES

Percutaneous ventricular assist device: 33997
Total replacement heart system (artificial heart): 33927, 33928, 33929

DESCRIPTION

Ventricular assist devices (VADs) compensate for the diminished ability of the heart to pump blood into the circulatory system in individuals with acute or advanced chronic heart failure. Such implanted devices do not replace the heart, but rather work the patient's own heart to pump sufficient blood throughout the body. The VAD consists of a pump, control system, and an energy supply. Ventricular assist devices may be used to sustain patients awaiting heart transplantation, to facilitate cardiac recovery in patients suffering from reversible cardiac dysfunction, and to provide permanent circulatory support in patients with end-stage heart failure who are not candidates for transplantation.

RELATED POLICIES/DOCUMENTS

Resource Coordination Policies:

- Designated Specialty Care Network: Transplant Services, 1370/20.000435
- Experimental, Investigational & Non-Standard Treatments, 1370/20.000152
- Out-of-Network Care, 1370/20.000145

Capital District Physicians' Health Plan, Inc.
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POLICY NAME: VENTRICULAR ASSIST DEVICE

Payment Policies:

- Organ Transplant – Donor,1550/20.000207

POSITION STATEMENT

CDPHP considers use of an FDA-approved ventricular assist devices (VADs) medically necessary when used as labeled for any of the following indications:

Post-cardiotomy Setting

Post-cardiotomy is the period following open heart surgery. VADs are covered in the post-cardiotomy setting when used as a means of myocardial recovery support for patients who cannot be weaned from cardiopulmonary bypass.

Advanced Heart Failure

Ventricular assist devices (VADs) are covered if they are FDA approved for short-term (e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) mechanical circulatory support for heart failure patients who meet the following criteria:

- Have New York Heart Association (NYHA) Class IV heart failure; and
- Have a left ventricular ejection fraction (LVEF) ≤ 25%; and
- Are inotrope dependent

OR

- Have a Cardiac Index (CI) < 2.2 L/min/m2, while not on inotropes, and also meet one of the following:
    - Are on optimal medical management (OMM), based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond; or
    - Have advanced heart failure for at least 14 days and are dependent on an intra-aortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least seven days.

The implanting facility must also be part of the CDPHP designated specialty care network for ventricular assist device services.

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Capital District Physicians' Healthcare Network, Inc.

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POLICY NAME: VENTRICULAR ASSIST DEVICE

Percutaneous Ventricular Assist Devices

CDPHP considers the use of a percutaneous ventricular assist device (e.g., Impella 2.5, Impella 5.0, Impella CP), medically necessary in the following situations:

- Treatment of ongoing cardiogenic shock that occurs immediately following acute myocardial infarction or open-heart surgery as a result of isolated left ventricular failure that is not responsive to optimal medical management and conventional treatment measures that include volume loading, use of pressors and inotropes support with or without IABP.
- As an adjunct to post coronary intervention (PCI) in high-risk patients with unprotected left main or last-remaining-conduit PCI with LVEF < 35%, or with 3-vessel disease and LVEF < 30%.

Artificial Heart

CDPHP considers the use of an FDA approved total artificial heart (i.e., SynCardia™ t-TAH) medically necessary as a bridge to heart transplant in patients who meet all of the following criteria:

- At risk of imminent death from biventricular failure
- Have no other medical or surgical treatment options
- Ineligible for other ventricular support devices
- Approved for cardiac transplant and is currently on a transplant list
- Have sufficient space in the chest cavity to accommodate the device
- Is able to receive adequate anti-coagulation while on the total artificial heart
- Absence of irreversible organ dysfunction

POLICY CONSIDERATIONS

CDPHP will consider VADs used as a bridge to transplantation reasonable and necessary only when performed at facilities that are part of the CDPHP designated specialty care network for heart transplant or ventricular assist device transplant services.

EXCLUSIONS

The following exclusions apply:

- Use of a non-FDA approved ventricular assist device is considered investigational.
- Use of a ventricular assist device for indications other than those described in this policy.
- Use of a percutaneous ventricular assist device for indications other than those described in this policy.
- Total artificial hearts are considered investigational in all other circumstances including:
    - For use as destination therapy (permanent replacement of the failing heart).

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POLICY NAME: VENTRICULAR ASSIST DEVICE

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS	Subject to all terms and conditions noted above in the policy.

MEDICARE ADVANTAGE	Subject to all terms and conditions noted above in the policy with the following additions.
	
	Destination VAD implantation must be performed in a Medicare approved heart transplant facility that has demonstrated competency in performing the procedure as follows:
	• Facilities must be credentialed by an organization approved by the Centers for Medicare & Medicaid Services and in compliance with the following requirements:
	  • At least one physician with cardiothoracic surgery privileges and individual experience implanting at least 10 durable, intracorporeal, VADs (as bridge-to-transplant or destination therapy) over the course of the previous 36 months with activity in the last year; and
	  • At least one cardiologist trained in advance heart failure with clinical competence in medical and device-based management including VADs, and clinical competence in the management of patients before and after heart transplant.
	  • A VAD program coordinator, social worker, and palliative care specialist.
	The listing of CMS approved credentialing organizations/VAD destination facilities can be located at: https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/VAD-Destination-Therapy-Facilities.html

SELECT PLAN/HARP:	Subject to all terms and conditions noted above in the policy.

SOURCES

1. Centers for Medicaid and Medicare National Coverage Determination (NCD) for Artificial Hearts and Related Devices (20.9), https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=246&ncdver=6&bc=AAAAgAAAAAAA&
2. Centers for Medicaid and Medicare National Coverage Determination (NCD) for Ventricular Assist Devices (20.9.1), https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=360&ncdver=1&bc=AAAAgAAAAAAA&
3. Centers for Medicare & Medicaid Services (CMS). Decision Memo for Ventricular Assist Devices for Bridge-to-Transplant and Destination Therapy (CAG-00432R). October 30, 2013. Available at:
https://www.cms.gov/medicare-coverage-database/details/nca-decision-

memo.aspx?NCAId=268
4. Medicare Claims Processing Manual, Chapter 32 - Billing Requirements for Special Services. Section 320.3: Ventricular Assist Devices, Rev.3181, 1-30-15.
5. Medicare National Coverage Determinations Manual, Chapter 1, Part 1, Section 20.9.1: Ventricular Assist Devices, Rev,187, 12-10-15.
6.Hayes, Inc. Directory: Left Ventricular Assist Devices (LVADs) in Adult Patients with Chronic, End Stage Heart Failure, August 18, 2010. Accessed 1/14/14.
7.Hayes Technology Brief Report: Impella 2.5 System for Cardiac Support in Patients Undergoing High Risk Percutaneous Coronary Intervention (PCI), July 2, 2015.
8.Hayes Technology Brief Report: Impella 2.5 System for Emergent Hemodynamic Support in Patients with Cardiogenic Shock, September 3, 2015.
9.Hayes Directory: Total Artificial Heart, Temporary or Permanent, Biventricular Mechanical Circulatory Support Device, May 28, 2015.
10.Other payers.
11. CMS 2020 Decision Memo: https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=298&type=Closed&bc=AIgAAAAACAAA&

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POLICY APPROVAL DATES

New:	03/12
Revised:	03/13, 01/14, 03/14, 03/15, 03/16, 05/17, 01/18, 05/18, 03/19, 01/21, 3/21, 3/23 3/26
Reviewed:	3/20, 3/22, 3/24, 3/25

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
1/1/26	Removed the following codes from the policy as HealthHelp will be reviewing the codes: 33975 33976 33977 33978

POLICY NAME: VENTRICULAR ASSIST DEVICE

	33979 33980 33981 33982 33983 33990 33991 33992 33993 33995
7/1/21 *No change to policy effective date	Under artificial hearts • For the bullet that states: o Have sufficient space in the chest cavity to accommodate the device- removed the body surface area (BSA) requirement as there are now artificial hearts that have different BSA requirements Under exclusions added: • Use of a percutaneous ventricular assist device for indications other than those described in this policy.
7/1/21	Added additional criteria for artificial hearts.
1/12/21	Revised title of policy. Added new code 33995 and 33997 To Procedure Codes section. Revised criteria for VADs for Advanced Heart Failure per updated Medicare NCD and removed references to retired Medicare NCD for Artificial Hearts.

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Policy/Procedure Name: Veopoz (pozelimab) **Control Number: 1350/20.000495**

Disclaimer Notice

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Background

Complement hyperactivation, angiopathic thrombosis, and protein-losing enteropathy (CHAPLE) is an ultra-rare, potentially fatal autoimmune disorder. This disorder causes complement system overactivation, caused by mutations in the CD55 gene, leading to the complement system attacking the body's own cells (lack of control of the complement activity).

Decay Acceleration Factor [DAF or CD55] regulates compliment activation by dissociating subunit proteins for the bimolecular C3 convertases and the trimolecular C5 convertases, among other functions and is expressed on the membrane of blood cells and endothelial/epithelial cells of organs in contact with blood and lymph. Without the proper functioning of the DAF, however, complement activations may continue to the formation of membrane attack complexes (MACs), leading to inflammatory response and tissue damage.

The FDA reports there are fewer than 100 patients diagnosed worldwide.

Clinical presentations of CHAPLE disease include hypoproteinemia, hypogammaglobulinemia, bowel obstructions, enteritis, thrombosis, edema, lymphangiectasia, and increased infection risk (GI and thrombosis sequelae).

There are no FDA approved therapies to manage this ultra-rare condition, however Soliris (eculizumab) has been used off-label to treat this disease. Eculizumab therapy functions to block C5 activation (to produce C5a and C5b) which eliminates most harmful effects of caused by self-incurred injuries through formation of MACs.[7]

Veopoz was studied in a very small subject population with CHAPLE disease. Patients received a single loading dose of pozelimab 30mg/kg intravenously on day 1, followed by weight-based doses subcutaneously weekly. Ten patients ranging from 3 to 19 years of age (median of 8.5 years) were assessed for efficacy. The primary endpoint of the study was the proportion of patients with active disease at baseline achieving both normalization of serum albumin and clinical outcome improvement. Results from this study showed all 10 patients achieved normalization of serum albumin at 12 weeks and maintained serum albumin concentrations within the normal range through at least 72 weeks of treatment. The median time for serum albumin to reach at least 3.5g/dL was reported to be 15.5 days (95% CI, 8-28). Additionally, all participants did demonstrate a reduction in the number of hospitalizations and number of albumin transfusions over the first 48 weeks of treatment compared to the 48 weeks prior to initiation of therapy.

The most common adverse reactions to Veopoz are upper respiratory tract infections, fractures, hives, and alopecia. A Black Box Warning exists for life-threatening and fatal meningococcal infections that have occurred in patients treated with complement inhibitors and may become rapidly life-threatening or fatal if not recognized and treated early. Patients receiving Veopoz should complete or update meningococcal vaccination at least two weeks before treatment.

Summary

Effective Date of Policy:	9/10/2025
Indications	Treatment of adult and pediatric patients one year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease
ICD10 Diagnosis Codes	D84.1
Availability	*Injection: 400 mg/2 mL (200 mg/mL) in a single-dose vial*
Duration	Initial: Six months Continuation: 12 months
HCPCS Code	J9376

Required Criteria for Initial Approval		
All of the following conditions for the requested indication must be met in order to approve therapy:		
Specific Indication	**Inclusion Criteria**	**Recommended Dosing Regimen**

Treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease
(FDA approval)
ICD10: D84.1
	• Enrollee is at least one year of age
	• Must be prescribed by or in consultation with a hematologists, gastroenterologist or prescriber who specializes in the treatment of PLE/CHAPLE disease
	• Must have a diagnosis of CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease, confirmed by biallelic CD55 loss-of function mutation by genetic testing
	• Must have active disease defined as:
	  ○ a. Hypoalbuminemia ≤ 3.2 g/dL AND
	  ○ b. One of the following signs or symptoms attributable to PLE/CHAPLE disease within the previous 6 months:
	  ▪ i. Diarrhea
	  ▪ ii. Vomiting
	  ▪ iii. Abdominal pain
	  ▪ iv. Peripheral or facial edema
	  ▪ v. Infection with concomitant hypogammaglobulinemia
	  ▪ vi. New thromboembolic event
	• Enrollee will not be receiving concomitant complement therapy (i.e., Soliris/Bkemv/ Epysqli (eculizumab), Ultomiris (ravulizumab-cwvz))
	
	Veopoz will be considered investigational when used for all other off-label indications and will not be covered.
		• Day 1 (loading dose): Administer a single 30 mg/kg dose by intravenous infusion after dilution
		• Day 8 and thereafter (maintenance dosage): Inject 10 mg/kg as a subcutaneous injection once weekly starting on Day 8
		• The maintenance dosage may be increased to 12 mg/kg once weekly if there is inadequate clinical response **after at least three weekly doses (i.e., starting from Week 4)**
		• **The maximum maintenance dosage is 800 mg once weekly**

Continuation Criteria
• Requests will be reviewed per criteria every twelve months • Documentation of clinical benefit (such as improvement in clinical symptoms [e.g., abdominal pain, bowel movement frequency, facial or peripheral edema severity], increase or stabilization of albumin and IgG concentrations, increase in growth percentiles)

Considerations
• Prior authorization is obtained through the CDPHP pharmacy department.

References

		Updated	Accessed
1	Yu CY, et al. Complement inhibitor for therapy of CHAPLE. Nat Immunol. 2021 Feb; 22(2):106-108.	2/21	8/23
2	Nature Journal. Methods of Diagnosing and Treating CHAPLE, A Newly Identified Orphan Disease: Collaborative Research and Licensing Opportunity article. Available at: https://www.nature.com/articles/d43747-020-00626-y		8/23
3	Medical Professionals Reference - FDA Greenlights Veopoz, the First Treatment for CHAPLE Disease (online article). Published August 21, 2023. Available at: https://www.empr.com/home/news/fda-greenlights-veopoz-the-first-treatment-for-chaple-disease/#:~:text=CHAPLE%20disease%20is%20a%20rare,recurrent%20infections%2C%20and%20blood%20clots.	8/23	8/23
4	Veopoz (pozelimab) Clinical Trial (NCT04209634). Available at: https://classic.clinicaltrials.gov/ct2/show/NCT04209634	5/24	7/24

5	FDA News & Events for Human Drugs: FDA Approves First Treatment for CD55-deficient protein-losing enteropathy (CHAPLE disease). Published 8/18/2023. Available at: https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-treatment-cd55-deficient-protein-losing-enteropathy-chaple-disease	8/23	8/23
6	Veopoz prescribing information, Regeneron Pharmaceuticals, Inc., Tarrytown, NY 10591. Revised 3/2024.	3/24	8/25
7	Ozen A, et al. Broadly effective metabolic and immune recovery with C5 inhibition in CHAPLE disease. Nat Immunol. 2021 Feb; 22(2): 128-139.	2/24	8/23
8	Ozen, A, et al. CD55 Deficiency, Early-Onset Protein-Losing Enteropathy, and Thrombosis. N Engl J Med 2017; 377:52-61.	2017	8/23

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE CHOICES: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 9/10/2025

New: 9/2023

Revised	Reviewed
9/25	9/24

Revision Date	Changes Made
9/25	Removed exclusion criteria section Updated signs/symptoms attributable to CHAPLE disease Removed trial of Soliris from inclusion criteria Specified prescribing/consulting providers specializing in CHAPLE disease Updated continuation criteria

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MEDICAL POLICY

Medical Policy Title	**Vision Therapy**
Policy Number	**9.01.04**
Current Effective Date	**August 1, 2026**
Next Review Date	**November 2026**

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Vision therapy that includes orthoptics and occlusion therapy is considered **medically appropriate** for the treatment of amblyopia.

II. Vision therapy that includes prism adaptation is considered **medically appropriate** when utilized for acquired esotropia prior to surgical intervention.

III. Vision therapy is considered **medically appropriate** for the treatment of convergence insufficiency.

IV. Vision therapy using web-based and/or digital programming/therapeutics is considered **investigational** (e.g., Luminopia, RevitalVision, CureSight-CS100).

V. Vision therapy is considered **investigational** for **ALL** other indications including, but not limited to, the following:

   A. All other accommodative and vergence dysfunctions, (e.g., fusional vergence dysfunction, divergence excess, convergence excess, divergence insufficiency, vertical phorias, basic exophoria, basic esophoria, accommodative insufficiency, sustained accommodation, accommodative infacility, and spasm accommodation);

   B. Low vision;

   C. Myopia;

   D. Nystagmus;

   E. Presbyopia;

   F. Strabismus, including esotropia (with the exception of acquired esotropia as stated above) and exotropia; and

   G. Age-related macular degeneration.

   H. Learning disabilities; including attention deficit hyperactivity disorder (ADHD)

   I. Dyslexia

RELATED POLICIES

Corporate Medical Policy

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

Not applicable

POLICY GUIDELINE(S)

Not Applicable

DESCRIPTION

Vision therapy (also known as visual therapy, visual training, vision training, or eye training) involves a range of treatment modalities that include the use of lenses, prisms, filters, optometric phototherapy (syntonics), occlusion therapy (eye patching), behavioral modalities, and eye exercises (orthoptics, pleoptics). The therapeutic goal of vision therapy is to correct or improve specific visual dysfunctions. Vision therapy is performed in an optometrist's or ophthalmologist's office one to two times weekly for a number of months, with additional home exercises done as reinforcement.

Luminopia is a software-only digital therapeutic designed to be used with commercially available Head-Mounted Displays (HMDs). Luminopia is indicated for improvement in visual acuity in amblyopia patients and is intended to be used as an adjunct to full-time refractive correction, such as glasses, which should also be worn under the HMD during Luminopia therapy. Their proprietary software uses a dual-action mechanism taking the content, modifying it in real-time, and presenting it differently to each eye to rebalance the input to the brain. The contrast of the stronger eye image is reduced to encourage the brain to pay more attention to the weaker eye and complementary masks remove parts of each eye's image, teaching the brain to combine input from both eyes.

RevitalVision is a perceptual learning vision training software program that aims to improve the brains visual processing and vision in amblyopic individuals. Training is done while the dominant eye is blurred with a semi-transparent white cover. By improving the brains visual processing to perform better, it compensates for some blurry images caused by small refractive error and allows patients to see better without correction.

CureSight-CS100 (NovaSight) is a digital eye tracking treatment using a special device and red-blue treatment glasses. The treatment is carried out while the child watches any streamed content of choice at home, under the remote supervision of an eye care provider and a dedicated Monitoring Center. By tracking the gaze position of both eyes in real-time, the CureSight system blurs the center of vision of the dominant eye and provides the amblyopic eye with a normal sharp image. This stimulates the visual system to use the information coming from the amblyopic eye to process the fine details, improving its acuity and developing stereoacuity as the eyes learn to work together. Indications for use include pediatric patients aged 4 to < 9 years with amblyopia associated with anisometropia and/or mild strabismus. CureSight is intended as an adjunct to full-time refractive correction (e.g., glasses). Available by prescription-only, for at-home use under supervision of an eye care provider.

SUPPORTIVE LITERATURE

Most studies evaluating the efficacy of vision therapy for visual disorders are small. In general, these studies are poorly designed, with significant methodological flaws, and the data derived from them

are relatively weak and inconclusive. There is some evidence to support the use of vision therapy that involves occlusion as a treatment for amblyopia (treatment success with patching are 72.3% -79%) and vision therapy that involves prism adaptation prior to surgery administered as a treatment for acquired esotropia (surgical success rates for prism adaption prior to surgery are 89% versus 72% for patients receiving no prism therapy). Large, well-designed studies comparing vision therapy with other treatment modalities, standardization of outcome measurements, and the criteria for defining patient selection are needed to adequately evaluate vision therapy for visual dysfunctions.

Hernández-Andrés (2025) published a randomized controlled trial comparing the results of three (3) treatments, two (2) combining patching with active therapy and one (1) with patching alone. Fifty-two amblyopic children (aged 4-12 years), were randomly assigned to three (3) monocular treatment groups: perceptual learning with a computer game designed to favor the medium-to-high spatial frequency-tuned achromatic mechanisms of parvocellular origin (n=17), vision therapy with a specific protocol and 2-h patching (n=17), and the third treatment group used 2-h patching only (n=18). Visual outcomes were analyzed after 3 months and compared with a control group (n = 36) of subjects with normal vision. Visual acuity (VA) and stereoacuity (STA) improved significantly after treatment for the three groups with the best results for patching plus vision therapy, followed by monocular perceptual learning, with patching only least effective. The authors concluded that this study showed visual acuity and STA improved with the two most active treatments, that is, vision therapy followed by perceptual learning. These results suggest that vision therapy should include monocular accommodative exercises, ocular motility, and central fixation exercises where the fovea is more active.

Singh et al (2021) published results of an RCT to assess and compare the effectiveness of home-based pencil push-up therapy (PPT) and office-based orthoptic therapy (OBOT) in 176 children and young adults with convergence insufficiency. Patients were randomized to 6 weeks of OBOT (3 times per week) or PPT (15 minutes per day). At study end, there was no difference between groups in near point of convergence or Convergence Insufficiency Symptom Survey scores, but there was a significantly greater improvement in positive fusional vergence with office-based therapy compared to home-based exercises ($p<.001$). Limitations of this study include lack of blinding, a wide range of patient ages, short duration compared to other studies, 20% to 30% loss to follow-up leading to a lack of power, and the study was conducted at a single center in India.

Verma et al (2025) published results from a one-year prospective, interventional, comparative study of the surgical outcomes of patients with acute acquired comitant esotropia (AACE) managed with and without pre-operative prism adaptation test (PAT). Forty patients with AACE were randomly divided into two groups by computerized randomization - those undergoing surgery after pre-operative PAT and those undergoing surgery without it. In the control group (Group C), patients underwent surgery based on the angle of deviation at distance measured by prism bar cover test (PBCT) and wearing full cycloplegic correction, while in test group (Group T), patients underwent surgery based on the preoperative prism-adapted angle at distance wearing prism power determined by PBCT and wearing full cycloplegic correction. The mean SD (standard deviation) of the PBCT for distance (measured in prism diopters - PD), PBCT for near (measured in prism diopters - PD) and stereopsis for near (measured in seconds of arc using Titmus Fly Test) at last follow-up visit (week

12) in the test versus control group were as follows: 1.70 ± 1.42 PD versus 4.75 ± 3.39 PD, 2.55 ± 1.82 PD versus 6.95 ± 3.35 PD and 74.90 ± 53.47 sec of arc versus 48.60 ± 31.97 sec of arc, respectively, which were statistically significant (p = <0.01, p = <0.01 and p = .03, respectively). The authors concluded that their study showed surgical outcomes in patients of AACE are better when surgical planning is done after performing pre-operative PAT as opposed to when surgery is planned without PAT. Better motor alignment (less under correction and over correction) and better sensory results in terms of improvement in stereopsis were observed.

Hofsli et al (2025) published results from an observational, retrospective study of individuals with symptomatic esophoria (SE) (that progresses into a manifest esotropia), comparing rates of repeated surgical interventions with or without PAT as a supplement to standard orthoptic evaluation. This study was conducted by reviewing records of patients who underwent surgery at the Department of Ophthalmology, Rigshospitalet, Glostrup, Denmark, from January 1, 2017, to August 31, 2023. Primary outcome was the need for repeated intervention either by reoperation or by postoperative adjustment of sutures. A total of 105 SE patients were included, with 61 in the non-PAT group and 44 in the PAT group. Repeated surgical interventions were less frequent in the PAT group (23%) compared to the non-PAT group (48%) (P 0.009). PAT resulted in an increase in median angles of deviation (AOD) at near and distance by 14PD and 16PD, respectively (p < .001 and p < .001). The authors concluded this study showed SE patients undergoing PAT had significantly lower rates of repeated surgical interventions and a significant increase in baseline AOD, compared to those who did not undergo PAT.

The use of digital programs (e.g., Luminopia, RevitalVision, CureSight-CS100) have been proposed for the treatment of amblyopia. Overall, the literature supporting its use consists of randomized trials with small sample sizes and short-term outcomes. Larger studies comparing digital programs to a relevant comparator with longer follow-ups are needed. The available evidence is insufficient to evaluate the effect of its use on health outcomes.

PROFESSIONAL GUIDELINE(S)

The American Academy of Pediatrics (AAP), American Association for Pediatric Ophthalmology and Strabismus (AAPOS), American Association of Certified Orthoptists (AACO) and American Academy of Ophthalmology (AAO) published a joint policy statement on learning disabilities, dyslexia, and vision (2009; reaffirmed 2014). They state:

- "Diagnostic and treatment approaches for dyslexia that lack scientific evidence of efficacy such as behavioral vision therapy, eye muscle exercises, or colored filters and lenses are not endorsed or recommended.
- Detailed review of the literature supporting vision therapy reveals that most of the information is poorly validated, because it relies on anecdotes, poorly designed studies, and poorly controlled or uncontrolled studies.
- There is currently no evidence that children who participate in vision therapy are more responsive to educational instruction than are children who do not participate."

The American Association for Pediatric Ophthalmology and Strabismus (AAPOS) describe vision therapy as an attempt to develop or improve visual skills and abilities; improve visual comfort, ease, and how well the eyes work; and change visual processing or understanding of visual information. (AAPOS 2023). A vision therapy program can consist of in-office and home eye exercises and may last for several months. Along with exercises, lenses, prisms, filters, patches, electronic targets, or balance boards may be used in vision therapy. They describe three (3) main types of vision therapy:

- Behavioral/perceptual vision therapy – eye exercises to improve visual processing and visual understanding.
- Vision therapy for prevention or treatment of myopia (nearsightedness).
- Orthoptic vision therapy - different type of eye exercises to improve binocular function (how well the two eyes work together). This type of eye exercise is taught in the office and done at home.

AAPOS states there is no evidence that vision therapy for learning disabilities, dyslexia or myopia, behavioral vision therapy or training glasses work to improve vision. They continue to state that orthoptics can be helpful in the treatment of eye movement problems that cause blurry vision, double vision, or headaches (like convergence insufficiency).

The American Academy of Ophthalmology (AAO) amblyopia preferred practice pattern (Cruz 2023) states:

- "Suitable treatment options for amblyopia include optical correction, patching, pharmacological treatment, optical treatment, Bangerter (translucent) filters, digital therapeutics, and managing the underlying cause of amblyopia.
- Most children who have moderate amblyopia (20/40 to 20/80) respond to initial treatment consisting of 2 hours of daily patching or weekend atropine."

The AAO esotropia and exotropia preferred practice pattern (Sprunger 2023) states treatment for esotropia includes the following:

- correction of refractive errors
- bifocal eyeglasses
- prism therapy
- extraocular muscle surgery:
- botulinum toxin injection
- other pharmacologic agents.

They go on to say in some patients with acquired esotropia less than 30 prism diopters who have diplopia, prism therapy may be beneficial in promoting binocular vision.

The American Optometric Association published optometric clinical practice guidelines for the care of the patient with amblyopia (2004). They explain the following treatment options:

- "Occlusion has been the cornerstone of treatment of amblyopia for over 200 years. The rationale for using occlusion is that occluding the better eye stimulates the amblyopic eye, decreasing inhibition by the better eye.
- Vision therapy refers to the total treatment program, which may include passive therapy options (e.g., spectacles, occlusion, pharmacologic agents) and active therapy. With such passive treatment options as optical correction and occlusion, the patient experiences a change in visual stimulation without any conscious effort. Active therapy is designed to improve visual performance by the patient's conscious involvement in a sequence of specific, controlled visual tasks or procedures that provide feedback about the patient's performance. When a reflexive response is achieved, it is anticipated that improved performance will transfer to other noncontrolled visual tasks, ultimately changing the underlying visual processing mechanism.
- Active vision therapy for amblyopia is designed to remediate deficiencies in four specific areas: eye movements and fixation, spatial perception, accommodative efficiency, and binocular function. The goal of vision therapy is remediation of these deficiencies, with subsequent equalization of monocular skills and, finally, integration of the amblyopic eye into binocular functioning.
- Active monocular and binocular amblyopia therapies, as opposed to passive management (e.g., occlusion), reduce the total treatment time needed to achieve the best visual acuity. Monocular therapy involves stimulation techniques that enhance amblyopic resolution and foster more normal eye movements, central fixation, and accommodation of the amblyopic eye. Because active binocular inhibition is one of the underlying etiologies of unilateral types of amblyopia, antisuppression procedures are performed under binocular conditions or in-instrument conditions simulating binocular conditions."

REGULATORY STATUS

CureSight-CS100 received FDA's 510(k) clearance for the CureSight-CS100 system (K221375) on September 29, 2022. More information is available from: https://www.accessdata.fda.gov/cdrh_docs/pdf22/K221375.pdf [accessed 2025 Sep 26].

Luminopia One received FDA's De Novo classification (DEN210005) on October 20, 2021. More information is available from: https://www.accessdata.fda.gov/cdrh_docs/pdf21/DEN210005.pdf [accessed 2025 Sep 26].

RevitalVision technology received FDA's 510(K) clearance August 31, 2001 (K012530), originally branded as the NeuroVision AA-1 system. More information is available from: https://www.accessdata.fda.gov/cdrh_docs/pdf/K012530.pdf [accessed 2025 Sep 26].

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than

policy updates).

- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
92065	Orthoptic training; performed by a physician or other qualified health care professional
92066	Orthoptic training; under supervision of a physician or other qualified health care professional
0687T (E/I)	Treatment of amblyopia using an online digital program; device supply, educational set-up, and initial session
0688T (E/I)	Treatment of amblyopia using an online digital program; assessment of patient performance and program data by physician or other qualified health care professional, with report, per calendar month.
0704T (E/I)	Remote treatment of amblyopia using an eye tracking device; device supply with initial set-up and patient education on use of equipment
0705T (E/I)	Remote treatment of amblyopia using an eye tracking device; surveillance center technical support including data transmission with analysis, with a minimum of 18 training hours, each 30 days
0706T (E/I)	Remote treatment of amblyopia using an eye tracking device; interpretation and report by physician or other qualified health care professional, per calendar month

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HCPCS Codes

Code	Description
A9292 (E/I)	Prescription digital visual therapy, software-only, FDA cleared, per course of treatment

ICD10 Codes

Code	Description
H50.00-H50.08	Esotropia (code range)
H51.11-H51.12	Convergence insufficiency and excess (code range)

Code	Description
H53.001-H53.039	Amblyopia (code range)

REFERENCES

American Academy of Pediatrics, Section on Ophthalmology, Council on Children with Disabilities; American Academy of Ophthalmology; American Association for Pediatric Ophthalmology and Strabismus; American Association of Certified Orthoptists. Joint statement--Learning disabilities, dyslexia, and vision. Pediatrics. 2009 Aug;124(2):837-44. (Reaffirmed 2014)

American Association for Pediatric Ophthalmology and Strabismus (AAPOS) [Internet]. Vision therapy; what is vision therapy? 2023 Apr [accessed 2025 Sep 30]. Available from: https://aapos.org/glossary/vision-therapy

American Optometric Association [Internet]. Clinical practice guideline. Care of the patient with amblyopia. Reviewed 2004 [accessed 2025 Sep 30]. Available from: https://www.aoa.org/AOA/Documents/Practice%20Management/Clinical%20Guidelines/Consensus-based%20guidelines/Care%20of%20Patient%20with%20Amblyopia.pdf

Cruz OA, et al; American Academy of Ophthalmology Preferred Practice Pattern Pediatric Ophthalmology/Strabismus Panel. Amblyopia preferred practice pattern. Ophthalmology. 2023 Mar;130(3): P136-P178.

Hernández-Andrés R, et al. Randomized trial of three treatments for amblyopia: Vision therapy and patching, perceptual learning and patching alone. Ophthalmic Physiol Opt. 2025 Jan;45(1):31-42.

Hofsli M, et al. Prism adaptation versus conventional orthoptic measurement for symptomatic esophoria: a retrospective study. Strabismus. 2025 Feb 19:1-8.

Pediatric Eye Disease Investigator Group. A randomized trial of atropine vs patching for treatment of moderate amblyopia in children. Arch Ophthalmol. 2002 Mar; 120:268-78.

Pediatric Eye Disease Investigator Group, et al. A randomized trial of atropine vs patching for treatment of moderate amblyopia: follow-up at age 10 years. Arch Ophthalmol. 2008 Aug;126(8):1039-44.

Singh A, et al. Comparison of home-based pencil push-up therapy and office-based orthoptic therapy in symptomatic patients of convergence insufficiency: a randomized controlled trial. Int Ophthalmol. 2021 Apr;41(4):1327-1336.

Sprunger DT, et al; American Academy of Ophthalmology Preferred Practice Pattern Pediatric Ophthalmology/Strabismus Panel. Esotropia and exotropia preferred practice pattern. Ophthalmology. 2023 Mar;130(3): P179-P221.

Verma P, et al. Comparative evaluation of surgical outcomes in acute acquired comitant esotropia managed with and without pre-operative prism adaptation test. Strabismus. 2025 Apr 25:1-6.

SEARCH TERMS

Acquired esotropia, Amblyopia, Convergence insufficiency, Orthoptics.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based on our review, vision therapy is not addressed in National or Regional Medicare coverage determinations or policies.

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION

Committee Approval Dates

New: 06/07

Revised: 07/08, 07/09, 07/19, 7/22, 1/23, 7/26

Reviewed: 05/08, 07/10 07/11, 07/12, 07/13, 07/14, 07/16, 07/17, 07/18, 07/20, 07/21, 7/23, 7/24, 7/25

Date	Summary of Changes
8/1/2026	• Transitioned Vision Therapy (Orthoptics) policy, 1370/20.000441 to Lifetime Healthcare Companies policy template and criteria.
1/1/2023	• Added new code 92066 effective 1/1/23 to Procedure Codes section.
7/1/2022	• Under Medicaid removed that prior authorization is required and updated with language from the MMIS Vision Care Manual.

Proprietary Information of Capital District Physicians' Health Plan, Inc. | CDPHP Universal Benefits,® Inc. | Capital District Physicians' Healthcare Network, Inc.

MEDICAL POLICY

Medical Policy Title	**Vitrectomy Chair/Face-down Positioning System**
Policy Number	**1.01.52**
Current Effective Date	**November 1, 2026**
Next Review Date	**April 2027**

Our medical policies are guides to evaluate technologies or services for medical necessity. Criteria are established through the assessment of evidence based, peer-reviewed scientific literature, and national professional guidelines. Federal and state law(s), regulatory mandates and the member's subscriber contract language are considered first in the determination of a covered service. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Use of a vitrectomy chair or face-down support system is considered **medically appropriate** following vitrectomy surgery, if a face-down position is required.

RELATED POLICIES

Not Applicable

POLICY GUIDELINE(S)

I. Benefits for a vitrectomy chair/face-down support system are provided through rental only.

DESCRIPTION

A vitrectomy is the surgical removal of the vitreous humor and is performed to clear blood and debris from the eye, to remove scar tissue, or to alleviate traction on the retina. At the completion of the surgery, gas or silicone oil may be injected into the eye, creating a bubble for retinal tamponade to keep the retina in place. As the retina is located in the back of the eye, recovering patients may be required to maintain a face-down position in order for the bubble to effectively apply pressure to the area, to enhance healing. The pressure allows the retina to re-bond with the eye wall, while new vitreous forms and replaces the bubble. Common indications for vitrectomy include macular hole repair, detached retina, vitreous hemorrhage, macular pucker, macular edema, diabetic retinopathy, and trauma.

A vitrectomy chair or face-down support system is designed for use by patients who have undergone vitrectomy surgery and thus assists with maintaining the face-down positioning requirement. Some patients may require the position for only a day, while others may have to maintain several hours daily of a face-down position for as long as three weeks.

SUPPORTIVE LITERATURE

A face-down vitrectomy system can assist in the maintenance of a face-down position, postoperatively, for those patients whose surgeon has recommended the device. Many patients are

more readily able to comply with the strict positioning requirements when utilizing the device. Some studies have demonstrated better outcomes in healing utilizing face-down positioning.

Hu Z, et al (2016) conducted a meta-analysis of four randomized control trials (RCTs) comprising 251 cases which concluded that no-face-down positioning had similar results to face-down positioning for holes smaller than 400 μm, but face-down positioning may be beneficial for holes larger than 400 μm.

Another meta-analysis (Ye 2019) of five randomized controlled trials composed of a total of 183 eyes in the face down positioning group (FDP) and 175 eyes in the non-face down positioning (nFDP) group which studied the closure rate of macular holes (MH) following surgery. Statistical meta-analysis revealed that the overall MH closure rate in the FDP group was significantly higher than that in the nFDP group (OR = 2.27, 95% CI: 1.02 to 5.05, P = 0.04). For MH sizes smaller than 400 μm, the subgroup meta-analysis indicated that the closure rate of the FDP group was not significantly higher than that of the nFDP group (OR = 1.32, 95% CI: 0.39 to 4.49, P = 0.66). However, when MH size was larger than 400 μm, there was a significantly higher closure rate in the FDP group (OR = 2.95, 95% CI: 1.10 to 7.94, P = 0.03). The authors concluded that the meta-analysis provides evidence that a face-down postoperative position seems to be unnecessary when MHs are smaller than 400 μm but may be highly recommended for MHs larger than 400 μm.

A Cochrane review (Cundy 2023) included eight randomized controlled trials (RCTs), comprised of 709 eyes (699 participants) total, in which postoperative face-down positioning was compared to no face-down positioning following surgery for macular holes. The primary outcome of interest was closure of the macular hole. The primary outcome of successful anatomical hole closure at one to six months following surgery was reported in 95 of every 100 eyes of participants advised to position face-down for at least three days after surgery, and in 85 of every 100 eyes of participants not advised to position face-down (RR 1.05, 95% CI 0.99 to 1.12, 709 eyes, 8 studies, I^2 = 44%). Amongst the 327 eyes of participants with macular holes of at least 400 μm, hole closure was noted in 94 of every 100 eyes of participants advised to position face-down, and in 84 of every 100 eyes of participants not advised to position face-down (RR 1.08, 95% CI 0.93 to 1.26, 5 studies, I^2 = 62%). Amongst the 129 eyes of participants with macular holes of less than 400 μm, hole closure was noted in 100 of every 100 eyes of participants advised to position face-down, and in 96 of every 100 eyes of participants not advised to position face-down (RR 1.03, CI 0.97 to 1.11, 4 studies, I^2 = 0%). The included studies were not all directly comparable due to differences in the surgical techniques used and the durations of postoperative positioning advised.

PROFESSIONAL GUIDELINE(S)

The American Academy of Ophthalmology (AAO) preferred practice pattern for idiopathic macular hole (2024) state in the early days of macular hole surgery, patients were instructed to maintain a face-down position for 10 to 14 days postoperatively to optimize macular hole closure. Postoperative prone positioning is uncomfortable for the patient, even though immobilization is not required. In some patients, positioning may be extremely difficult or even lead to pressure sores or neuropathy. Studies have reported excellent results using face-down positioning for 1 to 3 days. Longer positioning may be required for holes larger than 400 μm or those with inadequate tamponade.

Extended duration of face-down positioning minimizes the risk of cataract progression and provides some tamponade of the macular hole.

REGULATORY STATUS

Not Applicable

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
Not Applicable	

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HCPCS Codes

Code	Description
	There is no specific HCPCS code; E1399 (durable medical equipment, miscellaneous) may be billed.

ICD10 Codes

Code	Description
E10.311	Type 1 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E11.311	Type 2 diabetes mellitus with unspecified diabetic retinopathy with macular edema
E10.319	Type 1 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E11.319	Type 2 diabetes mellitus with unspecified diabetic retinopathy without macular edema
E10.329	Type 1 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema

Code	Description
E11.329	Type 2 diabetes mellitus with mild nonproliferative diabetic retinopathy without macular edema
E10.339	Type 1 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema
E11.339	Type 2 diabetes mellitus with moderate nonproliferative diabetic retinopathy without macular edema
E10.349	Type 1 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema
E11.349	Type 2 diabetes mellitus with severe nonproliferative diabetic retinopathy without macular edema
E10.359	Type 1 diabetes mellitus with proliferative diabetic retinopathy without macular edema
E11.359	Type 2 diabetes mellitus with proliferative diabetic retinopathy without macular edema
H33.001-H33.009	Unspecified retinal detachment with retinal break (code range)
H33.011-H33.019	Retinal detachment with single break (code range)
H33.021-H33.029	Retinal detachment with multiple breaks (code range)
H33.031-H33.039	Retinal detachment with giant retinal tear (code range)
H33.041-H33.049	Retinal detachment with retinal dialysis (code range)
H33.051-H33.059	Total retinal detachment (code range)
H33.20-H33.23	Serous retinal detachment (code range)
H33.40-H33.43	Traction detachment of retina (code range)

Code	Description
H33.8	Other retinal detachments
H35.351-H35.359	Cystoid macular degeneration (code range)
H35.371-H35.379	Puckering of macula (code range)
H35.721-H35.729	Serous detachment of retinal pigment epithelium (code range)
H35.731-H35.739	Hemorrhagic detachment of retinal pigment epithelium (code range)
H35.81	Retinal edema
H43.10-H43.13	Vitreous hemorrhage (code range)

REFERENCES

American Academy of Ophthalmology [Internet]. American Academy of Ophthalmology Retina/Vitreous Committee, Hoskins Center for Quality Eye Care. Idiopathic macular hole preferred practice pattern 2024. 2024 Sep 13 [accessed 2026 Mar 24]. Available from: https://www.aao.org/preferred-practice-pattern/idiopathic-macular-hole-ppp

Cundy O, et al. Face-down positioning or posturing after macular hole surgery. Cochrane Database Syst Rev. 2023 Nov;11(11):CD008228.

Hu Z, et al. Face-down or no face-down posturing following macular hole surgery: A meta-analysis. Acta Ophthalmol. 2016 Jun;94(4):326-33.

Solebo AL, et al. Face-down positioning or posturing after macular hole surgery. Cochrane Database Syst Rev 2011 Dec 7;(12):CD008228.

Ye T, et al. Macular hole surgery recovery with and without face-down posturing: a meta-analysis of randomized controlled trials. BMC Ophthalmol. 2019 Dec 21;19(1):265.

SEARCH TERMS

Vitrectomy Recovery Solutions, Vitrectomy Solution Day Timer System Seat, Comfort Solutions, Day Timer Face Down Chair, NightTimer Face-Support System

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

A vitrectomy chair/face-down support system is not addressed in National or Regional Medicare

coverage determinations or policies.

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- If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.

POLICY HISTORY/REVISION	
Committee Approval Dates	
New: 7/26 **Revised**: **Reviewed**:	
Date	**Summary of Changes**
11/1/2026	• New

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Vyvgart is a first-in-class human immunoglobulin G1 (IgG1) antibody fragment that binds the neonatal Fc receptor (FcRn), keeping antibodies in circulation and preventing FcRn from recycling IgG back into the blood. This causes a reduction in overall levels of IgG, including the abnormal AChR antibodies that are present in most patients with gMG.

Generalized myasthenia gravis is a chronic autoimmune, neuromuscular disease that causes muscle weakness and fatigue. The muscle weakness presenting in MG is due to an antibody-mediated immunologic attack directed at proteins in the postsynaptic membrane of the neuromuscular junction. Myasthenia gravis has been associated with antibodies against 3 postsynaptic proteins: acetylcholine receptor (AChR), muscle-specific kinase (MuSK), and low-density lipoprotein receptor-related protein 4 (LRP4). AChR antibody–positive patients represent the vast majority of gMG patients. There are two classifications of MG: ocular and generalized. In the ocular form the weakness is limited to the eyelids and extraocular muscles whereas in generalized the weakness involves the ocular, limb, and the respiratory tract. Many patients suffer from bulbar weakness (impairment of lower cranial nerves). This results in difficulty chewing, swallowing, talking, and even holding the head up. The degree of muscle weakness can fluctuate and vary in severity from person to person; however, it will generally improve with rest and worsen with physical activity. Other precipitating factors include pregnancy, infection, surgery, and stress. There is no cure for gMG, with symptoms progressing and often reaching their worst after a few years of disease onset.

Treatment options are aimed as managing the disease as no cure is known. Goals are restoring muscle strength and reducing disease activity as well as preventing myasthenic crisis. Therapeutic options are:

1. Symptomatic therapy with acetylcholinesterase inhibitors (e.g., oral pyridostigmine) to increase acetylcholine at the neuromuscular junction
2. Chronic immunosuppressive therapies to manage immune dysregulation (e.g., glucocorticoids, nonsteroidal immunosuppressants)
3. Rapid immunomodulatory therapies (e.g., intravenous [IV] immunoglobulin [IVIG], plasma exchange) for patients with severe disease or those experiencing myasthenic crisis
4. Thymectomy (i.e., surgical removal of the thymus gland); usually reserved for patients with a thymoma (10%–15% of MG patients) or for those < 60 years of age without a thymoma with AChR antibodies (the thymus plays a role in the pathogenesis of MG in seropositive patients)

Initial therapy is oral pyridostigmine for mild to moderate disease, whereas more severe disease is treated with IVIG (myasthenic crisis) followed by immunosuppressive therapy (corticosteroids, azathioprine, mycophenolate mofetil, cyclosporine, tacrolimus). It is noted that individuals will very likely utilize more than one of these medications in combination with each other. Those that are eligible for a thymectomy typically continue their medications and see an improvement approximately one year after surgery. Unfortunately, between 10 and 30 percent of those with MG do not respond to conventional immunosuppressive therapy and will require treatment with other therapies such as off-label Rituximab, IVIG, Plasma Exchange, or Soliris.

The approval of Vyvgart was based on results from the Phase 3 ADAPT trial, which evaluated the drug's safety and efficacy in 167 patients with gMG. The trial met its primary endpoint, demonstrating that Vyvgart provided clinically meaningful improvements in symptom severity compared with placebo (with background gMG therapy) (67.7% versus 29.7%, respectively) as measured by the Myasthenia Gravis Activities of Daily Living score. The most frequently reported adverse effects in this trial included headache and nasopharyngitis.

Vyvgart Hytrulo received approval by the FDA in June 2024 for the treatment of adult patients with chronic inflammatory demyelinating polyneuropathy (CIDP) following the stage 3 ADHERE trial. Patients who were improved with the use of Vyvgart Hytrulo in the open-label phase of the trial (n = 221) entered a randomized, double-blind, placebo-controlled withdrawal period. The Vyvgart Hytrulo group has a 61% reduction in the risk of relapse compared to the placebo group based on the time to the first adjusted Inflammatory Neuropathy Cause and Treatment Disability Scale (INCAT) deterioration of ≥ 1 point.

Summary

Effective Date of Policy:	6/9/2026
Indications	Treatment of adult patients with generalized myasthenia gravis (gMG) Treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP)

ICD10 Diagnosis Codes	G70.0, G61.81
HCPCS	Vyvgart: J9332 Vyvgart Hytrulo: J9334
Availability	*Vyvgart Injection: 400 mg in 20 mL (20 mg/mL) single-dose vial* *Vyvgart Hytrulo: 1,008mg-11,200 units/5.6mL solution for injection vials (per FDA prescribing information, administer by healthcare professional only) and 1000 mg-10,000 units per 5 mL in a prefilled syringe*
Duration	Six months

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy:

Indication	Inclusion Criteria	Recommended Dosing

Generalized Myasthenia Gravis
 	
(FDA approval)
 	
ICD10: G70.0
	• Enrollee is ≥ 18 years of age
	• Must be prescribed by or in consultation with a neurologist. If geographically available, it is also recommended for patients to have been evaluated by a neuromuscular specialist.
	• Documentation of a diagnosis of gMG that must have all of the following characteristics:
	  o One of the following clinical findings:
	  ▪ History of abnormal neuromuscular transmission test demonstrated by single-fiber electromyography (SFEMG) or repetitive nerve stimulation
	  ▪ Demonstrated improvement in MG signs on oral cholinesterase inhibitors, as assessed by neurologist
	• Myasthenia Gravis Foundation of America (MGFA) Clinical Classification Class II-IV
	  o Ocular MG is considered MGFA Class I, therefore not eligible to receive Vyvgart therapy
	• MG-Activities of Daily Living (MG-ADL) total score ≥ 5 with 50% of total score due to non-ocular symptoms at initiation of therapy
	• Must meet one of the following (A or B)
	  o A. Must have had serious side effects or drug failure to ONE of the following treatments for gMG (1 or 2).
	  ▪ 1. Corticosteroids for at least 3 months of treatment **OR**
	  ▪ 2. Non-steroidal immunosuppressive therapy (i.e., azathioprine, mycophenolate mofetil, cyclosporine) for at least 6 months of treatment **OR**
	  o B. Despite treatment with at least ONE immunosuppressant agent (i.e., corticosteroid, non-steroidal immunosuppressive therapy), the member required at least ONE treatment with plasma exchange, plasmapheresis, or intravenous immunoglobulin within the previous 12 months
	• For enrollee's who are not being treated with IVIG, enrollee has IgG levels of at least 6 g/L prior to starting therapy
	• Enrollee will not concurrently be receiving IVIG, Rituximab or Soliris (eculizumab)
	• Additional criteria for Vyvgart Hytrulo:
	  o Enrollee has adherently trialed at least 6 months of Vyvgart intravenous therapy with serious side effects or lack of clinical benefit, not expected to occur with Vyvgart Hytrulo
		Vyvgart:
		• 10 mg/kg administered as an intravenous infusion over one hour once weekly for four weeks (one cycle).
		• In patients weighing 120 kg or more, the recommended dose is 1200 mg per infusion.
		• Therapy cycles are repeated as needed depending on clinical response no sooner than eight weeks after initiation of the previous cycle.
		
		Vyvgart Hytrulo:
		• Vial is 1,008 mg / 11,200 units administered subcutaneously over approximately 30 to 90 seconds in cycles of once weekly injections for 4 weeks.
		• Administer subsequent treatment cycles based on clinical evaluation

Chronic Inflammatory demyelinating polyneuropathy
 	
ICD10: G61.81
	• Enrollee is ≥ 18 years of age
	• Therapy is being requested by a neurologist with expertise in the treatment of CIDP
	• Enrollee has a confirmed diagnosis of CIDP with supporting documentation (e.g., electrodiagnostic testing, clinical assessment, nerve biopsy)
	• Enrollee is refractory to treatment with at least 2 of the following:
	  o IVIG treatment lasting at least 3 months in duration
	  o Plasma exchange for at least one cycle (e.g., 4-6 exchanges over 8 to 10 days with subsequent exchange intervals dependent on response)
	  o Corticosteroid treatment (evidence-based regimen for CIDP)
	  o Rituximab (e.g., 375 mg/m^2 once weekly for 4 weeks per cycle) for at least one cycle
	• Must have documentation of baseline score on an objective scale to assess clinical response (e.g., Rankin, Modified Rankin, Medical Research Council (MRC), Inflammatory Rasch-built Overall Disability Scale (I-RODS), Inflammatory Neuropathy Cause and Treatment (INCAT) disability scale)
	• Additional criteria for Vyvgart Hytrulo:
	  o Enrollee has adherently trialed at least 6 months of Vyvgart intravenous therapy with serious side effects or lack of clinical benefit, not expected to occur with Vyvgart Hytrulo	

Exclusion Criteria

Therapy will not be authorized if any of the above Inclusion Criteria are not met OR any of the below noted Exclusion Criteria are met:

- Enrollee has Myasthenia Gravis Foundation of America Class I or V
- Enrollee has worsening muscle weakness secondary to concurrent infections or medications
- Enrollee has known seropositivity or who test positive for an active viral infection with:
  - Hepatitis B Virus (HBV) (except patients who are seropositive because of HBV vaccination)
  - Hepatitis C Virus (HCV)
  - Human Immunodeficiency Virus (HIV)
- Vyvgart/ Vyvgart Hytrulo will not be approved in combination with Uplizna, Soliris/Bkemv/ Epysqli, Ultomiris, Rystiggo, Imaavy, Zilbrysq, intravenous immunoglobulin (other than when used as rescue therapy), or rituximab-containing products as Vyvgart/ Vyvgart Hytrulo has not been studied in combination with these therapies.

Continuation Criteria

- Requests will be reviewed per criteria every six months.
- Enrollees should be assessed by provider after the first two cycles of Vyvgart to assess for disease response. Continuation of therapy will be authorized if disease response occurs defined as at least a two-point improvement in the MG-ADL score from the members pre-treatment baseline.

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.
- Because Vyvgart causes transient reduction in IgG levels, immunization with live-attenuated or live vaccines is not recommended during treatment with Vyvgart. Evaluate the need to administer age-appropriate vaccines according to immunization guidelines before initiation of a new treatment cycle with Vyvgart.
- Delay administration of Vyvgart to patients with an active infection. Monitor for signs and symptoms of infection in patients treated with Vyvgart.
- Quantity limit for Vyvgart Hytrulo PFS: 4 syringes (20 mL) per 28 days
- Vyvgart and Vyvgart Hytrulo vials will be covered under the medical benefit as these are intended to be administered by a healthcare provider.

Myasthenia Gravis Foundation of America Clinical Classification

Class	Description
Class I	Any ocular muscle weakness; may have weakness of eye closure. All other muscle strength is normal.
Class II	Mild weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
Class III	Moderate weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
Class IV	Severe weakness affecting muscles other than ocular muscles; may also have ocular muscle weakness of any severity.
Class V	Defined as intubation, with or without mechanical ventilation, except when employed during routine postoperative management.

References

		Updated	Accessed
	ICER. Eculizumab and Efgartigimod for the Treatment of Myasthenia Gravis: Effectiveness and Value. Final Report, Report-at-a-Glance, Key Policy Recommendations. Evidence Report. 2021 Oct 20.	10/2021	1/2022
	Vyvgart (efgartigimod) Prescribing information, Argenx US, Inc., Boston, MA 02110. Revised 12/2021. Reviewed 1/2022	8/2024	8/2024
	Vyvgart (efgartigimod) Clinical Trial ADAPT (NCT03669588) Available at: https://clinicaltrials.gov/ct2/show/NCT03669588	3/2021	1/2022
	Vyvgart (efgartigimod) Clinical Trial ADAPT+ (NCT03770403) Available at: https://clinicaltrials.gov/ct2/show/NCT03770403	7/2022	1/2023
	IPD Analytics. New Drug Review: Vyvgart (efgartigimod). Published January 2022. Available by subscription only.	1/2022	1/2022
	Narayanaswami P, et al. International Consensus Guidance for Management of Myasthenia Gravis. Neurology. 2021. 96; 3:114-122.	1/2021	1/2023
	Howard, J. F. (2022, April 5). Long-term Safety, Tolerability, and Efficacy of Efgartigimod in Patients with Generalized Myasthenia Gravis: Interim Results of the ADAPT+ Study [PowerPoint slides]. Argenx. https://www.argenx.com/sites/default/files/media-documents/AAN_2022_Oral_Presentation_Final_04.05.22.pdf.	4/2022	1/2023
	Vyvgart Hytrulo (efgartigimod alfa and hyaluronidase-qvfc) Prescribing information, Argenx US, Inc., Boston, MA 02110. Revised 6/2023. Reviewed 8/2023	6/2024	8/2024
	Hu J, Sun C, Lu J, et al. Efficacy of rituximab treatment in chronic inflammatory demyelinating polyradiculoneuropathy: a systematic review and meta-analysis. J Neurol. 2022 Mar;269(3):1250-1263. doi: 10.1007/s00415-021-10646-y. Epub 2021 Jun 12. PMID: 34120208.	6/2021	8/2024

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE CHOICES:	Subject to all terms and conditions noted in above application.
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application. Vyvgart Hytrulo PFS: Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program.

CDPHP Pharmacy Services 6/9/2026

New: 2/2022

Revised	Reviewed
4/22, 4/23, 9/23, 9/24, 9/25	

Revision Date	Changes Made
4/2022	Removed Inclusion Criteria: History of positive anticholinesterase test (e.g., edrophonium chloride test) Updated wording of Inclusion Criteria with the addition of the **bolded** text: Enrollee has had an adequate trial **with clinically documented therapeutic failure** of at least one of the following options for the management of gMG: IVIG or Plasmapheresis.
4/2023	Updated IgG level to be applicable for enrollees who are not receiving IVIG therapy.
9/2023	Changed policy name from Vyvgart (efgartigimod) to Vyvgart and Vyvgart Hytrulo; added Vyvgart Hytrulo to policy.
9/2024	Added criteria for CIDP indication and included criteria requiring 6-month trial of Vyvgart before Vyvgart Hytrulo would be covered
9/2025	Added Vyvgart Hytrulo prefilled syringe to policy. Quantity limit for Vyvgart Hytrulo PFS: 4 syringes (20 mL) per 28 days.
6/2026	Removed positive serologic test of AChR antibodies for gMG Reworded medication trial for gMG

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: WIGS/CRANIAL PROSTHESES &TOUPEES

POLICY EFFECTIVE DATE:	7/1/2025
Policy Control #:	1370/20.000086
Next Annual Review:	September 2027

DISCLAIMER

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

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PROCEDURE CODES

A9282

DESCRIPTIONS

Wigs/cranial prostheses and toupees are manufactured coverings of natural or synthetic hair for the head.

POSITION STATEMENT

CDPHP administers benefits for a medically necessary wig/cranial prosthesis or toupee when there is severe hair loss due to injury or disease or as a side effect of the treatment of a disease. Severe hair loss due to injury, disease and/or side effect of treatment of a disease includes:

- Alopecia areata affecting a significant portion of the scalp and expected to be chronic in nature (lasting a year or more)
- Alopecia totalis
- Alopecia universalis
- Chemo or radiation therapy
- Congenital baldness
- Severe burns - 2nd degree full thickness and 3rd degree burns with resulting permanent alopecia

Capital District Physicians' Health Plan, Inc.
CDPHP Universal Benefits,® Inc.
Capital District Physicians' Healthcare Network, Inc.

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POLICY NAME: WIGS/CRANIAL PROSTHESES &TOUPEES

EXCLUSIONS

Duplicate wigs for convenience purposes.

Billing of code D5924 (cranial prosthesis) is not an appropriate code for purposes of this policy as this is a specific dental procedure designed to restore craniofacial structures.

Wigs/cranial prostheses and toupees are not considered to be medically necessary if balding or hair loss is due to any of the following conditions:

- Androgenetic alopecia (male/female pattern baldness)
- Natural aging process
- Pregnancy or postpartum alopecia
- Premature balding at a young age

CDPHP PRODUCT VARIATIONS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted above in the policy.
MEDICARE ADVANTAGE:	Subject to all terms and conditions noted above in the policy.
SELECT PLAN/HARP:	Subject to all terms and conditions noted above in the policy.

SOURCES

1. Other payers
2. Model Contract Language: https://www.dfs.ny.gov/apps_and_licensing/health_insurers/model_language

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RESOURCE COORDINATION POLICY

Capital District Physicians' Health Plan, Inc.
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Capital District Physicians' Healthcare Network, Inc.

(Collectively referred to within this policy as "CDPHP®")

POLICY NAME: WIGS/CRANIAL PROSTHESES &TOUPEES

POLICY APPROVAL DATES

New: 3/25

Revised:

Reviewed: 9/26

POLICY HISTORY

This section is intended to provide only highlights of the policy changes. The policy should always be reviewed in its entirety to ensure a comprehensive understanding of coverage.

Effective Date	Update
7/1/2025	New policy

This Resource Coordination Policy is the exclusive property of Capital District Physicians' Health Plan, Inc. (CDPHP®) and its affiliated companies, CDPHP Universal Benefits,® Inc. (CDPHP UBI) and Capital District Physicians' Healthcare Network, Inc. (CDPHN). The contents and form of this policy are proprietary to CDPHP. Any reproduction or replication of this policy without the express written permission of CDPHP, CDPHP UBI, and CDPHN is strictly prohibited. This policy is subject to contractual limitations and/or parameters established in any Employer sponsored Summary Plan Description (SPD) and/or Benefit Design Document (BDD).

Policy/Procedure Name: Xenpozyme (olipudase alfa) **Control Number: 1350/20.000465**

Disclaimer Notice

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Background

Acid sphingomyelinase deficiency (ASMD) is a rare, autosomal recessive, progressive genetic disorder that results from a deficiency of the enzyme acid sphingomyelinase, which is required to break down (metabolize) a fatty substance (lipid) called sphingomyelin. As a result, sphingomyelin and other substances accumulate around the body tissues. ASMD can be considered as a spectrum of disease, as it is variable in symptoms, severity, and age of onset. Niemann-Pick disease Type A (NPD Type A) represents a severe end of this spectrum (fatal neurodegenerative disorder presenting in infancy) and conversely a mild representation includes either no or minimal neurological symptoms with survival into adulthood (Niemann-Pick disease Type B, NPD Type B). Many cases of ASMD fall between the two aforementioned extremes and are referred to as types A/B disease (intermediate disease). Some information suggests that mild to intermediate cases of disease may be considered Type B, even with neurological findings.

NPD Type A and B are due to mutations in the SMPD1 gene, which causes a deficiency of the Acid Sphingomyelinase (ASM) enzyme.

According to the National Organization for Rare Disorders, ASMD affects males and females in equal numbers with the exact incidence and prevalence of the disorder unknown. It has been estimated at 1 in 250,000 individuals in the general population are affected, however because some cases go misdiagnosed or undiagnosed, determining the true frequency of ASMD in the general population is difficult.

Diagnosis involves determining whether the ASM activity is reduced or absent. Peripheral blood leukocytes or cultured skin fibroblasts are examined to assess residual ASM activity, where a confirmation is achieved if a sample demonstrates < 10% that of a control sample. Molecular testing is available in specialized laboratories and can detect mutations in the SMPD1 gene. The diagnosis also relies upon clinical documentation of symptoms and laboratory abnormalities, although the condition is heterogeneous in extent and systems affected.

Treatment is largely supportive, attempting to manage the various bodily systems involved in the disease. Xenpozyme (olipudase alfa) is the first FDA approved medication (enzyme replacement therapy) to treat symptoms of ASMD not related to the central nervous system.

Given that Xenpozyme is not expected to cross the blood-brain barrier or modulate the CNS manifestations of ASMD, it was only studied in patients with ASMD type B or type A/B. The neurologic manifestations of ASMD type A are rapidly progressive and fatal, and Xenpozyme has not been studied in these patients.

Replacement of the ASM enzyme with the genetically engineered, recombinant form helps reduce sphingomyelin accumulation in the liver, spleen, and lungs. Xenpozyme is an intravenous infusion given every two weeks that has been studied in three clinical trials (ASCEND, NCT02004691, ASCEND-Peds, NCT02292654, and a long-term trial, NCT02004704). ASCEND evaluated the efficacy and safety of Xenpozyme in 31 adult patients with ASMD type A/B or type B who were randomized to receive Xenpozyme or placebo for 52 weeks with an extension treatment following for up to four years. ASCEND- Peds evaluated eight pediatric patients under 12 years of age with ASMD type A/B or type B. The primary endpoints were assessed at week 52 and included percent predicted diffusing capacity of the lungs for carbon monoxide (DLco), Spleen volume, liver volume, and platelet count. Improvements were seen in all assessed endpoints, which reached statistical significance (week 52), and this benefit was appreciated at week 104, as well as those who crossed over into active treatment at week 52. From a safety perspective, this agent carries a Black Box Warning for severe hypersensitivity reactions so it must be administrated where appropriate measures are readily available. Additionally, the most common adverse effects are headache, cough, diarrhea, hypotension, and ocular hyperemia.

Summary

Effective Date of Policy:	12/3/2025
Indications	Treatment of non–central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients
ICD10 Diagnosis Codes	E75.249
Availability	*For injection: 4 or 20 mg of olipudase alfa-rpcp as a lyophilized powder in a single-dose vial for reconstitution*
Duration	Initial: 12 months Continuation: 12 months

Required Criteria for Initial Approval		
All of the following conditions for the requested indication must be met in order to approve therapy:		
Specific Indication	**Inclusion Criteria**	**Recommended Dosing Regimen**

Treatment of non–central nervous system manifestations of acid sphingomyelinase deficiency (ASMD) in adult and pediatric patients
 	
(FDA approval)
ICD10: E75.249
	• Therapy must be prescribed by or in consultation with a physician knowledgeable in the treatment of acid sphingomyelinase deficiency (ASMD)
	• Enrollee has a diagnosis of Type B or A/B ASMD with non-central nervous system (non-CNS) manifestations AND
	  o a. Must have documented deficiency, defined as < 10% enzyme compared to controls, of acid sphingomyelinase as measured in peripheral leukocytes, cultured fibroblasts, or lymphocytes OR
	  o b. Molecular genetic testing identifying a mutation in the SMPD1 gene
	• Enrollee does not have type A ASMD (also known as Niemann-Pick disease type A)
	• Baseline documentation of at least one of the following parameters will be required in order to verify clinical benefit upon recertification:
	  o Percent predicted diffusion capacity of the lungs for carbon monoxide (DLco).
	  ▪ i. Note: considerations will be granted for other age-appropriate lung function tests in pediatric patients unable to perform this test
	  o Spleen volume
	  o Liver volume
	  o Platelet count
	  o Linear growth progression (as measured by height Z-score) (only applicable to pediatric patients < 18 years of age)
	  o Lyso-sphingomyelin levels
		• Adults: Recommended starting dose is 0.1 mg/kg administered as an intravenous infusion.
		• Pediatrics: Recommended starting dose is 0.03 mg/kg administered as an intravenous infusion.
		• See Full Prescribing Information for the recommended dose escalation and maintenance dosage, dosage modifications to reduce the risk of adverse reactions, and preparation and administration instructions.
		• Xenpozyme is administered via intravenous infusion every 2 weeks

Continuation Criteria

- Requests will be reviewed per criteria every 12 months
- Documentation of improvement from baseline in at least one of the following:
  - Percent predicted diffusion capacity of the lungs for carbon monoxide (DLco).
    - i. Note: considerations will be granted for other age-appropriate lung function tests in pediatric patients unable to perform this test
  - Spleen volume
  - Liver volume
  - Platelet count
  - Linear growth progression (as measured by height Z-score) (only applicable to pediatric patients < 18 years of age)
  - Lyso-sphingomyelin levels

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.

- Xenpoxyme therapy carries a Black Box Warning for severe hypersensitivity reactions including anaphylaxis and that appropriate medical support measures, including cardiopulmonary resuscitation equipment, should be readily available. If a severe hypersensitivity reaction occurs, XENPOZYME should be discontinued immediately, and appropriate medical treatment should be initiated.
- Risk of fetal malformations during dosage initiation or escalation in pregnancy: Xenpozyme carries a pregnancy warning at any time during therapy. Use is not recommended as it may lead to elevated sphingomyelin metabolite levels that may increase the risk of fetal malformations. Advise females of reproductive potential to use effective contraception during treatment and for 14 days after the last dose if therapy is discontinued.

References

		Updated	Accessed
1	National Organization for Rare Disorders (NORD) - Acid Sphingomyelinase Deficiency. Published 2019. Available at: https://rarediseases.org/rare-diseases/acid-sphingomyelinase-deficiency/	9/22	9/24
2	Xenpozyme prescribing information, Genzyme Corporation, Cambridge, MA 02141.	12/23	9/24
3	Wasserstein MP, et al. Olipudase alfa for treatment of acid sphingomyelinase deficiency (ASMD): safety and efficacy in adults treated for 30 months. J Inherit Metab Dis. 2018 Sep; 41(5):829-838.	2018	11/22
4	Wasserstein M, et al. A randomized, placebo-controlled clinical trial evaluating olipudase alfa enzyme replacement therapy for chronic acid sphingomyelinase deficiency (ASMD) in adults: One-year results. Genet Med. 2022 Jul; 24(7):1425-1436.	7/22	11/22
5	Diaz GA, et al. One-year results of a clinical trial of olipudase alfa enzyme replacement therapy in pediatric patients with acid sphingomyelinase deficiency. Genet Med 2021 Aug; 23(8):1543-1550.	8/21	11/22
6	IPD Analytics New Drug Review – Xenpozyme (olipudase alfa). Published October 2022. Available at: https://www.ipdanalytics.com/ (subscription required)	10/22	11/22
7	Xenpozyme (olipudase alfa) Clinical Trial (NCT02004691) Ascend. Available at: https://clinicaltrials.gov/ct2/show/NCT02004691	12/23	9/24
8	Xenpozyme (olipudase alfa) Clinical Trial (NCT02292654) Ascend-Peds. Available at: https://clinicaltrials.gov/ct2/show/NCT02292654	3/22	9/24
9	Xenpozyme (olipudase alfa) Clinical Trial (NCT02004704) Long-term pediatric trial. Available at: https://clinicaltrials.gov/ct2/show/NCT02004704	7/23	9/24

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE CHOICES:	Subject to all terms and conditions noted in above application.
SELECT/HARP PLAN:	Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 12/3/2025

New: 12/2022

Policy History

Revised	Reviewed
12/25	12/23, 12/24

Date	Note
12/2025	Updated approval duration to 12 months Removed exclusion criteria section Updated continuation criteria to at least one of the listed criteria improvements

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Policy/Procedure Name: Xiaflex (collagenase clostridium histolyticum) **Control Number: 1350/20.000574**

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Background

Fibroproliferative disorders, characterized by excessive collagen deposits, can affect the musculoskeletal system, causing pain, limiting joint range of motion, and negatively impacting quality of life. Examples of these fibrotic tissue disorders include Dupuytren's contracture, adhesive capsulitis, and Peyronie's disease.

Collagenases, enzymes that digest native collagen and lead to the disruption of contracted cords, are being investigated as a non-surgical treatment for fibroproliferative disorders. Injection of collagenase clostridium histolyticum, a bacterial collagenase, is intended to provide a non-operative treatment option and is usually an office-based procedure.

Xiaflex (collagenase clostridium histolyticum, CCH) is FDA-approved for the treatment of Dupuytren's contracture with a palpable cord. The FDA labeling for Xiaflex states that up to three injections at four-week intervals may be given into a palpable Dupuytren's cord with a contracture of a metacarpophalangeal (MP) joint or a proximal interphalangeal (PIP) joint. This should be followed by manual manipulation of the affected joint to attempt rupture of the cord.

Additionally, Xiaflex has been FDA-approved for treatment of men with Peyronie's disease who have a penile curvature of at least 30 degrees. The dose of Xiaflex is 0.58 mg per injection, administered into a Peyronie's plaque. Up to eight injections (four treatment cycles) may be administered in the course of treatment. Also, a penile modeling procedure is recommended after every treatment cycle of two injections, in an effort to further disrupt the plaque. Expert opinion defines "functionally straight" as penile curvature less than or equal to 20 degrees.

In a prospective cohort study by Wymer and colleagues (2018), 115 patients with Peyronie's disease who completed at least two CCH cycles were analyzed for improvement in penile curvature, to assess for characteristics predictive of treatment success. Thirty-four of the 115 men included were found to have calcification. Patients with calcified plaque were more likely to have dorsal curvature and severe erectile dysfunction. Patients with noncalcified plaque and curvature of at least 60 degrees had the greatest improvement in curvature (defined as improvement in curvature greater than 20%). The authors concluded that calcification is one of the strongest predictors for CCH failure and that men with baseline curvature greater than 60 degrees are approximately 2.5 times more likely to experience a 20% or more improvement, compared to lesser curvatures.

Summary

HCPCS Code	J0775
Effective Date of Policy:	2/12/2026

Required Criteria for Initial Approval

Dupuytren's Contracture

1. Must be 18 years of age or older
2. Must be used for the treatment of Dupuytren's contracture in either the metacarpophalangeal (MCP) or proximal interphalangeal (PIP) joint when there is a palpable palmar cord.
3. Must have documentation that the contracture is at least 20 degrees prior to initiating Xiaflex therapy
4. Provider must attest to all of the following:
    a. The provider is experienced in
        i. Injection procedures of the hand
        ii. Treatment of patients with Dupuytren's contracture

   b. The provider has completed the necessary training to administer Xiaflex
   c. The provider and health care site are enrolled in the Xiaflex Managed Distribution Program for Dupuytren's contracture
5. The provider must specify the location of the cord being treated on the hand; indicating the hand, finger(s), and joint(s) affected
6. The dose of Xiaflex is 0.58 mg per injection into a palpable cord with a contracture of a MP joint or PIP joint
   a. Each vial of Xiaflex (supplied as 0.9 mg) and sterile diluent should only be used for a single injection
   b. Approximately 24 to 72 hours after injection, a finger extension procedure should be performed if a contracture persists to facilitate cord disruption
   c. If two joints on the same hand are to be treated during a treatment visit, separate vials and syringes should be used for each reconstitution and injection
7. Xiaflex injection is administered at four-week intervals for a total of 3 injections per cord/joint
   a. Xiaflex will not be authorized for retreatment beyond a total of 3 injections per cord/joint
8. If requesting two injections (two vials) in the same hand for a single treatment visit, one of the following must be met:
   a. The patient has two palpable cords affecting two joints on the same hand **OR**
   b. The patient has one palpable cord affecting two joints in the same finger
9. Approval duration as follows:
   a. For all **non-Managed Medicaid/HARP** lines of business: 6 months (for a total of 3 injections per cord/joint), to allow adequate time to complete treatment.
   b. For **Managed Medicaid/HARP**: 4 weeks **(limited to a maximum of 2 injections in the same hand for a single treatment visit as outlined in criterion #8)**
10. **Managed Medicaid/HARP ONLY**: Per New York State Department of Health Requirements, requests for Xiaflex require eligibility verification via EDVS system (13 years of age and older).

Peyronie's Disease

1. Must be 18 years of age or older
2. Must have a diagnosis of Peyronie's disease
3. Must have stable disease, defined by no change in symptoms (e.g., penile curvature and pain) for at least three months
4. Must have the presence of a palpable plaque at the site of maximum curvature
5. Must have documentation at the start of therapy of a curvature deformity between 30 and 90 degrees that causes a functional deficit (e.g., an inability to engage in sexual intercourse, sexual intercourse is painful for either partner, or penile pain) not attributable to other causes
6. Provider must attest that Xiaflex will be used in combination with a penile modeling procedure
7. Provider must attest that both of the following are met:
   a. The provider has experience in the treatment of male urological diseases
   b. The provider and health care site are certified through the Xiaflex REMS Program
8. The dose of Xiaflex is 0.58 mg (supplied as a 0.9 mg vial) per injection administered into a Peyronie's plaque. If more than one plaque is present, inject into the plaque causing the curvature deformity. A treatment course consists of a maximum of 4 treatment cycles. Each treatment cycle consists of two Xiaflex injection and one penile modeling procedure. The second Xiaflex injection procedure is performed 1 to 3 days after the first. The penile modeling procedure is performed 1 to 3 days after the second injection of the treatment cycle. The interval between treatment cycles is approximately 6 weeks. The treatment course, therefore, consists of a maximum of 8 injection procedures and 4 modeling procedures (four treatment cycles).

9. Xiaflex will be authorized for a maximum of four treatment cycles (two Xiaflex injection procedures and one penile modeling procedure per cycle), each separated by six weeks. Xiaflex will not be authorized beyond four treatment cycles (8 injections) per plaque.
10. Approval duration will be 12 months (for a total of 8 injections) to allow adequate time to complete treatment
11. Retreatment with Xiaflex will not be authorized when the penis is functionally straight (i.e., the curvature deformity is less than or equal to 20 degrees) after the first, second or third treatment cycle, or if further treatment is not clinically indicated.
12. **Managed Medicaid/HARP ONLY: The use of Xiaflex for the treatment of Peyronie's disease is not a covered benefit.**

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department

References

		Accessed
1	Xiaflex [prescribing information]. Rochester, MI: Endo USA; 2024 Apr.	7/2025
2	Boe C, Blazar P, Iannuzzi N. Dupuytren contractures: an update of recent literature. J Hand Surg Am. 2021; 46(10):896-907.	7/2025
3	Krishnappa P, et al. Surgical management of Peyronie's disease with co-existent erectile dysfunction. Sex Med 2019 Sep 17. pii: S2050-1161(19)30178-3.	7/2025
4	Wymer K, et al. Plaque calcification: an important predictor of collagenase clostridium histolyticum treatment outcomes for men with Peyronie's disease. Urology 2018 Sep;119:109-114.W	7/2025

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE CHOICES:	Subject to all terms and conditions noted in above application.
SELECT PLAN/HARP:	Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services *2/12/2026*

New:9/2025

Revision Date	Notes
2/2026	For a diagnosis of Dupuytren's contracture approval timeframe was shortened to 4 weeks for MMC/HARP Updated provider attestation requirement for Peyronie's Disease

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Policy/Procedure Name: Xolair (omalizumab) and biosimilars **Control Number: 1350/20.000103**

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Background

Asthma

Xolair (omalizumab) and Omlyclo (omalizumab-igec) are indicated for moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids.

Asthma is a heterogeneous syndrome that might be better described as a constellation of phenotypes, each with distinct cellular and molecular mechanisms, rather than as a singular disease. One of these phenotypes is allergic asthma, which is associated with allergies to allergens such as pollen or dust mites. Chronic airway inflammation results in symptoms that include wheezing, shortness of breath, chest tightness, and cough.

Immunoglobulin E (IgE) plays a central role in the pathogenesis of allergic asthma. IgE activation of mast cells, and basophils causes the release of inflammatory mediators such as histamine, prostaglandins, cysteinyl-leukotrienes, and cytokines. Xolair (omalizumab) and Omlyclo (omalizumab-igec) are recombinant humanized monoclonal antibodies that inhibit the binding of IgE to the IgE receptors on the surface of mast cells, basophils, and dendritic cells. This results in receptor down-regulation on these cells and leads to a reduction in blood/tissue eosinophils and other inflammatory mediators.

Chronic Spontaneious Urticaria (CSU)

Xolair (omalizumab) and Omlyclo (omalizumab-igec) are indicated for chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

Chronic spontaneous urticaria is defined by the presence of wheals (hives), angioedema (swelling), or both, most days of the week, for a duration of 6 weeks or longer. The hives may appear at any age, can occur anywhere on the body, and vary in size. They are typically itchy, raised, and appear as reddish areas on the skin. Angioedema may be painful and usually occurs in the face, throat, hands, and feet, though it can occur in other areas of the body as well. Usually, the cause of chronic urticaria cannot be identified.

Xolair (omalizumab) and Omlyclo (omalizumab-igec) are recombinant humanized monoclonal antibodies that binds to IgE and lowers free IgE levels, resulting in receptor down-regulation on cells. It is unknown how this mechanism improves symptoms in CIU.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Xolair (omalizumab) and Omlyclo (omalizumab-igec) are indicated for chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment.

CRSwNP is a subtype of chronic rhinosinusitis (CRS). It is a heterogeneous chronic inflammatory disease of the nasal lining and sinuses, resulting in the development of noncancerous soft tissue growth (polyps) in the sino-nasal cavity. Symptoms include loss of smell, nasal congestion, and nasal drainage. Most patients with CRSwNP show evidence of type 2 inflammation. Nasal polyp tissue is characterized by local eosinophil inflammation in a large majority of patients with this condition. Despite optimized treatment, nasal polyps have a high rate of recurrence.

Xolair (omalizumab) and Omlyclo (omalizumab-igec) are recombinant humanized monoclonal antibodies that inhibits the binding of IgE to the IgE receptors on the surface of mast cells, basophils, and dendritic cells. This results in receptor down-regulation on these cells and leads to a reduction in blood/tissue eosinophils and other inflammatory mediators.

Food Allergies

Xolair (omalizumab) and Omlyclo (omalizumab-igec) are indicated for IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance.

IgE-mediated food allergic reactions are rapid in onset, typically beginning within minutes to two hours from the time of ingestion. Most patients react to one or two specific foods/food groups, although an increasing number of patients react to multiple foods.

Xolair and Omlyclo are recombinant humanized monoclonal antibodies that inhibit the binding of IgE to the high-affinity on the surface of mast cells, basophils, and dendritic cells, which down-regulates the IgE receptors on these cells and reduces allergic reactions.

Summary	
Effective date	9/25/2026
Indications	Moderate to severe persistent allergic asthma, chronic idiopathic urticaria (CIU), nasal polyps, IgE-mediated food allergies
ICD10 diagnosis codes	J45, L50, J33.9, Z91 (select subcodes for specific allergens)
Availability	Xolair: 75 mg/0.5 mL, 150 mg/mL, and 300/2mL solution in a single-dose prefilled syringe and autoinjector; 150 mg lyophilized powder in a single-dose vial for reconstitution Omlyclo: 75 mg/0.5 mL, 150 mg/mL, and 300/2mL solution in a single-dose prefilled syringe
Limitations	Not indicated for other allergic conditions, other forms of urticaria, acute bronchospasm, or status asthmaticus
HCPCS	Xolair: J2357 Omlyclo: Q5154
Duration	Initial: Six (6) months Continuation: Two (2) years

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve Xolair (omalizumab) or Omlyclo (omalizumab-igec).

Indication	Criteria
Severe persistent allergic asthma (FDA approval) ICD10: J45	1. Must be at least 6 years of age 2. Must be followed by, and drug ordered by a pulmonologist, allergist, or immunologist 3. Must have a diagnosis of moderate to severe persistent asthma 4. Must be a non-smoker defined as someone who has not smoked in the past 6 months 5. Must have baseline IgE levels between 30 and 700 IU/mL Coverage for IgE levels outside of this range will be considered as follows: a. Members with a baseline IgE level between 700 and 1300 IU/mL will be considered for Xolair therapy if all other criteria is met as long as the dose required based on IgE and body weight is not > 750 mg per month OR b. Member with baseline IgE level below 30 IU/mL will not be considered for coverage as there is not enough free IgE with which to bind for the drug to exert its effect 6. Must have at least one perennial aeroallergen (examples: dust mites, pet dander, cockroach) 7. Must have experienced two or more asthma exacerbations within the preceding 12 months that required medical management 8. Must have well documented use of high-dose inhaled corticosteroids for at least 3 months, be compliant with existing therapy, and have followed GINA guidelines for asthma treatment including adequate trial of a high-dose inhaled steroid in combination with a long-acting beta agonist 9. Initial approval will be for 6 months. Continuation can be approved for 2 years and will require objective assessment of response to therapy with Xolair or Omlyclo as well as compliance with the inhaled corticosteroid and controller medication.
Chronic Spontenaeous urticaria (FDA approval) ICD10: L50	1. The request is obtained by or in consultation with an allergist, immunologist, or dermatologist 2. Must be at least 12 years of age 3. Must have a minimum six-week history of urticaria characterized by wheals (hives), angioedema, or both despite adequate trials of: a. A second generation H1-antihistamine at standard dosing AND a second generation H1-antihistamine trialed at 2-4 times the standard dose

	i. This criterion may be satisfied by using either the same second generation H1-antihistaime at standard dosing and 2-4 times standard dosing OR using two different second generation H1-antihistamines with at least one agent being at 2-4 times standard dosing 4. Initial approval will be for 6 months 5. Continuation of therapy can be approved for 2 years and will require documentation that the patient has responded to or continues to benefit from therapy
Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) (FDA approval) ICD10: J32.9 (chronic sinusitis), J33.9 (nasal polyp, unspecified)	1. The prior authorization is requested by or in consultation with an allergist, immunologist, or otolaryngologist 2. Must be at least 18 years of age 3. Must have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) a. Chronic is defined as having lasted for at least 12 weeks AND b. Must currently have nasal polyposis, confirmed by evidence (such as direct examination, nasal endoscopy, imaging studies (such as a sinus CT scan)) 4. Must have a documented inadequate response despite at least 3 months of compliant use of mometasone nasal spray at a dose of 2 sprays in each nostril twice daily 5. Must have a documented inadequate response despite at least 3 months of compliant use of Xhance nasal spray at a dose of 2 sprays in each nostril twice daily. 6. Must have had either: a. Prior nasal surgery **OR** b. Prior treatment with a course of systemic corticosteroids 7. Must be used in combination with an intranasal corticosteroid a. Xolair as monotherapy for this indication will not be authorized as it is only FDA approved as an add-on maintenance treatment for this indication 8. Must have baseline IgE level between 30 and 1500 IU/mL a. Dosing is based on IgE level and body weight b. Members with a baseline IgE level above 1500 IU/mL will be considered for Xolair or Omlyclo therapy if all other criteria are met and as long as the dose required based on IgE and body weight does not exceed 600 mg every 2 weeks 9. Initial approval will be granted for 6 months. Continuations can be approved for 2 years and will require documentation of continued use of an intranasal corticosteroid and clinical benefit from Xolair or Omlyclo use
Mitigation of IgE mediated allergic food reactions, including anaphylaxis, that may occur with accidental exposure (FDA approval) ICD10: Z91.010-014, Z91.018 Z91.010 (peanuts), Z91.011 (milk), Z91.012 (eggs), Z91.013 (seafood), Z91.014 (mammalian meats), Z91.018 (other foods)	1. Request is obtained by an allergist or immunologist 2. Enrollee is at least one year of age 3. Enrollee has a confirmed diagnosis of IgE-mediated food allergy a. Must have documentation of a positive skin test or allergen-specific IgE blood test for each allergy within 12 months of the request b. Must have documentation of occurrence of significant allergic symptoms (moderate to severe skin, respiratory or gastrointestinal symptoms) when exposed to applicable allergens 4. Xolair is being used in conjunction with a food avoidant diet to the particular allergens 5. Pretreatment serum IgE levels must be provided on initial requests a. Coverage will be excluded for patients with an IgE of greater than or equal to 1850 IU/mL 6. Weight must be provide on initial and all continuation requests 7. Coadministration of Xolair or Omlyclo with a peanut protein desensitization therapy (Palforzia) or other oral immunotherapy has not been studied and will be considered experimental/investigational and will not be authorized. 8. Initial approval will be for 6 months. Continuation can be approved for 2 years and will require progress notes documenting that the member has had no severe allergic symptoms to food allergens while on Xolair or Omlyclo therapy AND that the member continues to practice food allergen avoidance.
Exclusion Criteria	
Xolair or Omlyclo will not be authorized in the following circumstances: a. Concurrent use with interleukin inhibitors (Dupixent, Nucala, Fasenra, Cinqair)	

b. Concurrent use with thymic stromal lymphopoietin (TSLP) inhibitors (Tezspire)
c. Concurrent use with peanut protein desensitization therapy (e.g., Palforzia) other oral immunotherapy (OIT)
d. Use for latex allergies, atopic dermatitis, or seasonal allergic rhinitis (hay fever)

Continuation Criteria

Continue current approval for Xolair or Omlyclo if following criteria are met.

- **For use in all indications:**
  - After initial approval period, requests will be reviewed every two years for clinical improvement or sustained efficacy.
- **For use in asthma:**
  - Improvement in asthma symptoms or asthma exacerbations is evidenced by decrease in one or more of the following:
    - Use of systemic corticosteroids
    - Two-fold or greater decrease in inhaled corticosteroid use for at least three days
    - Hospitalizations
    - ER visits
    - Unscheduled visits to healthcare provider
    - Improvement from baseline in forced expiratory volume in one second (FEV_1)
  - Approval will be contingent on the continued use of standard of care for asthma (inhaled corticosteroids and additional controlled medications such as long-acting beta-agonist inhalers). Xolair/Omlyclo is not FDA approved for monotherapy.
  - CDPHP expects that the use of Xolairtherapy will be part of a comprehensive asthma treatment regimen that includes, but is not limited to, intensive counseling on the importance of medication compliance and avoidance of allergic asthma triggers.

- **For use in urticaria: improvement is demonstrated by:**
  - Member demonstrate improvement in symptoms such as:
    - A decrease in the number and severity of hives and itching or increase in angioedema-free days
    - Decrease use of antihistamines

- **For CRSwNP-related requests:**
  - Member demonstrates improvement in symptoms of CRSwNP such as:
    - Reduction in nasal congestion
    - Reduction in rhinorrhea
    - Reduction in polyp size
    - Improvement in loss of smell
    - Reduction of facial pressure/pain or fullness
    - Reduction in oral corticosteroid use
  - Member continues to be adherent to intranasal corticosteroid

- **For IgE mediated food allergic reaction requests**:
  - Enrollee is continuing to demonstrate clinical benefit as assessed by the provider
  - Physician attests that the enrollee has not had anaphylaxis through accidental exposure where Xolair or Omlyclo is expected to exert an effect (dose limited exposure)

Definitions

References and explanations

Inadequate control of asthma	History of exacerbations (two within one year, three within two years, or one severe exacerbation requiring hospitalization in the last year)
ICS (inhaled corticosteroids)	flunisolide (Aerospan), ciclesonide (Alvesco), fluticasone furoate (Arnuity Ellipta), mometasone (Asmanex), fluticasone propionate (Flovent), budesonide (Pulmicort), beclomethasone (QVAR)
LABA (long-acting beta agonist)	indacaterol (Arcapta Neohaler), salmeterol (Serevent Diskus), olodaterol (Striverdi Respimat)
Combination asthma products	fluticasone and salmeterol (Advair, Airduo, Wixela), fluticasone and vilanterol (Breo Ellipta), mometasone and formoterol (Dulera), budesonide and formoterol (Symbicort)
SGA (second-generation H1	loratidine (Claritin), desloratadine (Clarinex), cetirizine (Zyrtec), levocetirizine (Xyzal), fexofenadine (Allegra)

antihistamine)	
First-generation antihistamines	diphenhydramine (Benadryl), meclizine, doxylamine, cyproheptadine, chlorpheniramine, brompheniramine
H2 antagonist	famotidine (Pepcid), cimetidine (Tagamet)

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department
- Enrollee must have prescription drug coverage administered by CDPHP for medication obtained at a pharmacy
- Drugs listed above in the definition section may not be all-inclusive (last updated 9/24/2026).
- CDPHP reserves the right to make decisions based on clinical judgment on a case-by-case basis.
- CDPHP will not administer benefits for replacement doses of Xolair or Omlyclo due to the improper storage or reconstitution of this drug. It is the responsibility of the requesting practitioner to ensure that all medical staff are following the unique guidelines for the stability, storage, and reconstitution of Xolair or Omlyclo as indicated in the product insert for this drug.

References

		Accessed
1	Xolair (prescribing information). South San Francisco, CA: Genentech, Inc.; 2024 Feb.	5/2025
2	Busse W, Corren J, Lanier B et al. Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. Journal of Allergy and Clinical Immunology. 2001;108(2):184-190.	10/2023
3	Solèr M, Matz J, Townley R et al. The anti-IgE antibody omalizumab reduces exacerbations and steroid requirement in allergic asthmatics. European Respiratory Journal. 2001;18(2):254-261.	10/2023
4	Lanier B, Bridges T, Kulus M, Taylor A, Berhane I, Vidaurre C. Omalizumab for the treatment of exacerbations in children with inadequately controlled allergic (IgE-mediated) asthma. Journal of Allergy and Clinical Immunology. 2009;124(6):1210-1216.	10/2023
5	Maurer M, Rosén K, Hsieh H et al. Omalizumab for the Treatment of Chronic Idiopathic or Spontaneous Urticaria. New England Journal of Medicine. 2013;368(10):924-935.	10/2023
6	Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Available from: www.ginasthma.org	10/2023
7	Bernstein J, Lang D, Khan D et al. The diagnosis and management of acute and chronic urticaria: 2014 update. Journal of Allergy and Clinical Immunology. 2014;133(5):1270-1277.e66.	10/2023
8	Zuberbier T et al. The EAACI/GA^{2}LEN/EDF/WAO guideline for the definition, classification, diagnosis, and management of urticaria. Allergy. 2018 Jul;73(7):1393-1414.	10/2023
9	Moore A. Nasal Polyps. American Academy of Allergy, Asthma, and Immunology. 2021.	10/2023
10	Naclerio R, Baroody F, Bachert C, et al. Clinical Research Needs for the Management of Chronic Rhinosinusitis with Nasal Polyps in the New Era of Biologics: A National Institute of Allergy and Infectious Diseases Workshop. American Academy of Allergy, Asthma and Immunology, May 2020.	10/2023
11	Gevaert P, Omachi T, Corren J, et al. Efficacy and safety of omalizumab in nasal polyposis: 2 randomized phase 3 trials. American Academy of Allergy, Asthma, and Immunology. September 2020.	10/2023
12	FDA approves first medication to help reduce allergic reactions to multiple foods after accidental exposure [Internet]. FDA; 2024 [cited 2024 Mar 6]. Available from: https://www.fda.gov/news-events/press-announcements/fda-approves-first-medication-help-reduce-allergic-reactions-multiple-foods-after-accidental	3/2024
13	Gupta RS, Warren CM, Smith BM, et al. Prevalence and Severity of Food Allergies Among US Adults. JAMA Netw Open. 2019;2(1):e185630. doi:10.1001/jamanetworkopen.2018.5630.	3/2024
14	Foong RX, Dantzer JA, Wood RA, Santos AF. Improving Diagnostic Accuracy in Food Allergy. J Allergy Clin Immunol Pract. 2021 Jan;9(1):71-80. doi: 10.1016/j.jaip.2020.09.037. PMID: 33429723; PMCID: PMC7794657.	3/2024
15	Sampson HA. Update on food allergy. J Allergy Clin Immunol. 2004 May;113(5):805-19; quiz 820. doi: 10.1016/j.jaci.2004.03.014. PMID: 15131561.	3/2024
16	Kim HL, Leigh R, Becker A. Omalizumab: Practical considerations regarding the risk of anaphylaxis. Allergy Asthma Clin Immunol. 2010 Dec 3;6(1):32. doi: 10.1186/1710-1492-6-32. PMID: 21129189; PMCID: PMC3006370.	3/2024
17	EpiPen/EpiPen Jr (epinephrine) [prescribing information]. St. Louis, MO: Meridian Medical Technologies LLC; February 2023.	3/2024

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE ADVANTAGE:	Refer to Medicare pharmacy policy: Xolair (Omalizumab).
SELECT PLAN/HARP:	Medical Benefit – Subject to all terms and conditions noted in above application. Pharmacy Benefit - Effective April 1, 2023, the pharmacy benefit for Medicaid is administered by NYRx, the Medicaid Pharmacy Program.

CDPHP Pharmacy Services 9/25/2026

New: 03/2017

Date	Notes
09/2018, 04/2020, 2/2021, 2/2022, 02/2023	Reviewed with no changes.
10/2017, 04/2019	Revised
2/2024	Background updated with 2023 GINA guidelines.
4/2024	Added new Indication of IgE mediated food allergic reactions.
6/2024	Revisions: Inclusion Criteria: Removed multiple food allergy requirement, specifically listed tree nut examples Continuation Criteria: Changed duration from six months to 12 months and removed continuation criteria involving Oral Food Challenge.
12/2024	Revised. Clinical criteria, exclusions, and continuation criteria all revised to align with other policies for medications used to treat the same indications to ensure consistency in the application of criteria.
6/2025	Revised. Added non-smoking requirement to asthma criteria. Added considerations for coverage when IgE levels are out of criteria range. Expanded duration of continuation approvals to 2 years.
12/2025	Defined IgE range for food allergy
9/2026	Renamed policy and added Omlyclo to policy

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Background

Spinal Muscular Atrophy (SMA) is a rare and irreversible neurodegenerative disease that affects the spinal cord, specifically the alpha motor neurons in the anterior horn.[1] As a result, SMA causes progressive proximal motor weakness and atrophy, in severe cases often resulting in early mortality. Critical muscle functions lost include walking, speaking, swallowing, and breathing, and the primary cause of death is respiratory muscle weakness leading to severe restrictive lung disease and progressive respiratory failure.[1]

SMA is linked to chromosome 5q and is recessive, caused by bi-allelic mutations in the SMN1 (Survival Motor Neuron 1) gene, which produces the SMN protein that is essential for motor neuron development. Specifically, the mutations include the homozygous deletion or deletion and mutation of the alleles of the SMN1 gene on chromosome 5q.[1-3] The SMN2 (Survival Motor Neuron 2) gene also produces SMN protein; however, only a small portion of the protein produced is functional. The number of SMN2 copies is important in determining the severity of SMA; however, those without SMN1 have an insufficient level of SMN protein regardless of the SMN2 copies. Prevalence is estimated at 1-2 per 100,000 persons, and incidence around 1 in 10,000 live births for SMA Type I accounting for 60% of all cases.[1]

There are five types of SMA based on age of onset and severity (Type 0-IV)[1-3]:
Type 0: This is the most severe subtype, which affects individuals in utero before birth and is very rare. These individuals often have joint contractures, respiratory distress and diffuse hypotonia (very low muscle tone) at birth and do not survive the neonatal period.
Type I (Infantile-onset SMA): This is the most common subtype of SMA (60% of cases) and has an age onset before six months where the highest achieved motor function includes sitting with support. The natural age of death is before two years without intervention, and there are typically 1-3 SMN2 copies.
Type II: This subtype has an onset from 6-18 months; children are able to sit but do not walk and survive into early adulthood, typically having 2-3 SMN2 copies.
Type III: This subtype has mild symptoms, comparatively, and has an onset of symptoms after 18 months of age. These individuals are able to walk independently; they may lose this ability in teens or later, but importantly, they are also able to survive into adulthood. There are typically 3-4 SMN2 copies present.
Type IV: This is the mildest subtype of the condition, with the onset of symptoms occurring as an adult and progressing very slowly. Individuals are able to stand and walk, and usually have normal lifespans. There are typically at least 4 SMN2 copies present in this subtype.

Clinical Classification of Spinal Muscular Atrophy (SMA)[5]

Type	Age of onset	Requires respiratory support at birth	Able to sit	Able to stand	Able to walk	Life expectancy	Predicted SMN2 copy number
0	Prenatal	Yes	No	No	No	< 6 months	1
1	< 6 months	No	No	No	No	< 2 years	2
2	6 to 18 months	No	Yes	No	No	10 to 40 years	3
3	> 18 months	No	Yes	Yes	Assisted	Adult	3 to 4
4	> 5 years	No	Yes	Yes	Yes	Adult	> 4

Zolgensma is an adeno-associated virus serotype 9 vector that delivers a copy of SMN to supplement the defective SMN1 gene.[2,4] This is a fully functional human SMN under control of a continuous promoter, which is designed to boost levels of SMN protein in a rapid and sustainable way.

Zolgensma has been studied in a Phase I open-label, two-cohort trial and an extension study (START) in infantile onset (Type 1 SMA).[3] Subjects in the open-label, single-arm clinical trial experienced an onset of clinical symptoms consistent with SMA prior to six months of age and had genetically confirmed bi-allelic SMN1 gene deletions alongside 2 copies of the SMN2 gene. The 12 *therapeutic dose* trial subjects also had absence of the c.859G>C modification in exon 7, which predicts a milder phenotype. Lastly, these individuals had a negative baseline anti-AAV9 antibody titer (< 1:50) and were less than six months of age by the time they received the Zolgensma infusion. Baseline

characteristics included a mean age of diagnosis of 8.6 weeks, with age at onset of 1.4 months.[3] The mean CHOP-INTEND (Children's Hospital of Philadelphia-Infant Test of Neuromuscular Disorders) score was 28 (range 12-50).[3] After treatment with Zolgensma, all infants were alive and even-free (death or permanent ventilation) through 24 months.[3] Motor milestones reached by the subjects included head control (n-11), rolling over (n-9), sitting unassisted (n-10), and feeding orally as well as speaking (n-11), and finally 2 subjects were able to walk independently.[3] The safety elements identified in this trial included two subjects having an elevation in serum aminotransferase following infusion; these were grade 4AEs, and oral prednisolone treatment was added as pre- and post- treatment to Zolgensma therapy following the first infant's liver function elevation.[3] Another Phase 3 trial, Gene Replacement Therapy Clinical Trial for Patients With Spinal Muscular Atrophy Type 1 (STR1VE), studied symptomatic children from less than six months of age with SMA Type 1 and 1-2 copies of SMN2.[2] The STR1VE trial showed that Zolgensma significantly increased event-free survival in these patients when compared to natural history patients (91% of patients were alive and free of permanent ventilation at the 14-months-of-age study visit).[6] The trial also showed 59% of Zolgensma-treated patients were able to sit without support for ≥ 30 seconds at the 18-month-of-age study visit. Another Phase 3 trial, Pre-Symptomatic Study of Intravenous AVXS-101 in Spinal Muscular Atrophy (SMA) for Patients with Multiple Copies of SMN2 (SPR1NT), investigated the use of Zolgensma in those that are considered pre-symptomatic with SMA alongside 2 or 3 copies of SMN2.[2] All 14 patients enrolled in the trial were able to sit without support for ≥ 30 seconds up to the 18-months-of-age visit.[7]

Itvisma (onasemnogene abeparvovec-brve) is an adeno-associated virus vector-based gene therapy indicated for the treatment of spinal muscular atrophy (SMA) in adult and pediatric patients 2 years of age and older with a confirmed mutation in the survival motor neuron 1 (SMN1) gene.

Summary	
Effective Date of Policy:	4/7/2026
ICD10 Diagnosis Codes	G12.0, G12.1, G12.9
Availability	Zolgensma: Customized kit to meet dosing requirements for each patient Itvisma: single-dose vial with an extractable volume of not less than 3 mL, containing 1.2×10^{14} vg
HCPCS Code	Zolgensma: J3399 Itvisma: no specific code (J3590)
Approval duration	Zolgensma: 3 months to allow for the administration of the one-time treatment or until 2 years of age, whichever occurs first Itvisma: 3 months to allow for the administration of the one-time treatment

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve Zolgensma:

Product	Inclusion	Recommended Dosing Regimen

Zolgensma (onasemnogene abeparvovec-xioi)	• Prescribed by, or in consultation with, a provider who specializes in the diagnosis and management of spinal muscular atrophy (SMA) and/or neuromuscular disorders
	• Enrollee is less than two years of age and weighs ≤ 21 kg
	  o For neonatal patients born prematurely, term gestational age (37 weeks) must be reached
	• Enrollee has a diagnosis of spinal muscular atrophy confirmed by:
	  o Genetic demonstration of bi-allelic SMN1 gene deletion or mutation:
	  ▪ Homozygous deletions of SMN1 gene OR
	  ▪ Homozygous mutation in the SMN1 gene (e.g., biallelic mutations of exon 7) OR
	  ▪ Compound heterozygous mutation in the SMN1 gene (e.g., deletion of SMN1 exon 7 and mutation of SMN1)
	• Must have genetic testing confirming 1, 2, 3, or 4 copies of the SMN2 gene
	• Enrollee must have baseline anti-AAV9 antibody titers of ≤ 1:50 (e.g., anti-AAV9 antibody titers of ≤ 1:25)
		• One lifetime administration of Zolgensma
		• Dosage should not exceed 1.1×10^{14} vector genomes (vg) per kg of body weight administered as an IV infusion over 60 minutes. Systemic corticosteroids (equivalent to oral prednisolone at 1mg/kg of body weight) must be administered starting one day prior to Zolgensma infusion and continuing for a total of 30 days
		• Refer to the prescribing information for the determination of the appropriate dose volume that corresponds to the patient's weight. Coverage will be limited to one customized Zolgensma kit that meets these dosage requirements

	• Clinical documentation supports that the enrollee does NOT have advanced SMA at baseline (i.e., complete paralysis of limbs OR permanent ventilator dependence)
	  o Permanent ventilator support defined as ventilator assistance for ≥ 16 hours/day for at least 14 days without an acute, reversible illness
	• Enrollee will not be concurrently receiving either Spinraza (nusinersen) or Evrysdi (risdiplam) or any other experimental therapy for spinal muscular atrophy with Zolgensma
	  o Member's medical record will be reviewed and any current Spinraza or Evrysdi approval will be terminated upon Zolgensma approval
	• Must not have previously received any gene therapy, including either formulation of onasemnogene abeparvovec or any other AAV9- or SMN1-directed gene-replacement therapy (including investigational treatments). This exclusion applies regardless of route of administration of prior therapy as antibody response is systemic.	

Itvisma (onasemnogene abeparvovec-brve)	1. Must be prescribed by, or in consultation with, a provider who specializes in the treatment of Spinal Muscular Atrophy (SMA) and/or neuromuscular disorders AND
	2. Must be between ≥ 2 years and < 18 years of age AND
	3. Must have a genetically confirmed diagnosis of Spinal Muscular Atrophy (SMA), supported by documentation of:
	  a. Biallelic SMN1 deletion or mutation confirmed by molecular genetic testing (homozygous deletion, homozygous mutation, or compound heterozygous mutation) AND
	  b. Genetic testing confirming 2, 3, or 4 copies of the SMN2 gene AND
	4. Must have a clinical presentation consistent with SMA Type 2 or non-ambulatory SMA Type 3, characterized by:
	  a. Absence of sustained independent ambulation at the time of the request OR documented loss of independent ambulation within the prior 12 months AND
	  b. Evidence of preserved motor neuron reserve, demonstrated by:
	  i. Ability to sit independently without external support (e.g., without a caregiver assisting, without positioning devices) OR
	  ii. Preserved antigravity upper-limb function on clinical examination or standardized assessment (e.g., RULM) AND
	  c. Must have objective evidence of disease progression, demonstrated by documentation of
	  i. A decline in standardized motor function assessments, (e.g., HFMS-E, RULM, or equivalent) within the prior 12 -months OR
		• Itvisma must be dosed and administered per the FDA-approved prescribing information which includes:
		• Single-dose intrathecal injection of 1.2×10^{14} vector genomes (vg) via lumbar puncture
		• Required corticosteroid regimen (prednisolone 1 mg/kg/day beginning one day prior to injection, continued for 30 days, followed by gradual taper)
		• Post-treatment monitoring of liver function and platelet counts as specified in the prescribing information

	ii. A loss of motor milestones within the prior 12-motnths 5. Must have a current (within 30 days prior to treatment) anti-AAV9 neutralizing antibody titer at or below the laboratory's validated cutoff (typically ≤ 1:50; some validated assays use ≤ 1:25) a. Laboratory report must specify assay type, date, and threshold AND 6. Vaccination and Infection Precautions a. Must have no active infection at the time of treatment; patient must be clinically stable b. Must have no live-attenuated vaccine (e.g., MMR, varicella, zoster) within 30 days before or 2 months after treatment c. Must have documentation of varicella immunity (IgG positive or prior vaccination) must be submitted AND 7. Documentation must confirm that the patient does not have any contraindication to lumbar puncture, including: a. Increased intracranial pressure due to mass lesion or hydrocephalus; b. Coagulopathy (INR > 1.4 or platelets < 100,000/μL) or current anticoagulant use; c. Local infection at the puncture site or systemic sepsis; d. Severe spinal deformity, fusion, or hardware precluding safe LP access; AND 8. Must have baseline laboratory assessment (within 7 days prior to treatment) a. AST, ALT, total bilirubin, PT/INR b. CBC with platelets c. BUN/creatinine d. LDH and haptoglobin e. Blood pressure f. Varicella IgG	

Exclusion Criteria

Zolgensma will not be authorized if **any** of the following criteria are met:

- Retreatment with Zolgensma has not been proven to be safe and effective and will be considered experiment/investigational. This includes patients who received a partial or incomplete dose of Zolgensma.

Itvisma will not be authorized if any of the following criteria are met:

- Enrollee has any of the following:
  - Significant hepatic impairment (AST/ALT > 5× ULN or bilirubin > 2× ULN);
  - Active infection or febrile illness within 30 days;
  - Uncorrected coagulopathy or thrombocytopenia;
  - Contraindication to lumbar puncture (see Section 6);
  - Ventilator dependence or end-stage SMA (complete paralysis of limbs, permanent ventilator use);
  - Recent major surgery or pulmonary decompensation (< 2 months);
  - Active varicella or herpes zoster infection;
  - Prior treatment with any AAV-based or other viral-vector gene therapy.
- Patients with advanced SMA (i.e., complete paralysis of limbs, permanent ventilator dependence) will be excluded from treatment due to lack of literature support

- Permanent ventilation is defined as requiring invasive ventilation (tracheostomy), or invasive/noninvasive respiratory assistance for ≥ 16 hours daily for ≥ 14 days in the absence of an acute reversible illness and excluding perioperative ventilation

- For SMA treatment experienced patients:
  - If previously treated with nusinersen (Spinraza), the patient must have received their last dose of nusinersen ≥ 4 months
  - If previously treated with risdiplam (Evrysdi), the patient must have received their last dose of risdiplam ≥ 15 days prior
- Itvisma will not be approved for use in combination with Spinraza or Evrysdi or any other experimental therapy for spinal muscular atrophy
- Must not have previously received any gene therapy, including either formulation of onasemnogene abeparvovec or any other AAV9- or SMN1-directed gene-replacement therapy (including investigational treatments). This exclusion applies regardless of route of administration of prior therapy as antibody response is systemic.
- Retreatment with Itvisma has not been proven to be safe and effective and will be considered experiment/investigational. This includes patients who received a partial or incomplete dose of Itvisma.

Continuation Criteria

- Not applicable; therapy is authorized only for one lifetime administration of Zolgensma

Considerations

- Physician acknowledges that CDPHP will request documentation, not more frequently than biannually, of follow-up patient assessments including serial CHOP INTEND (Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders) or HFMSE (Hammersmith Functional Motor Scale Expanded) assessments while the patient is under the care of the physician
- Systemic corticosteroids should be administered to all enrollees before and after Zolgensma infusion[4]
- Enrollees receiving Zolgensma therapy should have liver function monitored for at least three months after receiving therapy, at intervals of weekly for the first month, followed by every other week for months two and three, until results are unremarkable.
- Enrollees receiving Zolgensma therapy should have troponin-I monitored before infusion and on a regular basis after infusion (weekly for the first month, and then monthly for the second and third months) until troponin-I levels return to baseline[4]
- Prior authorization is obtained through the CDPHP pharmacy department

References

		Updated	Accessed
1	Verhaart IEC, Robertson A, Wilson IJ, et al. Prevalence, incidence, and carrier frequency of 5q-linked spinal muscular atrophy – a literature review. Orphanet J Rare Dis. 2017;12(1):124. Accessed 7/22	2017	7/2022
2	Rao VK, Kapp D, Schroth M. Gene Therapy for Spinal Muscular Atrophy: An Emerging Treatment Option for a Devastating Disease. J Manag Care Spec Pharm. 2018;24(12-a):S3-S16. Accessed 7/22	2018	7/2022
3	Institute for Clinical and Economic Review (ICER). Sprinaza and Zolgensma for Spinal Muscular Atrophy: Effectiveness and Value. Final Evidence Report. 2019 Apr 3. Accessed 7/22	4/2019	7/2022
4	Zolgensma Prescribing Information, AveXis, Inc., Bannockburn, IL 60015.	2/2025	4/2026
5	Butchbach ME. Copy Number Variations in the Survival Motor Neuron Genes: Implications for Spinal Muscular Atrophy and Other Neurodegenerative Diseases. Front Mol Biosci 2016; 3:7. Copyright © 2016 Butchbach. Available at: http://journal.frontiersin.org/article/10.3389/fmolb.2016.00007/full. Accessed 7/22	7/2022	7/2022
6	Day JW, Finkel RS, Chiriboga CA, Connolly AM, Crawford TO, Darras BT, Iannaccone ST, Kuntz NL, Peña LDM, Shieh PB, Smith EC, Kwon JM, Zaidman CM, Schultz M, Feltner DE, Tauscher-Wisniewski S, Ouyang H, Chand DH, Sproule DM, Macek TA, Mendell JR. Onasemnogene abeparvovec gene therapy for symptomatic infantile-onset spinal muscular atrophy in patients with two copies of SMN2 (STR1VE): an open-label, single-arm, multicentre, phase 3 trial. Lancet Neurol. 2021 Apr;20(4):284-293. doi: 10.1016/S1474-4422(21)00001-6. Epub 2021 Mar 17. PMID: 33743238. Accessed 7/22	7/2022	7/2022
7	Day JW, Finkel RS, Chiriboga CA, et al. Onasemnogene abeparvovec gene therapy for symptomatic infantile-onset spinal muscular atrophy in patients with two copies of SMN2 (STR1VE): an open-label, single-arm, multicentre, phase 3 trial. Lancet Neurol. 2021 Apr;20(4):284-293. doi: 10.1016/S1474-4422(21)00001-6. Epub 2021 Mar 17. PMID: 33743238. Accessed 7/22	7/2022	7/2022
8	Novartis Gene Therapies, Inc. Itvisma (onasemnogene abeparvovec-brve). Package insert. Novartis Gene Therapies, Inc.; 2025.	11/2025	4/2026

9	Mendell JR, Al-Zaidy S, Shell R, et al. Single-dose gene-replacement therapy for spinal muscular atrophy. N Engl J Med. 2017;377(18):1713-1722. doi:10.1056/NEJMoa1706198	11/2017	4/2026
10	Strauss KA, Farrar MA, Muntoni F, et al. Onasemnogene abeparvovec for presymptomatic infants with two copies of SMN2 at risk for spinal muscular atrophy type 1: the phase III SPR1NT trial. Nat Med. 2022;28(7):1381-1389. doi:10.1038/s41591-022-01866-4	7/2022	4/2026
11	Weiß C, Ziegler A, Becker LL, et al. Gene replacement therapy with onasemnogene abeparvovec in children with spinal muscular atrophy aged 24 months or younger and bodyweight up to 15 kg: an observational cohort study. Lancet Child Adolesc Health. 2022;6(1):17-27. doi:10.1016/S2352-4642(21)00287-X	10/2021	4/2026

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS: Subject to all terms and conditions noted in above application.

MEDICARE ADVANTAGE: Subject to all terms and conditions noted in above application.

SELECT/HARP PLAN: Subject to all terms and conditions noted in above application.

CDPHP Pharmacy Services 4/6/2026

New: 8/2019

Revised	Reviewed
9/20, 9/22, 9/23, 9/25, 4/26	9/2021, 9/2024

Revision Date	Changes Made
09/2022	Added SMA classification criteria table, updated clinical trial results, added systemic corticosteroid consideration, added troponin-I monitoring consideration
9/2023	Added to inclusion criteria statement excluding concomitant nusinersen or risdiplam treatment following Zolgensma administration
9/2025	Updated approval duration
4/2026	Renamed policy from Zolgensma (onasemnogene abeparvovec-xioi) Added Itvisma Updated number of copies of SMN2 gene for Zolgensma Removed labs for Zolgensma

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Policy/Procedure Name: Zynteglo (Betibeglogene autotemcel) **Control Number:** 1350/20.000451

Disclaimer Notice

The purpose of this policy is to provide guidance for benefit and coverage determinations only. Benefit and coverage determinations are subject to the contractual limitations of an enrollee's individual benefit plan.

If there is a discrepancy between this policy and an enrollee's individual benefit plan, the benefit plan will control. It is not the intent of this policy to dictate to health care practitioners how to provide appropriate health care to their patients. Health care practitioners shall exercise their own medical judgment when deciding the most appropriate care to enrollees. The CDPHP® coverage determinations are benefit decisions only and are not to be interpreted as providing health care services. CDPHP reserves the right to review this policy at any time and change it without notice.

Background

Thalassemias are inherited hemoglobinopathies in which impaired production of one type of globin chain; either alpha or beta, causes an imbalance in the ratio between those chains. These chains precipitate and cause significant cellular damage, thus causing issues with red blood cell maturation and leads to ineffective erythropoiesis, hemolytic anemia, iron overload, and ensuing complications. Specifically in beta-thalassemia, this impaired production is caused by mutations in the hemoglobin beta globin gene. There are more than 350 beta-thalassemia mutations currently known, and while distinction of the various phenotypes of thalassemia is mostly based on clinical parameters, genotype-phenotype associations are commonly established. There are four different phenotypes in beta-thalassemia: Major, intermedia, trait/minor, and silent carriers. However, in terms of treatment, individuals with beta thalassemia are classified as either being transfusion dependent (TDT) or non-transfusion dependent (NTDT).

Transfusion dependent individuals are those patients that require regular, life-long transfusions to mitigate severe anemia and extramedullary hematopoiesis. This classification does not include those patients who only periodically require transfusions for anemia, but they may become fully transfusion dependent over time. Non-transfusion dependent individuals do not require regular transfusions.

Whichever the category a patient falls into, the management of beta thalassemia mainly involves treating the anemia if it is severe enough to cause symptoms, reducing ineffective erythropoiesis, preventing excess iron stores from forming, and treating the complications of such iron overload if it occurs. Both TDT and NTDT are fluid categories based on clinical parameters, and a patient can switch from one group to the other over the course of their lives. As such, these designations should primarily represent a patient's current clinical status.

If iron overload occurs from the frequent transfusions, it can cause organ toxicity and potentially mortality. In this case, it may be necessary to use iron chelation therapy to remove excess iron from the body. Currently, there are three iron chelating agents on the market for iron overload: deferasirox, deferiprone, and deferoxamine. No single agent is considered the "gold standard," and long-term randomized, prospective studies for this comparison are lacking. However, all three are approved for the treatment of iron overload in transfusion-dependent thalassemia, and the choice of agent is largely dependent on preference of the prescriber and patient, patient age, comorbidities, and side effect profile.

Transfusion-dependent patients will also have ineffective erythropoiesis. If this is the case, then the patient can be prescribed an activin receptor ligan trap. The only drug currently on the market is luspatercept, approved for use in 2019 and indicated for the treatment of adult patients with beta thalassemia who require regular red blood cell (RBC) infusions. In these patients who require regular transfusions, luspatercept can serve to reduce the number of transfusions a patient may need, but individuals who are tolerating regular transfusions may continue to stay on just transfusion therapy. Other patients may seek curative treatment with hematopoietic stem cell transplant (which, due to complications such as graft-versus-host-disease, is only recommended in young children with an HLA-identical sibling) or gene therapy. The primary evidence for efficacy of luspatercept comes from the BELIEVE trial, which showed that compared to placebo, luspatercept was able to significantly increase hemoglobin levels and reduce the number of transfusions participants needed to receive. This can reduce a patient's transfusion burden and maintain quality of life. Patients who may qualify for luspatercept may also benefit from undergoing a splenectomy, however splenectomy is associated with a variety of adverse outcomes in patients, namely hypercoagulable states. Considering that undergoing splenectomy may not eliminate the need for other therapy, and its adverse effects, splenectomy is best reserved for certain patients.

Until now, the only curative treatment for beta-thalassemia was hemopoietic stem cell transplant from an HLA-matched donor. Zynteglo (betibeglogene autotemcel (beti-cel)) was approved in August 2022 as an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of adult and pediatric patients with β-thalassemia who require regular red blood cell (RBC) transfusions. Zynteglo is intended to be a one-time gene therapy product administered as a single dose. Zynteglo works by adding functional copies of a modified form of the beta-globin gene (βA-T87Q-globin gene) into a patient's own hematopoietic (blood) stem cells (HSCs) in the ex vivo setting, and the HSCs are then administered via a onetime hospital inpatient infusion.

The approval of Zynteglo is based on data from the single-arm, open-label, Phase 3 HGB-207 (Northstar-2) and HGB-212 (Northstar-3) trials and the long-term follow-up study, LTF-303. The Phase 3 trials included 41 patients between 4 and 34 years of age with both non-β0 /β0 and β0 /β0 genotypes. Of the evaluable patients, 89% (32/36) achieved transfusion independence (TI), which is defined as no longer needing RBC transfusions for at least 12 months while maintaining a weighted average total hemoglobin level of at least 9 g/dL.

Policy/Procedure Name: Zynteglo (Betibeglogene autotemcel) **Control Number:** 1350/20.000451

Summary	
Effective Date of Policy:	2/12/2026
Indications	Transfusion Dependent Beta Thalassemia (TDT)
ICD10 Diagnosis Codes	D56.1
HCPCS Code	J3393
Availability	*Per FDA Prescribing Information*
Duration	Authorization will be for 6 months to allow sufficient time for administration

Required Criteria for Initial Approval

All of the following conditions for the requested indication must be met in order to approve therapy:

Specific Indication	Inclusion Criteria	Recommended Dosing

Indication
Transfusion Dependent Beta Thalassemia
ICD10: D56.1
	• Enrollee is between four and 50 years of age
	  ○ If enrollee is less than five years of age they must weigh ≥ 6 kilograms and be expected to provide the minimum number of cells to initiate the therapeutic manufacturing process
	• Therapy is prescribed by or in consultation with a hematologist
	• Enrollee has diagnosis of Transfusion Dependent Beta Thalassemia with genetic confirmation of the following:
	  ○ Non-β0/β0 genotype (i.e., β0/β+, βE/β0, and β+/β+) OR
	  ○ β0/β0 genotype (other examples include: β0/β+(IVS-I-110) and β+(IVS-I-110)/β+(IVS-I-110))
	• Enrollee has had regular peripheral blood transfusions to maintain target hemoglobin levels
	• Enrollee has been treated and followed for at least the past two years in a specialized center that maintained detailed medical records, including transfusion history
	• Clinical documentation supports the enrollee has had the following in the previous two years (one of the below two options):
	  ○ Receipt of ≥ 8 transfusions of packed red blood cells (pRBC) per year OR
	  ○ Receipt of ≥ 100 mL/kg/year of pRBC per year
	• Karnofsky performance status of ≥80 for adults (≥16 years of age) or a Lansky performance status of ≥80 for adolescents (<16 years of age)
	• Negative serologic test for HIV infection (as per US FDA prescribing label, apheresis material from individuals with a positive test for HIV will not be accepted for betibeglogene autotemcel manufacturing).
		• Per FDA Prescribing Information

Exclusion Criteria

Therapy will not be covered if any of the above noted Inclusion Criteria are NOT met OR any of the below noted Exclusion Criteria are met:

- Presence of HBB mutations other than what is specifically noted in the above Inclusion Criteria
- Enrollee has received a HSCT or Gene therapy previously in their lifetime
- Enrollee has a known and available HLA-matched family donor willing to participate in an allogeneic HSCT
- Enrollee is ineligible for HSCT (separate from points in above Exclusion Criteria)
- Contraindication to the use of granulocyte colony stimulating factor (G-CSF), plerixafor, busulfan, or any other medicinal products required during myeloablative conditioning, including hypersensitivity to the active substances or to any of the excipients.
- White Blood Cell (WBC) count < 3×10^9/L
- Platelet count < 100×10^9/L (not related to hypersplenism)
- Uncorrected bleeding disorder
- Any prior or current malignancy (with the exception of adequately treated cone biopsied in situ carcinoma of the cervix uteri and basal or squamous cell carcinoma of the skin) or myeloproliferative or significant immunodeficiency disorder

- Any immediate family member (i.e., parent or siblings) with a known Familial Cancer Syndrome (including but not limited to hereditary breast and ovarian cancer syndrome, hereditary nonpolyposis colorectal cancer syndrome and familial adenomatous polyposis)
- Evidence of advanced liver disease (meets any of the following):
    - Persistent aspartate transaminase, alanine transaminase, or direct bilirubin value greater than 3 times the upper limit of normal.
    - Baseline prothrombin time or partial thromboplastin time greater than 1.5 times the upper limit of normal.
    - Magnetic resonance imaging of the liver demonstrating clear evidence of cirrhosis.
    - Liver biopsy demonstrating cirrhosis, any evidence of bridging fibrosis, or active hepatitis
- T2*-weighted magnetic resonance imaging measurement of myocardial iron of less than 10 msec or other evidence of severe iron overload in the opinion of treating physician.
- Baseline estimated glomerular filtration rate less than 70 mL/min/1.73 m^2
- Active, uncontrolled HCV or HBV infection

Continuation Criteria

Continuation criteria is not applicable, this is a one-time lifetime treatment only and therefore repeat administration will not be covered.

Considerations

- Prior authorization is obtained through the CDPHP pharmacy department.
- Zynteglo (betibeglogene autotemcel) is considered investigational when the above criteria are not met
- Zynteglo (betibeglogene autotemcel) is considered investigational for all other indications
- Retreatment with Zynteglo (betibeglogene autotemcel) will be considered investigational when FDA approved gene therapy, or any other gene therapy under investigation, has been previously administered

References

		Updated	Accessed
	BB305 (Beti-Cel) Clinical Trial (NCT03207009). NORTHSTAR 3. Available at: https://clinicaltrials.gov/ct2/show/NCT03207009	2/22	6/22
	BB305 (Beti-Cel) Clinical Trial (NCT02906202). NORTHSTAR 2. Available at: https://clinicaltrials.gov/ct2/show/NCT02906202	4/22	6/22
	ICER. Betibeglogene Autotemcel for Beta Thalassemia: Effectiveness and Value. Evidence Report. June 2, 2022.	6/22	6/22
	2021 Guidelines for the Management of Transfusion Dependent Thalassaemia (TDT). 4th Edition (Version 2.0). June 25, 2021. Available at: https://issuu.com/internationalthalassaemiafederation/docs/final_guideline_4th	6/21	6/22
	Gene Therapy in β-thalassemia and other haemoglobin disorders. Thalassaemia International Foundation. Available at: https://issuu.com/internationalthalassaemiafederation/docs/tif_gene_therapy_final	9/19	6/22
	Thompson AA, Walters MC, Kwiatkowski, et al. Gene Therapy in Patients with Transfusion-Dependent B-Thalassemia. N Eng J Med 2018;378:1479. Doi: 10.1056/NEJMoa1705342	4/18	2/22
	Locatelli F, Thompson AA, Kwiatkowski JL, et al. Betibeglogene Autotemcel Gene Therapy for Non-B^0/B^0 Genotype B-Thalassemia. *N Eng J Med.* doi: 10.1056/NEJMoa2113206.	12/21	5/22
	Payen E. Efficacy and Safety of Gene Therapy for Beta-Thalassemia. N Engl J Med 2022; 386:488-490. DOI: 10.1056/NEJMe2118580	2/22	4/22
	Zynteglo (Prescribing Information). Bluebird bio, Inc., Somerville, Massachusetts 02145. Revised 8/22	8/22	4/25

GOVERNMENT PROGRAMS

CHILD HEALTH PLUS:	Subject to all terms and conditions noted in above application.
MEDICARE CHOICES:	Subject to all terms and conditions noted in above application.
SELECT/HARP PLAN:	Refer to MEDICAID - Zynteglo (Betibeglogene autotemcel) policy 1350/20.000489. Zynteglo (betibeglogene autotemcel) is reimbursed by Medicaid fee-for-service pharmacy program for Medicaid Managed Care Members

CDPHP Pharmacy Services 2/12/2026

New: 6/2022

Revised	Reviewed
12/2022, 9/2024, 4/2025, 2/2026	

Revision Date	Changes Made
12/2022	Changed title of Policy from Betibeglogene autotemcel (beti-cel) to Zynteglo (Betibeglogene autotemcel) Updated Select/HARP applicability to reflect that BlueBird is not participating in the MDRP and therefore not eligible for coverage.
12/2022	Changed Applicability to include Select/HARP plan.
9/2024	Updated background, Inclusion Criteria Revisions: Clarified prescriber requirement to include consultation of hematologist; Added non-β0/β0 mutation; Reduced transfusion requirement - receipt of ≥ 8 transfusions of packed red blood cells (pRBC) per year (previously 11 transfusions)
2/2026	Updated authorization will be for 6 months to allow sufficient time for administration Updated youngest age from 5 years of age to 4 years of age Added Karnofsky performance score and negative HIV test Updated exclusion criteria Removed duplicative criteria from inclusion criteria that was already encompassed in exclusion criteria Removed Enrollee has been treated and followed for at least the past two years in a specialized center that maintained detailed medical records, including transfusion history Clarified mutations Updated iron overload exclusion criteria

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